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The Code of Federal Regulations is sold by the Superintendent of Documents.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2021–0108]

RIN 3150–AK64

List of Approved Spent Fuel Storage Casks: TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System Certificate of Compliance No. 1029, Renewal of Initial Certificate and Amendment Nos. 1, 3, and 4

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of October 27, 2021, for the direct final rule that was published in the **Federal Register** on August 13, 2021. The direct final rule amended the NRC's spent fuel storage regulations by revising the TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System listing within the ''List of approved spent fuel storage casks'' to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029.

DATES: *Effective date:* The effective date of October 27, 2021, for the direct final rule published August 13, 2021 (86 FR 44594), is confirmed.

ADDRESSES: Please refer to Docket ID NRC–2021–0108 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0108. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The proposed certificates of compliance, the proposed changes to the technical specifications, and the preliminary safety evaluation report are available in ADAMS under Package Accession No. ML21067A164. The final certificates of compliance, the final changes to the technical specifications, and the final safety evaluation report are available in ADAMS under Package Accession No. ML21246A086.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Irene Wu, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1951, email: *Irene.Wu@nrc.gov.*

SUPPLEMENTARY INFORMATION: On August 13, 2021 (86 FR 44594), the NRC published a direct final rule amending its regulations in part 72 of title 10 of the *Code of Federal Regulations* to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 3, and 4 of the TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System Certificate of Compliance No. 1029. The renewal of the initial certificate and Amendment Nos. 1, 3, and 4 revise the certificate of compliance's conditions and technical specifications to address aging management activities related to the structures, systems, and components of the dry storage system to ensure that these will maintain their intended functions during the period of extended storage operations.

In the direct final rule, the NRC stated that if no significant adverse comments were received, the direct final rule would become effective on October 27, 2021. The NRC did not receive any comments on the direct final rule. Therefore, this direct final rule will become effective as scheduled.

Dated: September 30, 2021.

For the Nuclear Regulatory Commission.

Cindy K. Bladey,

Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2021–21796 Filed 10–4–21; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0548; Project Identifier MCAI–2021–00046–T; Amendment 39–21731; AD 2021–19–13]

RIN 2120–AA64

Airworthiness Directives; ATR–GIE Avions de Transport Régional Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all ATR–GIE Avions de Transport Régional Model ATR42–500 and ATR72–212A airplanes. This AD was prompted by reports indicating that certain Thales global positioning system (GPS) satellite based augmentation system (SBAS) receivers provided, under certain conditions, erroneous outputs on aircraft positions. This AD requires replacing affected GPS SBAS receivers with new, improved receivers, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 9, 2021.

The Director of the Federal Register approved the incorporation by reference

of a certain publication listed in this AD as of November 9, 2021.

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0548.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0548; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3220; email: *shahram.daneshmandi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0013, dated January 13, 2021 (EASA AD 2021–0013) (also referred to as the MCAI), to correct an unsafe condition for all ATR–GIE Avions de Transport Régional Model ATR42–500 and ATR72–212A airplanes.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all ATR–GIE Avions de Transport Régional Model ATR42–500 and ATR72–212A airplanes. The NPRM published in the **Federal Register** on July 7, 2021 (86 FR 35697). The NPRM was prompted by reports indicating that Thales GPS SBAS receivers provided, under certain conditions, erroneous outputs on aircraft positions. The NPRM proposed to require replacing affected GPS SBAS receivers with new, improved receivers, as specified in EASA AD 2021–0013.

The FAA is issuing this AD to address erroneous aircraft position outputs from the GPS SBAS receivers, which could result in controlled flight into terrain, and consequent loss of control of the airplane. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from the Air Line Pilots Association, International, (ALPA) who supported the NPRM without change.

Conclusion

The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products.

Related AD

AD 2020–08–02, Amendment 39–21108 (85 FR 20586, April 14, 2020) (AD 2020–08–02) applies to certain Thales GPS SBAS receivers installed on airplanes (including Model ATR42–500 and ATR72–212A) and helicopters. AD 2020–08–02 requires the installation of a software update to the aircraft navigation database and insertion of a change to the applicable airplane flight manual (AFM). The FAA issued AD 2020–08–02 to address erroneous aircraft position outputs from the affected Thales GPS SBAS receivers, which could result in controlled flight into terrain and loss of the aircraft. AD 2020–08–02 corresponds to EASA AD 2019–0004, dated January 11, 2019. Upon completion of EASA AD 2021–0013 by Model ATR42–500 and ATR72–212A airplanes, all requirements of EASA AD 2019–0004 are effectively terminated for those airplanes.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0013 describes procedures for replacing certain GPS SBAS receivers with new, improved receivers. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 15 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × $85 per hour = $170	$0 *	$170	$2,550

The manufacturer will provide replacement receivers at no cost to the operators. The FAA has received no definitive data on which to base the cost estimates for these parts.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a

substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2021–19–13 ATR–GIE Avions de Transport Régional: Amendment 39–21731; Docket No. FAA–2021–0548; Project Identifier MCAI–2021–00046–T.

(a) Effective Date

This airworthiness directive (AD) is effective November 9, 2021.

(b) Affected ADs

This AD affects AD 2020–08–02, Amendment 39–21108 (85 FR 20586, April 14, 2020) (AD 2020–08–02).

(c) Applicability

This AD applies to all ATR–GIE Avions de Transport Régional Model ATR42–500 and ATR72–212A airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Reason

This AD was prompted by reports that Thales global positioning system (GPS) satellite based augmentation system (SBAS) receivers provided, under certain conditions, erroneous outputs on aircraft positions. The FAA is issuing this AD to address the potential for these erroneous outputs, which could result in controlled flight into terrain, and consequent loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0013, dated January 13, 2021 (EASA AD 2021–0013).

(h) Exceptions to EASA AD 2021–0013

(1) Where EASA AD 2021–0013 refers to its effective date, this AD requires using the effective date of this AD.

(2) The requirements specified in paragraphs (2) and (3) of EASA AD 2021–0013 do not apply to this AD. Instead, the airplane flight manual (AFM) changes required by AD 2020–08–02 must be removed from the existing AFM before further flight after compliance with all other actions required by this AD.

(3) The ''Remarks'' section of EASA AD 2021–0013 does not apply to this AD.

(i) Terminating Action for AD 2020–08–02

Accomplishment of this AD terminates all requirements of AD 2020–08–02 for Model ATR42–500 and ATR72–212A airplanes.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or ATR–GIE Avions de Transport Régional's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3220; email: *shahram.daneshmandi@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2021–0013, dated January 13, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0013, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on September 7, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–21620 Filed 10–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0789; Project Identifier MCAI–2020–01607–T; Amendment 39–21736; AD 2021–19–18]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A310 series airplanes. This AD was prompted by a determination that new or more restrictive maintenance requirements and airworthiness limitations are necessary. This AD requires revising the existing maintenance or inspection

program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective October 20, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 20, 2021.

The FAA must receive comments on this AD by November 19, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax*: 202–493–2251.
- *Mail*: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For EASA material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0789.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0789; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0267, dated December 3, 2020 (EASA AD 2020–0267) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes.

EASA AD 2020–0267 specifies that it requires a task (limitation) related to the retraction actuator assembly sliding rod already in Airbus A310 ALS Part 4 Revision 03 that is required by EASA AD 2017–0202 (which corresponds to FAA AD 2018–18–21, Amendment 39–19400 (83 FR 47054, September 18, 2018) (AD 2018–18–21)) and that incorporation of EASA AD 2020–0267 invalidates (terminates) prior instructions for that task. This AD therefore terminates the limitations for the retraction actuator assembly sliding rod having part number D52952, D52952–1, D52952–2, or D58006, as required by paragraph (g) of AD 2018–18–21, for Model A310 series airplanes only.

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address the effects of aging on airplane systems. Such effects could change system characteristics, leading to an increased potential for failure of certain life-limited parts. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2020–0267 describes new or more restrictive airworthiness limitations for airplane structures and safe life limits. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Requirements of This AD

This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, which are specified in EASA AD 2020–0267 described previously, as incorporated by reference. Any differences with EASA AD 2020–0267 are identified as exceptions in the regulatory text of this AD.

This AD requires revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (k)(1) of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2020–0267 is incorporated by reference in this AD. This AD requires compliance with EASA AD 2020–0267 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2020–0267 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2020–0267. Service information required by EASA AD 2020–0267 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0789 after this AD is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under ''Additional FAA Provisions.'' This new format includes a ''New Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action, interval, or CDCCL.

FAA's Justification and Determination of the Effective Date

There are currently no domestic operators of these products. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3). In addition, for the foregoing reason, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0789; Project Identifier MCAI–2020–01607–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act (RFA)

The requirements of the RFA do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the U.S. Register in the future, the FAA provides the following cost estimates to comply with this AD:

The FAA has determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although the FAA recognizes that this number may vary from operator to operator. In the past, the FAA has estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the FAA estimates the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2021–19–18 Airbus SAS: Amendment 39–21736; Docket No. FAA–2021–0789; Project Identifier MCAI–2020–01607–T.

(a) Effective Date

This airworthiness directive (AD) becomes effective October 20, 2021.

(b) Affected ADs

This AD affects AD 2018–18–21, Amendment 39–19400 (83 FR 47054, September 18, 2018) (AD 2018–18–21).

(c) Applicability

This AD applies to all Airbus SAS Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a determination that new or more restrictive maintenance requirements and airworthiness limitations are necessary. The FAA is issuing this AD to address the risks associated with the effects of aging on airplane systems. Such effects could change system characteristics, leading to an increased potential for failure of certain life-limited parts.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2020–0267, dated December 3, 2020 (EASA AD 2020–0267).

(h) Exceptions to EASA AD 2020–0267

(1) Where EASA AD 2020–0267 refers to its effective date, this AD requires using the effective date of this AD.

(2) The requirements specified in paragraph (1) of EASA AD 2020–0267 do not apply to this AD.

(3) Paragraph (2) of EASA AD 2020–0267 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(4) The initial compliance time for doing the tasks specified in paragraph (2) of EASA AD 2020–0267 is on or before the applicable ''limitations'' as incorporated by the requirements of paragraph (2) of EASA AD 2020–0267, or within 90 days after the effective date of this AD, whichever occurs later.

(5) The provisions specified in paragraph (3) of EASA AD 2020–0267 do not apply to this AD.

(6) The ''Remarks'' section of EASA AD 2020–0267 does not apply to this AD.

(i) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2020–0267.

(j) Terminating Action for Certain Requirement of AD 2018–18–21

Accomplishing the actions required by this AD terminates the limitations for the retraction actuator assembly sliding rod having part number D52952, D52952–1, D52952–2, or D58006, as required by paragraph (g) of AD 2018–18–21 for Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes only.

(k) Additional FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (k)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(l) Related Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2020–0267, dated December 3, 2020.

(ii) [Reserved]

(3) For EASA AD 2020–0267, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* Internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0789.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on September 9, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–21627 Filed 10–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 732, 734, 736, 738, 740, 744, 748, 750, 770, 772, and 774

[Docket No. 210802–0157]

RIN 0694–AI24

The Export Administration Regulations; Editorial Revisions, Clarifications, and Corrections

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule; corrections.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by making targeted editorial corrections and clarifications. The errors addressed by this rule were inadvertent and these corrections will provide clarity and facilitate understanding of the regulations. This rule ensures that the language and policies already set forth in the EAR remain consistent throughout.

DATES: This rule is effective October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Logan Norton, Regulatory Policy Division, *Logan.Norton@bis.doc.gov,* (202) 812–1762.

SUPPLEMENTARY INFORMATION:

Background

This final rule updates eleven parts of the Export Administration Regulations (EAR), parts 732, 734, 736, 738, 740, 744, 748, 750, 770, 772, and 774, such that most-recent language elsewhere in the EAR is consistent with the language in these parts. These changes are minor editorial revisions that either reflect Bureau of Industry and Security (BIS) policies that were previously published in the **Federal Register** and added to the EAR or reflect the modernization of procedures implemented by BIS. These revisions do not change the substance of the EAR.

Part 732 Steps for Using the EAR

In 2004, supplement no. 2 to part 732, the ''Subject to the EAR?'' flowchart, was revised to make it simpler and easier to read. However, the language of the supplement is not consistent with the language in other parts of the EAR, including language implemented before and after the 2004 amendment. In 1999, paragraphs (a) and (b) of § 734.5 were amended to better represent U.S. policy objectives but the 2004 update to supplement no. 2 did not capture these changes. Further, in 2009, paragraph (c) of § 734.5 was dropped from the EAR and in 2016, ''transfer (in-country)'' was added to the EAR in § 734.16. Elsewhere in this rule, § 734.3(a)(4) and (5) are being amended to align with § 736.2(b)(3) of the EAR; the changes to these sections also impact the flowchart in supplement no. 2 to part 732. This rule changes the ''Subject to the EAR?'' flowchart in supplement no. 2 of part 732 to reflect these changes. For example, the first text bubble of the supplement no longer mentions § 734.5(c) and the final text bubble simply refers readers to § 736.2(b)(3), rather than to any specific destinations.

Part 734 Scope of the Export Administration Regulations

Parts 734 and 736 were added to the EAR in 1996. Section 736.2 has been revised several times since then, updating the language regarding what constitutes a ''foreign-produced direct product.'' The most recent update to part 736 was in August of 2020. This rule amends § 734.3(a)(4) and (5) to reflect the terms currently used in § 736.2(b)(3) of the EAR. The definition for the term ''direct product'' is removed from § 734.3(a)(4), because it is being added to part 772, as detailed below.

Part 736

On January 15, 2021, BIS published an interim final rule (86 FR 4865) that inadvertently removed paragraphs (B) and (C) from § 736.2(b)(7)(i). Paragraphs (B) and (C) are added back by this rule. Those paragraphs dictate which schedules of chemicals listed in supplement no. 1 to part 745 a ''U.S. person'' may not export without complying with specific provisions and requirements of the EAR. In addition, as the January 15 interim final rule removed the definition of ''U.S. person'' from § 744.6(c) of the EAR (while leaving the identical definition in § 772.1 of the EAR), BIS is making conforming changes to § 736.2(b)(7)(i)(B) and (C). Specifically, BIS is revising both paragraphs to reference § 772.1, instead of § 744.6(c), for the definition of the term ''U.S. person.'' Quotation marks are also added around the term ''U.S. person'' in both paragraphs, given it is a defined term in part 772. Quotation marks are also added around the term ''direct product'' in § 736.2(b) for the same reason and as detailed below.

Part 738 Commerce Control List Overview and the Country Chart

In June of 2020, License Exception Civil End Users (CIV) was removed from the EAR. After the removal, a sample Commerce Control List entry set forth in § 738.4(b)(2) of the EAR unintentionally retained a reference to License Exception CIV. This rule rectifies this by removing the CIV reference from § 738.4(b)(2) while retaining the remainder of the sample entry.

Part 740 License Exceptions

On December 28, 2020, BIS published a final rule (85 FR 84211) adding Cyprus and Mexico to Country Group A:6. As there were issues with the amendatory instruction to that rule, this rule corrects the amendatory instruction and adds an ''X'' in Column ''[A:6]'' in Supplement No. 1 to Part 740 for ''Cyprus'' and ''Mexico.''

Part 744 Control Policy: End-User and End-Use Based

In April of 2020, BIS published a rule regarding military end users (85 FR 23459). In supplement no. 2 to part 744 of the EAR, paragraph (3)(viii) inadvertently reprinted out-of-date text from Export Control Classification Number (ECCN) 3A992 when referring to ECCN 3E991 technology for those 3A992 items. This rule updates the paragraph to reflect the current text in that ECCN. This edit does not change the scope of the license requirement for items controlled under the ECCN. Quotation marks are also added around the term ''direct product'' in supplement no. 4 to part 744, because the term is being added to part 772 by this rule, as detailed below.

Part 748 Applications (Classification, Advisory, and License) and Documentation

As has been the case for some time, the public may submit advisory opinion requests to BIS in a variety of ways in addition to through the mail (*e.g.,* the U.S. Postal Service or via a shipping and logistics delivery service). This rule revises § 748.3(c) of the EAR to include how to submit advisory opinion requests via email or through the BIS website.

Supplement no. 2 to part 748, ''Unique Application and Submission Requirements,'' is being clarified to reflect BIS policy regarding the letters of assurance described in paragraph (o)(3)(i), which are applicable to license applications submitted for the export of technology controlled for national security reasons to certain countries. Specifically, this clarification reflects BIS policy that license applicants must always obtain letters of assurance, which must be submitted to BIS upon request. Quotation marks are also added around the term ''direct product'' in supplement no. 2, because the term is being added to part 772 by this rule, as

detailed below. This rule also adds in that this applies to exports, reexports, and transfers (in-country), which is currently BIS policy regarding this paragraph.

This rule amends paragraph (b)(6) ''Block 6: Ultimate Consignee,'' of supplement no. 3 to part 748, ''Statement by Ultimate Consignee and Purchaser Content Requirements.'' Prior to publication of this rule, paragraph (b)(6) indicated that an ink signature is required on the BIS–711 ''Statement by Ultimate Consignee and Purchaser'' form. However, following public comments, in a March 2015 final rule, BIS confirmed that electronic signatures are permissible. This rule revises paragraph (b)(6) to more accurately reflect existing text found in § 748.11 of the EAR.

Part 750 Application Processing, Issuance and/or Denial

Sections 750.1, 750.8, and 750.9 are being updated to reflect BIS's use of the Simplified Network Application Process—Redesign (SNAP–R) system by eliminating or rewording parts of the sections that are no longer relevant given the online nature of the system. The SNAP–R system has been in place since October of 2006 and has largely replaced the previous system that involved the submission of paper license applications, but the EAR has not been fully updated to reflect that change. Now that BIS does not mail copies of licenses to applicants with SNAP–R accounts, and almost all exporters have access to licenses electronically (via the SNAP–R system) and can therefore save and print out multiple copies of their licenses themselves, a requirement to return a revoked license or a duplicate copy of a license is, under most circumstances, unnecessary. In § 750.8, the text specific to the return of a revoked license was relevant when BIS sent validated hard copies of licenses to exporters. This rule revises § 750.8 by removing the text requiring the return of revoked or suspended licenses. The remaining text specifies that if BIS revokes or suspends a license, the licensee must retain all applicable supporting documents and records of shipments in accordance with the recording keeping provisions of part 762 of the EAR. In § 750.9, the text specific to the return of duplicate licenses was relevant when BIS sent validated hard copies of licenses to exporters. This rule revises § 750.9 regarding lost, stolen or destroyed paper licenses by removing and reserving § 750.9(a)(3) of the EAR, which required the return of either the original or duplicate paper licenses should the original paper license be found. Doing so aligns the EAR with existing BIS policies and procedures. This rule also revises § 750.1 to reflect the changes this rule makes to §§ 750.8 and 750.9 of the EAR.

Section 750.7(a) is corrected by adding a sentence that directs readers to more detailed information regarding the release of ''technology'' authorized by the issuance of a BIS license, which is set forth within § 734.20 of the EAR. Section 750.7(a) is also broken up into subparagraphs (1), (2), and (3) to make it easier to read.

Part 770 Interpretations

''Release'' as it is used in the context of the EAR is defined in § 734.15, which was added to the EAR in 2016. However, § 770.3(d)(1)(ii) was never updated to reflect the definition. This rule rectifies this omission by amending § 770.3(d)(1)(ii) to direct readers to the definition of a ''release'' in § 734.15 and by altering the language in paragraph (d)(1)(ii) such that it answers the preceding question in § 770.3(d)(1)(i) correctly given the 2016 change in the definition of ''release.''

Part 772 Definitions of Terms

This final rule removes the definition of the term ''direct product'' from § 734.3(a)(4) and adds it to § 772.1. Given the changes to part 734 detailed above, the term ''direct product'' is better suited to appear as a defined term in part 772. This rule does not alter the definition of ''direct product'' or the BIS policy specific to the term.

BIS is also amending paragraph (a) of the definition of ''U.S. person'' in § 772.1 of the EAR to clarify that the definition applies for purposes of §§ 732.3(j), 736.2(b)(7), and 745.2(a)(1) of the EAR. This change does not alter BIS policy, but does bring the definition of ''U.S. person'' in line with the rest of the EAR.

Part 774 The Commerce Control List

This final rule corrects ECCN 0D617 to remove text that was inadvertently included from 0D606 and published as part of a revision of 0D617 on June 3, 2020 (85 FR 34306). In ECCN 0D617, this final rule removes references to 0x606 ECCNs and adds in its place text referencing the 0x617 ECCNs. This final rule also revises the Related Controls paragraph and Items paragraph (a) in the List of Items Controlled section of ECCN 0D617 to remove text that was inadvertently included from 0D606 and to add in its place the intended text from 0D617. The publication of this correction does not change existing BIS policy.

This final rule corrects a reference in the control chart for ECCN 7A611 from ''§ 724.6(a)(7)'' to ''§ 742.6(a)(7)'' in supplement no. 1 to part 774.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. Sections 4801–4852. ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866.

2. Notwithstanding any other provision of law, no person may be required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves a collection currently approved by OMB under control number 0694–0088, Simplified Network Application Processing System. This collection includes, among other things, license applications and commodity classification, and carries a burden estimate of 29.6 minutes for a manual or electronic submission for a total burden estimate of 31,835 hours. BIS does not expect the burden hours associated with this collection to change.

3. This rule does not contain policies with federalism implications as that term is defined under Executive Order 13132.

Administrative Procedure Act and Regulatory Flexibility Act Requirements

Pursuant to Section 4821 of ECRA, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of

proposed rulemaking, opportunity for public participation and delay in effective date.

Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects

15 CFR Part 732

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 738

Exports.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Parts 740, 748 and 750

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Parts 736, 770, and 772

Exports.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, parts 732, 734, 736, 738, 740, 744, 748, 750, 770, 772, and 774 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 732—[AMENDED]

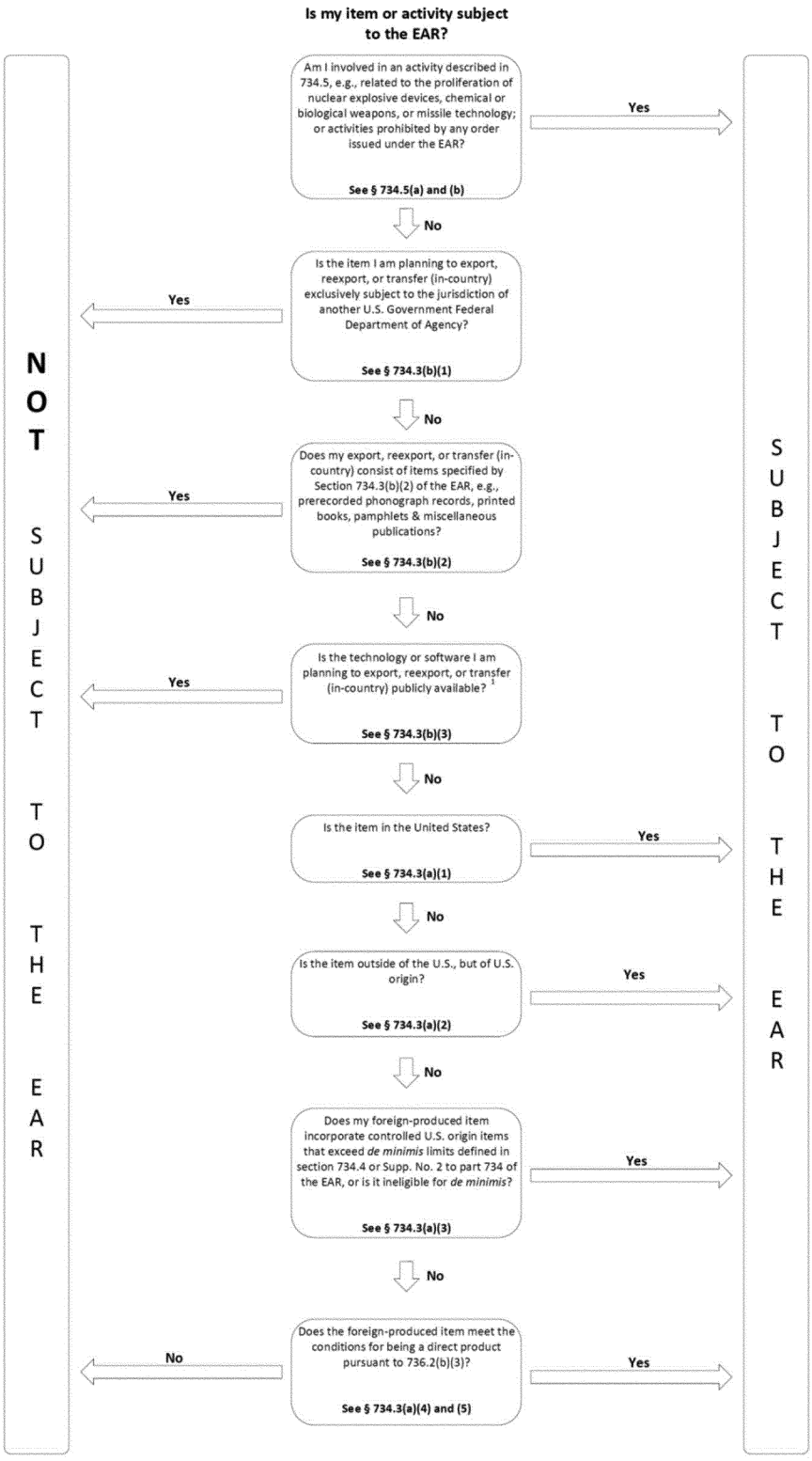
■ 1. The authority citation for part 732 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 2. Supplement no. 2 to part 732 is revised to read as follows:

Supplement No. 2 to Part 732—Subject to the EAR?

BILLING CODE 3510–33–P



[1] Encryption source code in electronic form or media (e.g., computer diskette or CD ROM) remains subject to the EAR (see §734.17)). Publicly available encryption object code "software" classified under ECCN 5D002 is not subject to the EAR when the corresponding source code meets the criteria specified in §742.15(b) of the EAR.

BILLING CODE 3510–33–C

PART 734—[AMENDED]

■ 3. The authority citation for part 734 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3

CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of November 12, 2020, 85 FR 72897 (November 13, 2020).

■ 4. Section 734.3 is amended by revising paragraphs (a)(4) and (5), to read as follows:

§ 734.3 Items subject to the EAR.

(a) * * *

(4) Certain foreign-produced ''direct products'' of specified ''technology'' and ''software,'' as described in § 736.2(b)(3) of the EAR; and

Note to paragraph (a)(4): Certain foreign-manufactured items developed or produced from U.S.-origin encryption items exported pursuant to License Exception ENC are subject to the EAR. See § 740.17(a) of the EAR.

(5) Certain foreign-produced ''direct products'' of a complete plant or any major component of a plant as described in § 736.2(b)(3) of the EAR.

* * * * *

PART 736—[AMENDED]

■ 5. The authority citation for part 736 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Notice of November 12, 2020, 85 FR 72897 (November 13, 2020); Notice of May 6, 2021, 86 FR 26793 (May 10, 2021).

■ 6. Section 736.2 is amended by:
■ a. Adding double quotation marks around the term ''Direct Product'' in paragraph (b) introductory text and the paragraph (b)(3) subject heading;
■ b. Adding double quotation marks around the term ''direct product'' wherever it appears in paragraph (b)(3);
■ c. Adding double quotation marks around the term ''direct products'' in paragraphs (b)(3)(ii)(B)(*2*), (b)(3)(iv)(B)(*2*), and (b)(3)(v); and
■ d. Adding paragraphs (b)(7)(i)(B) and (C).

The additions read as follows:

§ 736.2 General prohibitions and determination of applicability.

* * * * *

(b) * * *

(7) * * *

(i) * * *

(B) If you are a ''U.S. person'' as that term is defined in § 772.1 of the EAR, you may not export a Schedule 1 chemical listed in Supplement No. 1 to part 745 without first complying with the provisions of §§ 742.18 and 745.1 of the EAR.

(C) If you are a ''U.S. person'' as that term is defined in § 772.1 of the EAR, you may not export a Schedule 3 chemical listed in Supplement No. 1 to part 745 to a destination *not* listed in Supplement No. 2 to part 745 without complying with the End-Use Certificate requirements in § 745.2 of the EAR that apply to Schedule 3 chemicals controlled for CW reasons in ECCN 1C350, ECCN 1C355, and ECCN 1C395.

* * * * *

PART 738—[AMENDED]

■ 7. The authority citation for part 738 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 8. Section 738.4 is amended by revising paragraph (b)(2) to read as follows:

§ 738.4 Determining whether a license is required.

* * * * *

(b) * * *

(2) Sample CCL entry.

2A000: Entry heading.

License Requirements

Reason for Control: NS, NP, AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
NS applies to entire entry.	NS Column 2.
NP applies to 2A000.b entire entry.	NP Column 1.
AT applies to entire entry.	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of all License Exceptions)

LVS: $5,000
GBS: Yes

List of Items Controlled

Related Definition: N/A
Related Controls: N/A
Items:

a. Having x.
b. Having z.

* * * * *

PART 740—LICENSE EXCEPTIONS

■ 9. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 7201 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 10. Supplement No. 1 to part 740 is amended by revising the entries for ''Cyprus'' and ''Mexico'' in the Country Group A table to read as follows:

Supplement No. 1 to Part 740—Country Groups

COUNTRY GROUP A

Country	[A:1] Wassenaar participating states [1]	[A:2] Missile technology control regime [2]	[A:3] Australia group	[A:4] Nuclear suppliers group [3]	[A:5]	[A:6]
*	*	*	*	*	*	*
Cyprus			X	X		X
*	*	*	*	*	*	*
Mexico	X		X	X		X
*	*	*	*	*	*	*

* * * * *

PART 744—[AMENDED]

■ 11. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 18, 2020, 85 FR 59641 (September 22, 2020); Notice of November 12, 2020, 85 FR 72897 (November 13, 2020).

■ 12. Supplement no. 2 to part 744 is amended by revising paragraph (3)(viii) to read as follows:

Supplement No. 2 to Part 744—List of Items Subject to the Military End Use or End User License Requirement of § 744.21

* * * * *

(3) * * *

(viii) 3E991 Limited to ''technology'' according to the General Technology Note for the ''development,'' ''production,'' or ''use'' of digital oscilloscopes and transient recorders using analog-to-digital conversion techniques, capable of storing transients by sequentially sampling single-shot inputs at successive intervals of less than 1 ns (greater than 1 giga-sample per second), digitizing to 8 bits or greater resolution and storing 256 or more samples.

* * * * *

Supplement 4 to Part 744 [Amended]

■ 13. Supplement no. 4 to part 744 is amended in footnote 1 by adding double quotation marks around the terms ''direct product'' and ''Direct product'' wherever they appear.

PART 748—[AMENDED]

■ 14. The authority citation for part 748 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 6, 2021, 86 FR 43901 (August 10, 2021).

■ 15. Section 748.3 is amended by revising the introductory text of paragraph (c) and the introductory text of paragraph (c)(1) to read as follows:

§ 748.3 Classification requests and advisory opinions.

* * * * *

(c) *Advisory Opinions.* Advisory opinion requests must be made in writing, and may be delivered to BIS by mail, by email, or through the BIS website. If delivering a request by mail, submit to the address listed in § 748.1(d)(2). Both your letter and envelope must be marked ''Advisory Opinion.'' If submitting by email, submit to *RPD2@bis.doc.gov* with the subject title ''Advisory Opinion.'' If submitting through the BIS website, see *http://www.bis.doc.gov.*

(1) Your submission must contain the following information if you are requesting guidance regarding interpretations of the EAR:

* * * * *

■ 16. Supplement no. 2 to part 748 is amended by revising paragraph (o)(3)(i) to read as follows:

Supplement No. 2 to Part 748—Unique Application and Submission Requirements

* * * * *

(o) * * *

(3) * * *

(i) *Technology controlled for national security reasons.* If you are submitting a license application to export, reexport, and transfer (in-country) technology controlled for national security reasons to a country *not* listed in Country Group D:1, E:1, or E:2 (see Supplement No. 1 to part 740 of the EAR), you must obtain the letter from the ultimate consignee verifying that, unless prior authorization is obtained from BIS, the consignee will not knowingly reexport the technology to any destination, or export the ''direct product'' of the technology, directly or indirectly, to a country listed in Country Group D:1, E:1, or E:2 (see Supplement No. 2 to part 740 of the EAR). If you are unable to obtain this letter of assurance from your consignee, you must state in your license application why the assurances could not be obtained. BIS may request a copy of this letter. * * *

* * * * *

■ 17. Supplement no. 3 to part 748 is amended by revising paragraph (b)(6) to read as follows:

Supplement No. 3 to Part 748—Statement by Ultimate Consignee and Purchaser Content Requirements

* * * * *

(b) * * *

(6) Block 6: Ultimate Consignee. Enter the requested information and sign the statement digitally or in ink. (For a definition of ultimate consignee, see § 748.5(e) of this part.)

* * * * *

PART 750—[AMENDED]

■ 18. The authority citation for part 750 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2013 Comp., p. 223; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320.

■ 19. Section 750.1 is revised to read as follows:

§ 750.1 Scope.

In this part, references to the EAR are references to 15 CFR chapter VII, subchapter C. This part describes the Bureau of Industry and Security's (BIS) process for reviewing your application for a license and the applicable processing times for various types of applications. Information related to the issuance, revocation, or suspension of a license and the denial of a license application is provided along with the procedures on obtaining a duplicate or replacement license (limited to those which BIS has validated and issued in hardcopy), the transfer of a license, and the shipping tolerances available on licenses. This part also contains instructions on obtaining the status of a pending application.

■ 20. Section 750.7 is amended by revising paragraph (a) to read as follows:

§ 750.7 Issuance of licenses.

(a) *Scope.* (1) Unless limited by a condition set out in a license, the export, reexport, or transfer (in-country) authorized by a license is for the item(s), end-use(s), and parties described in the license application and any letters of explanation. The applicant must inform the other parties identified on the license, such as the ultimate consignees and end users, of the license's scope and of the specific conditions applicable to them.

(2) BIS grants licenses in reliance on representations the applicant made or submitted in connection with the license application, letters of explanation, and other documents submitted. Any license obtained in which a false or misleading representation was made, or a material fact was falsified or concealed on the license application, letters of explanation, or any document submitted in connection with the license application, shall be deemed void as of

the date of issuance. See § 750.8(a) of the EAR, which provides that all licenses are subject to revocation, in whole or in part, without notice. See part 764 of the EAR for other sanctions that may result in the event a violation occurs.

(3) A BIS license authorizing the release of ''technology'' to an entity also authorizes the release of the same ''technology'' to the entity's foreign persons who are permanent and regular employees (and who are not proscribed persons) of the entity's facility or facilities authorized on the license, except to the extent a license condition limits or prohibits the release of the ''technology'' to foreign persons of specific countries or country groups. See § 734.20 of the EAR for additional information regarding the release of ''technology'' authorized by a BIS license.

* * * * *

■ 21. Section 750.8 is amended by revising paragraph (b) to read as follows:

§ 750. 8 Revocation or suspension of licenses.

* * * * *

(b) *Revoked or suspended licenses.* If BIS revokes or suspends a license, the licensee must retain all applicable supporting documents and records of shipments in accordance with the recordkeeping provisions of part 762 of the EAR.

■ 22. Section 750.9 is amended by revising paragraph (a) to read as follows:

§ 750.9 Duplicate licenses.

(a) *Lost, stolen or destroyed.* For licensees whom BIS authorized the submission of paper applications, if a license is lost, stolen or destroyed, you, as the licensee, may obtain a duplicate of the license by submitting a letter to the BIS at the address listed in § 748.1(d)(2) of the EAR, Attention: Duplicate License Request.'' You must certify in your letter:

(1) That the original license ([number] issued to [name and address of licensee]) has been lost, stolen or destroyed; and

(2) The circumstances under which it was lost, stolen or destroyed.

* * * * *

PART 770—[AMENDED]

■ 23. The authority citation for 15 CFR part 770 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 24. Section 770.3 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 770.3 Interpretations related to exports of technology and software to destinations in Country Group D:1.

* * * * *

(d) * * *

(1) * * *

(ii) *Answer 1.* Export of technology includes release of U.S.-origin data in a foreign country as defined in § 734.15 of the EAR. So long as the circumstances described here would not exceed that permitted under the License Exception TSU for operation technology and software, as described in § 740.13(a) of the EAR, this is not a ''release'' of technology and a license would not be required.

* * * * *

PART 772—[AMENDED]

■ 25. The authority citation for part 772 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 26. Section 772.1 is amended by:

■ a. Adding a definition for ''direct product'' in alphabetical order; and

■ b. Revising paragraph (a) introductory text of the definition of ''U.S. person''.

The addition and revision read as follows:

§ 772.1 Definitions of terms as used in the Export Administration Regulations (EAR).

* * * * *

Direct product. The immediate product (including processes and services) produced directly by the use of technology or software.

* * * * *

U.S. Person. (a) For purposes of §§ 732.3(j), 736.2(b)(7), 740.21(e)(1), 744.6, 744.10, 744.11, 744.12, 744.13, 744.14, and 745.2(a)(1) of the EAR, the term U.S. person includes:

* * * * *

PART 774—[AMENDED]

■ 27. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 28. Supplement No. 1 to Part 774 is amended by revising ECCN 0D617 and ECCN 7A611 to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

0D617 ''Software'' ''specially designed'' for the ''development,'' ''production,'' operation, or maintenance of commodities controlled by 0A617, ''equipment'' controlled by 0B617, or materials controlled by 0C617 (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT, UN

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
NS applies to entire entry, except 0D617.y.	NS Column 1.
RS applies to entire entry, except 0D617.y.	RS Column 1.
RS applies to 0D617.y.	China, Russia, or Venezuela (see § 742.6(a)(7)).
AT applies to entire entry.	AT Column 1.
UN applies to entire entry, except 0D617.y.	See § 746.1(b) for UN controls.

List Based License Exceptions (See Part 740 for a description of all license exceptions)

TSR: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any ''software'' in 0D617.

List of Items Controlled

Related Controls: (1) ''Software'' directly related to articles controlled by USML Category XIII is subject to the control of USML paragraph XIII(l). (2) See ECCN 0A919 for foreign-made ''military commodities'' that incorporate more than a *de minimis* amount of U.S.-origin ''600 series'' controlled content.

Related Definitions: N/A

Items:

a. ''Software'' (other than ''software'' controlled in paragraph .y of this entry) ''specially designed'' for the ''development,'' ''production,'' operation or maintenance of commodities controlled by ECCNs 0A617 (except 0A617.y), 0B617, or 0C617.

b. to x. [Reserved].

y. Specific ''software'' ''specially designed'' for the ''production,'' ''development,'' operation or maintenance of commodities controlled by ECCN 0A617.y.

* * * * *

7A611 Military fire control, laser, imaging, and guidance equipment, as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, MT, RS, AT, UN

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
NS applies to entire entry except 7A611.y.	NS Column 1.
MT applies to commodities in 7A611.a that meet or exceed the parameters in 7A103.b or .c.	MT Column 1.
RS applies to entire entry except 7A611.y.	RS Column 1.
RS applies to 7A611.y.	China, Russia, or Venezuela (see § 742.6(a)(7)).
AT applies to entire entry.	AT Column 1.
UN applies to entire entry except 7A611.y.	See § 746.1(b) for UN controls.

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: $1500
GBS: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 7A611.

List of Items Controlled

Related Controls: (1) Military fire control, laser, imaging, and guidance equipment that are enumerated in USML Category XII, and technical data (including software) directly related thereto, are subject to the ITAR. (2) See Related Controls in ECCNs 0A504, 2A984, 6A002, 6A003, 6A004, 6A005, 6A007, 6A008, 6A107, 7A001, 7A002, 7A003, 7A005, 7A101, 7A102, and 7A103. (3) See ECCN 3A611 and USML Category XI for controls on countermeasure equipment. (4) See ECCN 0A919 for foreign-made ''military commodities'' that incorporate more than a *de minimis* amount of U.S. origin ''600 series'' controlled content.

Related Definitions: N/A

Items:

a. Guidance or navigation systems, not elsewhere specified on the USML, that are ''specially designed'' for a defense article on the USML or for a 600 series item.

b. to w. [Reserved]

x. ''Parts,'' ''components,'' ''accessories,'' and ''attachments,'' including accelerometers, gyros, angular rate sensors, gravity meters (gravimeters), and inertial measurement units (IMUs), that are ''specially designed'' for defense articles controlled by USML Category XII or items controlled by 7A611, and that are NOT:

x.1. Enumerated or controlled in the USML or elsewhere within ECCN 7A611;

x.2. Described in ECCNs 6A007, 6A107, 7A001, 7A002, 7A003, 7A101, 7A102 or 7A103; or

x.3. Elsewhere specified in ECCN 7A611.y or 3A611.y.

y. Specific ''parts,'' ''components,'' ''accessories,'' and ''attachments'' ''specially designed'' for a commodity subject to control in this ECCN or a defense article in Category XII and not elsewhere specified on the USML or in the CCL, as follows, and ''parts,'' ''components,'' ''accessories,'' and ''attachments'' ''specially designed'' therefor:

y.1 [Reserved]

* * * * *

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2021–20649 Filed 10–4–21; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 742 and 774

[Docket No. 210928–0198]

RIN 0694–AI08

Commerce Control List: Expansion of Controls on Certain Biological Equipment ''Software''

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) publishes this final rule to amend the Export Administration Regulations (EAR) to implement the decision made at the Australia Group (AG) Virtual Implementation Meeting session held in May 2021, and later adopted pursuant to the AG's silence procedure. This decision updated the AG Common Control List for dual-use biological equipment by adding controls on nucleic acid assembler and synthesizer ''software'' that is capable of designing and building functional genetic elements from digital sequence data. Prior to this AG decision, BIS, consistent with the interagency process described in the Export Control Reform Act of 2018 (ECRA), identified this ''software'' as a technology to be evaluated as an emerging technology. The decision by BIS to amend the CCL to include this ''software'' complies with the requirements of ECRA and also reflects the decision of the AG to add it to the regime's Common Control List, thereby making exports of this ''software'' subject to multilateral control through the implementation of these changes by individual AG participating countries (including the United States).

DATES: This rule is effective October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Wesley Johnson, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482–0091, Email: *Wesley.Johnson@bis.doc.gov.*

SUPPLEMENTARY INFORMATION: The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the decision made at the Australia Group (AG) Virtual Implementation Meeting session held in May 2021, and subsequently adopted pursuant to the AG silence procedure (the AG silence procedure provides for the adoption of a measure, subsequent to its provisional acceptance at an AG plenary or intersessional meeting, provided that no participating country submits an objection on or before a specified date). The AG is a multilateral forum consisting of 42 participating countries and the European Union. These participants maintain export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

Addition of New Export Control Classification Number (ECCN) 2D352—''Software'' for Nucleic Acid Assemblers/Synthesizers

This final rule amends the Commerce Control List (CCL), in Supplement No. 1 to part 774 of the EAR, to add a new ECCN 2D352 to reflect a decision made at the May 2021 Virtual Implementation Meeting session to modify the AG biological equipment list to add controls on ''software'' that is: (1) Designed for nucleic acid assemblers and synthesizers described on this AG Common Control List; and (2) capable of designing and building functional genetic elements from digital sequence data. Specifically, new ECCN 2D352 controls ''software'' designed for nucleic acid assemblers and synthesizers controlled by ECCN 2B352.j that is capable of designing and building functional genetic elements from digital sequence data.

This ''software,'' as controlled under new ECCN 2D352, requires a license for chemical and biological weapons (CB) reasons and anti-terrorism (AT) reasons to the destinations indicated under CB Column 2 and AT Column 1, respectively, on the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR (also see the AT license requirements described in part 742 that apply to Iran, North Korea and Syria). A license also is required to certain

destinations in accordance with the embargoes and other special controls described in part 746 of the EAR.

ECCN 2E001 Amended To Include ''technology'' for New ECCN 2D352

In addition, this rule amends ECCN 2E001 (which controls, *inter alia,* ''technology'' for the ''development'' of the nucleic acid assemblers and synthesizers described in ECCN 2B352.j) to indicate that ''technology'' for the ''development'' of ''software'' controlled by new ECCN 2D352 is controlled by ECCN 2E001 for CB reasons and AT reasons to the destinations indicated under CB Column 2 and AT Column 1, respectively, on the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR. The CB control entry in the License Requirements table for ECCN 2E001 is amended to reflect this change. The heading of ECCN 2E001 does not need to be amended to reflect this change because the ECCN heading indicates that, with limited specified exceptions, this ECCN controls ''technology'' for the ''development'' of ''software'' listed under Category 2D of the CCL, which now includes new ECCN 2D352.

Conforming Amendments to § 742.2 (Proliferation of Chemical and Biological Weapons)

Consistent with the May 2021 AG decision described above, this final rule amends Section 742.2 of the EAR by revising paragraphs (a)(2)(viii) and (a)(2)(ix) to reflect the addition of ECCN 2D352 to the CCL and to indicate that ''technology'' for the ''development'' of ''software'' controlled by new ECCN 2D352 is controlled by ECCN 2E001. These changes were not included in a proposed rule that BIS published on November 6, 2020 (85 FR 71012), which is described in more detail, below. However, because they are merely conforming changes that cross reference the aforementioned amendments to the CCL, BIS is making the changes in this final rule.

Evaluation of Nucleic Acid Assembler/Synthesizer ''Software'' as an Emerging Technology

Prior to the addition of nucleic acid assembler/synthesizer ''software'' to the AG biological equipment list, BIS identified this ''software'' as a technology to be evaluated as an emerging technology, consistent with the interagency process described in Section 1758 of the Export Control Reform Act of 2018 (ECRA) (codified at 50 U.S.C. 4817). This identification was based on a finding that this ''software'' is capable of being used to operate nucleic acid assemblers and synthesizers controlled under ECCN 2B352 for the purpose of generating pathogens and toxins without the need to acquire controlled genetic elements and organisms. Consequently, the absence of export controls on this ''software'' could be exploited for biological weapons purposes.

Consistent with the emerging and foundational technologies notice and comment requirements in Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), BIS published a proposed rule on November 6, 2020 (85 FR 71012) (hereinafter, ''November 6 proposed rule''), to provide the public with notice and the opportunity to comment on adding new ECCN 2D352 to control ''software'' for the operation of nucleic acid assemblers and synthesizers described in ECCN 2B352.j that is capable of designing and building functional genetic elements from digital sequence data. The November 6 proposed rule also indicated that ''technology'' for the ''development'' of such ''software'' would be controlled under ECCN 2E001.

As stated above, the imposition of controls on this ''software'' by this final rule (under new ECCN 2D352) reflects a decision by the AG to add this ''software'' to its biological equipment control list. Consequently, this action by BIS also conforms with Section 1758(c) of ECRA, which specifies that ''the Secretary of State, in consultation with the Secretary [of Commerce] and the Secretary of Defense, and the heads of other Federal agencies, as appropriate, shall propose that any technology identified pursuant to Section 1758(a) of ECRA be added to the list of technologies controlled by the relevant multilateral export control regimes.''

Comments Submitted in Response to BIS's November 6 Proposed Rule

BIS received comments from four respondents in response to the publication of its November 6 proposed rule. The comments from these respondents, together with BIS's responses, are described below.

Comment: One respondent stated that BIS should not treat commodities and ''software'' as potential emerging technologies, because Section 1758 of ECRA, which provides the statutory standard for establishing new controls on emerging and foundational technologies, refers only to ''technology,'' as defined in Section 1742 of ECRA (codified at 50 U.S.C. 4801). The respondent noted that Section 1758 of ECRA makes no mention of commodities or ''software,'' which, together with ''technology,'' are included in the statutory definition of ''item.'' The respondent further observed that the term ''item'' is included in other sections of ECRA and that its absence from Section 1758 is given meaning by considering only ''technology'' as defined in Section 1742 of ECRA. The respondent also noted that this interpretation would be consistent with the EAR definition of ''technology,'' which does not include commodities or ''software.'' Consequently, the respondent recommended that BIS should follow this interpretation of the statute, as well as its own regulations regarding the definition of ''technology,'' by identifying only emerging ''technology'' and not related emerging commodities and ''software.''

BIS response: The terms ''technologies,'' ''emerging technologies'' and ''critical technologies'' are used in Section 1758 of ECRA (50 U.S.C. 4817) and Section 721(a)(6) of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. 4565(a)(6)), with the latter defining ''critical technologies'' to mean those described in 50 U.S.C. 4565(a)(6)(A)(i) through (vi). The DPA indicates that the term ''critical technologies'' includes by definition emerging and foundational technologies controlled pursuant to Section 1758 of ECRA, as well as ''items included on the Commerce Control List'' for multilateral reasons or for surreptitious listening or regional stability reasons. As the respondent noted, the term ''items'' includes ''commodities,'' ''software'' and ''technology.'' Consequently, the term ''technologies,'' as used within the context of these ECRA and DPA provisions, encompasses ''commodities,'' ''software'' and ''technology,'' and not ''technology'' only (*e.g.,* as that term is more narrowly defined in Section 1742 of ECRA). Furthermore, note that BIS's August 27, 2020 (85 FR 52934), advance notice of proposed rulemaking on the identification and review of controls for certain foundational technologies stated that the term ''technologies,'' as used in Section 1758 of ECRA, includes not only ''technology,'' but also ''commodities'' and ''software'' as those terms are used in the EAR.

Comment: One respondent observed that the ''capable of'' standard does not place sufficient emphasis upon the purpose for which an item is designed. Consequently, this standard might inadvertently control technology that is not designed to produce a controlled item, even when the ability of the technology to produce the controlled item is wholly unrelated to the primary

purpose of the technology. Furthermore, the respondent noted that an exporter could be unaware that a given technology is ''capable of'' performing a function for which the technology was not designed and for which it is not commonly used.

BIS response: The consensus of the interagency process followed in accordance with Section 4817 of ECRA was that emerging technology controls should apply to ''software'' designed for nucleic acid assemblers and synthesizers controlled by 2B352.j that is ''capable of'' designing and building functional genetic elements from digital sequence data. The scope of this control is also consistent with the decision made at the AG's May 2021 Virtual Implementation Meeting session to add this ''software'' to its ''Control List of Dual-Use Biological Equipment and Related Technology and Software.'' If the controls on this ''software'' applied only to ''software'' ''designed'' or ''specially designed'' for the purpose of generating pathogens and toxins without the need to acquire controlled genetic elements and organisms, the scope of the controls would have been far too narrow. Consequently, there would have been a significantly increased risk that certain ''software'' not captured by narrower controls could have been exploited for biological weapons purposes.

Comment: One respondent stated that the ''software'' controls proposed to be implemented in new ECCN 2D352, and all future emerging and foundational technology controls, should be implemented multilaterally, rather than unilaterally. The respondent noted that a multilateral approach to export controls would increase their effectiveness and minimize their impact on U.S. industry. Specifically, multilateral export controls are preferable to unilateral controls, because the former typically place U.S. industry on a more level playing field versus producers/suppliers in other countries.

BIS response: This final rule imposes controls on ''software'' designed for nucleic acid assemblers and synthesizers controlled by 2B352.j to reflect the decision made at the AG's May 2021 Virtual Implementation Meeting session to add such ''software'' to its ''Control List of Dual-Use Biological Equipment and Related Technology and Software.'' This action by BIS is in accordance with Section 4817(c) of ECRA, which specifies that ''the Secretary of State, in consultation with the Secretary [of Commerce] and the Secretary of Defense, and the heads of other Federal agencies, as appropriate, shall propose that any technology identified pursuant to Section 4817(a) of ECRA be added to the list of technologies controlled by the relevant multilateral export control regimes.''

Comment: One respondent recommended that BIS issue emerging and foundational technology controls as proposed rules and closely follow ECRA's statutory requirements and guidance. This would provide industry with the opportunity to provide formal comments to government officials so that the latter could address industry's questions and concerns. The respondent further noted that such consultations are critical to the effectiveness of regulations in achieving national security goals, without placing undue or unintended burdens on U.S. exports.

BIS response: Consistent with the emerging and foundational technologies notice and comment requirements in Section 4817(a)(2)(C) of ECRA, BIS published a proposed rule on November 6, 2020 (85 FR 71012), to provide the public with notice and the opportunity to comment on adding a new ECCN 2D352 to control ''software'' for the operation of nucleic acid assemblers and synthesizers described in ECCN 2B352.j that is capable of designing and building functional genetic elements from digital sequence data. As indicated above, BIS received comments from four respondents in response to the publication of its November 6 proposed rule. These comments are addressed by BIS in the preamble of this final rule.

Comment: One respondent expressed concern that the acquisition of the nucleic acid assembler and synthesizer ''software'' proposed for control under new ECCN 2D352 by BIS's November 6 proposed rule could be used to generate pathogens and toxins without the need to directly acquire controlled genetic elements and organisms. This respondent indicated that ''the capabilities of this ''software'' lower the bar for acquisition of controlled genetic elements and so represent an increase in the risk of proliferation of biological weapons-related technology.'' According to this respondent, automated benchtop synthesis devices could allow unskilled individuals to create DNA sequences that might be used to produce a biological weapon. This respondent also expressed a growing concern about the potential for active circumvention of ''software'' for the operation of nucleic acid assemblers and synthesizers. For example, ''software'' for operating benchtop nucleic acid synthesis devices could be written to incorporate biosecurity screening onboard the device. Consequently, if such ''software'' were easily acquired (*e.g.,* in the absence of export controls), these devices could be hacked to circumvent biosecurity screening, thereby enabling covert synthesis of otherwise controlled genetic elements. For this reason, these devices (and, in certain instances, their components and operating ''software'') should be subject to export controls. In this regard, the respondent indicated a preference for multilateral export controls (*e.g.,* the adoption of export controls by the Australia Group).

BIS Response: The views expressed by this respondent support, and expand upon, the rationale provided by BIS (both in its November 6 proposed rule and in this final rule) for the imposition of controls on this nucleic acid assembler/synthesizer ''software'' under new ECCN 2D352. In addition, as noted in response to other comments described in this final rule, the controls on this ''software'' reflect the decision made at the AG's May 2021 Virtual Implementation Meeting session and, consequently, are being imposed multilaterally by all AG participating countries (including the United States).

Comment: One respondent expressed concern that the establishment by BIS of more restrictive controls on ''software'' for the operation of certain automated nucleic acid assemblers and synthesizers could damage trade and collaboration in this field with certain U.S. allies and thereby decrease the United States' global competitiveness in this field. Consequently, this respondent stated that any controls that are placed on such ''software'' should not impair the ability of the United States and its allies to trade in intermediate goods or to collaborate on R&D, both of which are crucial to maintaining their shared advantages vis-à-vis other foreign competitors. In this regard, the respondent noted that the methods for manipulating, growing, recovering, concentrating, stabilizing, and testing biological materials for use in weapons employ many of the same materials and equipment used to produce vaccines, pharmaceuticals, and a wide variety of food products.

BIS response: As indicated above, new ECCN 2D352 controls ''software'' designed for nucleic acid assemblers and synthesizers controlled by 2B352.j, consistent with the decision made at the AG's May 2021 Virtual Implementation Meeting session to add such ''software'' to its ''Control List of Dual-Use Biological Equipment and Related Technology and Software.'' This ''software,'' as controlled under new ECCN 2D352, requires a license for CB reasons and AT reasons to the destinations indicated under CB

Column 2 and AT Column 1, respectively, on the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR. Consequently, this ''software'' generally does not require a license for export, reexport or transfer (in-country) to destinations located in AG-participating countries. That being the case, the controls that apply to this ''software'' under new ECCN 2D352 should not impair the ability of the United States to trade in intermediate goods with most of its allies or to collaborate on R&D with such countries.

Comment: One respondent asserted that the nucleic acid assembler and synthesizer ''software'' proposed for control under new ECCN 2D352 by BIS's November 6 proposed rule is currently subject to the controls described in Category XIV (m) of the United States Munitions List (USML) (22 CFR 121.1), as well as the controls described in USML Category XIV(f)(8). Specifically, this respondent stated that such ''software'' involves technical data directly related to the defense articles enumerated in paragraphs (a) through (l) and (n) of USML Category XIV and that, as such, it is subject to the export licensing jurisdiction of the Directorate of Defense Trade Controls, U.S. Department of State, under the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120–130). Furthermore, the respondent asserted that such ''software'' is also restricted per USML Category XIV(f)(8)(ii) and (f)(8)(iii), which apply to any part, component, accessory, attachment, equipment, or system that is either manufactured using classified production data or being developed using classified information.

BIS Response: The ''software'' that this final rule controls under new ECCN 2D352 on the CCL is dual-use ''software'' that, as noted above, was added to the AG ''Control List of Dual-Use Biological Equipment and Related Technology and Software'' following a decision made at the AG's May 2021 Virtual Implementation Meeting session. As indicated in its title, all of the items included on this AG common control list are dual-use items—not military items. Consequently, the respondent is mistaken in claiming that such ''software'' is restricted per USML Category XIV(f)(8)(ii) and (f)(8)(iii), which apply to any part, component, accessory, attachment, equipment, or system that is either manufactured using classified production data or being developed using classified information. New ECCN 2D352 does not control ''software'' that was manufactured, or is in the process of being developed, using classified information subject to control under the ITAR or the regulations of any other U.S. Government agency.

Saving Clause

Shipments of items removed from eligibility for export, reexport or transfer (in-country) under a license exception or without a license (*i.e.,* under the designator ''NLR'') as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on October 5, 2021, pursuant to actual orders for export, reexport or transfer (in-country) to a foreign destination, may proceed to that destination under the previously applicable license exception or without a license (NLR) so long as they are exported, reexported or transferred (in-country) before December 6, 2021. Any such items not actually exported, reexported or transferred (in-country) before midnight, on December 6, 2021, require a license in accordance with this regulation.

''Deemed'' exports of ''technology'' and ''source code'' removed from eligibility for export under a license exception or without a license (under the designator ''NLR'') as a result of this regulatory action may continue to be made under the previously available license exception or without a license (NLR) before December 6, 2021. Beginning at midnight on December 6, 2021, such ''technology'' and ''source code'' may no longer be released, without a license, to a foreign national subject to the ''deemed'' export controls in the EAR when a license would be required to the home country of the foreign national in accordance with this regulation.

Export Control Reform Act of 2018

The Export Control Reform Act of 2018 (ECRA), as amended, codified at 50 U.S.C. 4801–4852, serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including: Potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits and of reducing costs, harmonizing rules, and promoting flexibility. This rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule contains the following collections of information subject to the requirements of the PRA. These collections have been approved by OMB under control numbers 0694–0088 (Simplified Network Application Processing System) and 0694–0096 (Five Year Records Retention Period). The approved information collection under OMB control number 0694–0088 includes license applications, among other things, and carries a burden estimate of 29.6 minutes per manual or electronic submission for a total burden estimate of 31,833 hours. The approved information collection under OMB control number 0694–0096 includes recordkeeping requirements and carries a burden estimate of less than 1 minute per response for a total burden estimate of 248 hours.

Although this final rule makes important changes to the EAR for items controlled for chemical/biological (CB) reasons, BIS has determined that the overall increase in costs and burdens due to this rule will be minimal. Specifically, BIS expects the burden hours associated with these collections will increase, slightly, by 7 hours and 39 minutes (*i.e.,* 15 applications × 30.6 minutes per response) for a total estimated cost increase of $230 (*i.e.,* 7 hours and 39 minutes × $30 per hour). The $30 per hour cost estimate for OMB control number 0694–0088 is consistent with the salary data for export compliance specialists currently available through *glassdoor.com* (*glassdoor.com* estimates that an export compliance specialist makes $55,280 annually, which computes to roughly $26.58 per hour). This increase is not expected to exceed the existing estimates currently associated with OMB control numbers 0694–0088 and 0694–0096.

Written comments and recommendations for the information collections referenced above should be sent within 30 days of the publication of this final rule to: *www.reginfo.gov/public/do/PRAMain.* Find these

particular information collections by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. As stated in the preamble of this final rule, the amendments contained in this rule reflect a decision made at the Australia Group (AG) Virtual Implementation Meeting session held in May 2021, and later adopted pursuant to the AG's silence procedure. Therefore, pursuant to Section 1762 of the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. Sec. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation and delay in effective date.

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this final rule by the APA or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*), are not applicable.

Consistent with the emerging and foundational technologies notice and comment requirements in Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), BIS published a proposed rule on November 6, 2020 (85 FR 71012), to provide the public with notice and the opportunity to comment on its proposal to add a new ECCN 2D352 to the Commerce Control List (CCL), for the purpose of controlling ''software'' for certain nucleic acid synthesizers and assemblers for chemical/biological (CB) reasons. In addition, consistent with the Regulatory Flexibility Act, BIS prepared an initial regulatory flexibility analysis (IRFA) of the impact that the proposed rule, if adopted, would have on small businesses. The IRFA prepared by BIS requested comments on the analyses and conclusions contained therein, including the overall conclusion that the amendments in BIS's November 6 proposed rule would not have a significant economic impact on a substantial number of small entities.

BIS received comments from four respondents on its November 6 proposed rule—these comments and BIS's responses are summarized in the preamble of this final rule. BIS did not receive any comments in response to the analyses and conclusions contained in the IRFA for its November 6 proposed rule. Accordingly, no regulatory flexibility analysis is required for this final rule, and none has been prepared.

List of Subjects

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements, Terrorism.

For the reasons stated in the preamble, parts 742 and 774 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 742—CONTROL POLICY—CCL BASED CONTROLS

■ 1. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 12, 2020, 85 FR 72897 (November 13, 2020).

■ 2. Section 742.2 is amended by revising paragraphs (a)(2)(viii) and (ix) to read as follows:

§ 742.2 Proliferation of chemical and biological weapons.

(a) * * *

(2) * * *

(viii) Software identified in ECCN 2D351 or 2D352, as follows:

(A) Dedicated software identified in ECCN 2D351 for the ''use'' of toxic gas monitoring systems and their dedicated detecting components controlled by ECCN 2B351;

(B) Software designed for nucleic acid assemblers and synthesizers controlled by 2B352.j that is capable of designing and building functional genetic elements from digital sequence data.

(ix) Technology identified in ECCN 2E001 for the ''development'' of software controlled by ECCN 2D351 or 2D352.

* * * * *

PART 774—THE COMMERCE CONTROL LIST

■ 3. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 4. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2, add an entry for ECCN 2D352 immediately following ECCN 2D351, and revise ECCN 2E001 to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

2D352 ''Software'' designed for nucleic acid assemblers and synthesizers controlled by 2B352.j that is capable of designing and building functional genetic elements from digital sequence data.

License Requirements

Reason for Control: CB, AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
CB applies to entire entry.	CB Column 2.
AT applies to entire entry.	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: N/A

List of Items Controlled

Related Controls: See ECCN 1E001 for ''development'' or ''production ''technology'' for genetic elements controlled by ECCN 1C353.

Related Definitions: See Section 772.1 of the EAR for the definitions of ''software,'' ''program,'' and ''microprogram.''

Items: The list of items controlled is contained in the ECCN heading.

* * * * *

2E001 ''Technology'' according to the General Technology Note for the ''development'' of equipment or ''software'' controlled by 2A (except 2A983, 2A984, 2A991, or 2A994), 2B (except 2B991, 2B993, 2B996, 2B997, 2B998, or 2B999), or 2D (except 2D983, 2D984, 2D991, 2D992, or 2D994).

License Requirements

Reason for Control: NS, MT, NP, CB, AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
NS applies to ''technology'' for items controlled by 2A001, 2B001 to 2B009, 2D001 or 2D002.	NS Column 1.

Control(s)	Country chart (see Supp. No. 1 to part 738)
MT applies to ''technology'' for items controlled by 2B004, 2B009, 2B104, 2B105, 2B109, 2B116, 2B117, 2B119 to 2B122, 2D001, or 2D101 for MT reasons.	MT Column 1.
NP applies to ''technology'' for items controlled by 2A225, 2A226, 2B001, 2B004, 2B006, 2B007, 2B009, 2B104, 2B109, 2B116, 2B201, 2B204, 2B206, 2B207, 2B209, 2B225 to 2B233, 2D001, 2D002, 2D101, 2D201, or 2D202 for NP reasons.	NP Column 1.
NP applies to ''technology'' for items controlled by 2A290, 2A291, or 2D290 for NP reasons.	NP Column 2.
CB applies to ''technology'' for equipment controlled by 2B350 to 2B352, valves controlled by 2A226 having the characteristics of those controlled by 2B350.g, and software controlled by 2D351 or 2D352.	CB Column 2.
AT applies to entire entry.	AT Column 1.

Reporting Requirements

See § 743.1 of the EAR for reporting requirements for exports under License Exceptions, and Validated End-User authorizations.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: Yes, except N/A for MT

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit ''technology'' according to the General Technology Note for the ''development'' of ''software'' specified in the License Exception STA paragraph in the License Exception section of ECCN 2D001 or for the ''development'' of equipment as follows: ECCN 2B001 entire entry; or ''Numerically controlled'' or manual machine tools as specified in 2B003 to any of the destinations listed in Country Group A:6 (See Supplement No. 1 to part 740 of the EAR).

List of Items Controlled

Related Controls: See also 2E101, 2E201, and 2E301

Related Definitions: N/A

Items:

The list of items controlled is contained in the ECCN heading.

Note 1 to 2E001: ECCN 2E001 includes ''technology'' for the integration of probe systems into coordinate measurement machines specified by 2B006.a.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2021–21493 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–33–P

FEDERAL TRADE COMMISSION

16 CFR Part 1

Procedures for Submission of Rules Under the Horseracing Integrity and Safety Act

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') is issuing rules pursuant to the Horseracing Integrity and Safety Act (''Act'') to provide procedures for the Horseracing Integrity and Safety Authority (''Authority'') to submit its proposed rules and proposed rule modifications to the Commission for review.

DATES: These rule revisions are effective on October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Austin King (202–326–3166), Associate General Counsel for Rulemaking, Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The Horseracing Integrity & Safety Act,[1] enacted on December 27, 2020, directs the Federal Trade Commission to oversee the activities of a private, self-regulatory organization called the Horseracing Integrity and Safety Authority.

Section 4(a) of the Act, 15 U.S.C. 3053(a), requires the Authority to submit to the Commission, in accordance with such rules as the Commission may prescribe under Section 553 of Title 5, United States Code, any proposed rule, or proposed modification to a rule, of the Authority relating to: (1) The bylaws of the Authority; (2) a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods; (3) laboratory standards for accreditation and protocols; (4) standards for racing surface quality maintenance; (5) racetrack safety standards and protocols; (6) a program for injury and fatality data analysis; (7) a program of research and education on safety, performance, and anti-doping and medication control; (8) a description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons; (9) a schedule of civil sanctions for violations; (10) a process or procedures for disciplinary hearings; and (11) a formula or methodology for determining the assessments described in 15 U.S.C. 3052(f).

Accordingly, the Commission is adding a new subpart S to part 1 of its Rules of Practice, to provide procedures for the Authority to file its proposed rules and proposed modifications to existing rules with the Commission for review.

I. Section 1.140—Definitions

Section 1.140 defines relevant terms used in the proposed regulations. Each definition is based on a corresponding definition contained in Section 2 of the Act, 15 U.S.C. 3051, except as otherwise noted below.

The definition of ''HISA Guidance'' derives from Section 5(g)(1) of the Act, 15 U.S.C. 3054(g)(1), which states the Authority may issue guidance that ''sets forth an interpretation of an existing rule, standard, or procedure of the Authority'' or a ''policy or practice with respect to the administration or enforcement of such an existing rule, standard, or procedure'' and ''relates solely to the administration of the Authority; or any other matter, as specified by the Commission, by rule, consistent with the public interest and the purposes of this subsection [15 U.S.C. 3054(g)(1)].'' The Commission is adopting this definition and adding that HISA Guidance does not have the force of law, to distinguish HISA Guidance from a proposed modification to a rule.

The Act does not contain definitions for ''proposed rule'' or ''proposed modification.'' However, because these terms are used frequently throughout the regulations, the Commission is defining them for clarity. ''Proposed rule'' is defined as any rule proposed by the Authority pursuant to the Act. ''Proposed rule modification'' or ''modification'' is defined as any proposed modification to a rule, proposed rule change, or any interpretation or statement of policy or practice relating to an existing rule of the Authority that is not HISA Guidance and would have the force of law if

[1] 15 U.S.C. 3051 through 3060.

approved as a final rule. A proposed modification is distinguished from HISA Guidance in that a modification would have the force of law if approved and must therefore be approved by the Commission pursuant to Section 4(b)(2) of the Act, 15 U.S.C. 3053(b)(2). HISA Guidance need not be approved by the Commission but takes effect upon submission to the Commission pursuant to Section 5(g)(3) of the Act, 15 U.S.C. 3054(g)(3).

II. Section 1.141—Required Submissions

The Act requires the Authority to submit proposed rules or proposed rule modifications on certain subjects to the Commission for approval. These subjects are set forth in Section 4(a) of the Act, 15 U.S.C. 3053(a), which states the Authority must submit to the Commission, in accordance with such rules as the Commission may prescribe under Section 553 of Title 5, any proposed rule, or proposed modification to a rule, of the Authority relating to: (1) The bylaws of the Authority; (2) a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods; (3) laboratory standards for accreditation and protocols; (4) standards for racing surface quality maintenance; (5) racetrack safety standards and protocols; (6) a program for injury and fatality data analysis; (7) a program of research and education on safety, performance, and anti-doping and medication control; (8) a description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons; (9) a schedule of civil sanctions for violations; (10) a process or procedures for disciplinary hearings; and (11) a formula or methodology for determining assessments described in 15 U.S.C. 3052(f). The Commission is adopting this language in its regulations.

The Commission is also adding a provision that the Authority must submit ''any other proposed rule or modification the Act requires the Authority to submit to the Commission for approval.'' For instance, the Act requires the Authority to submit rules regarding modifications to baseline anti-doping standards (15 U.S.C. 3055(g)(3)(b)) and modifications to racetrack safety rules (15 U.S.C. 3056(c)(2)(B)(ii)). Section 5(c)(2) of the Act, 15 U.S.C. 3054(c)(2), requires the Authority to submit to the Commission for approval any rules and procedures under Section 5(c)(1)(A) of the Act, 15 U.S.C. 3054(c)(1)(A), authorizing access to offices, racetrack facilities, other places of business, books, records, and personal property of covered persons used in the care, treatment, training, and racing of covered horses; authorizing the issuance and enforcement of subpoenas and subpoenas duces tecum; and authorizing other investigatory powers of the nature and scope exercised by State racing commissions before the program effective date. Such proposed rules and modifications must also be submitted to the Commission for approval.

III. Section 1.142—Submission of Proposed Rule or Modification

The Act requires the Commission to evaluate the Authority's proposed rules and modifications to determine whether they are consistent with the Act and the applicable rules approved by the Commission. *See* 15 U.S.C. 3053(c)(2). To avoid delays in the rule review process, the Commission is requiring the Authority to submit the information necessary for it to evaluate the proposed rule or modification promptly and efficiently. Section 1.142 is designed to elicit the information the Commission needs to determine whether the proposed rule or modification is consistent with the Act and the rules and regulations issued thereunder.

A. Contents of Submission

For a submission to qualify as a proposed rule or proposed modification to a rule under Section 4(a) of the Act, 15 U.S.C. 3053(a), the Authority must submit a complete draft of the **Federal Register** document for its proposed or modified rule, which includes the text of the rule and a statement of the purpose of, and statutory basis for, the proposed rule or modification. The Commission's intention is to require the Authority to provide an explanation of its rules that will allow both the Commission and the public to understand the nature and purpose of its proposed rules or modifications—the reasons for adopting the proposed rule or modification; any problems the proposed rule or modification is intended to address and how the proposed rule or modification will resolve those problems; and how the proposed rule or modification will affect covered persons, covered horses, and covered horseraces.

The Commission is also requiring the Authority to explain the statutory basis for its proposed rules or modifications. To evaluate a proposed rule or modification, the Commission must be able to understand why the Authority believes its proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission. Evaluation of a proposed rule or modification will also be aided by the Authority's description of any reasonable alternatives it considered and the reasons it selected the proposed rule or modification over the alternatives.

The Act does not give the Authority broad discretion in developing rules. It sets forth guardrails, in the form of baseline standards for anti-doping and medication control (15 U.S.C. 3055(g)(2)(A)), racetrack safety standards which the Authority must consider (15 U.S.C. 3056(a)(2)), guidelines for determining funding and calculating costs (15 U.S.C. 3052(f)(1)(C)(ii)), a specific formula for the assessment and collection of fees (15 U.S.C. 3052(f)(3)(C)), who must register with the Authority and the conditions of registration (15 U.S.C. 3054(d)), guidelines for establishing rule violations (15 U.S.C. 3057(a)(2)), requisite elements of the Authority's results management and disciplinary program (15 U.S.C. 3057(c)(2)), guidelines for establishing civil sanctions (15 U.S.C. 3057(d)(2)), and more. Accordingly, the Authority must explain why its proposed rule or modification is consistent with any standards in the Act and the rules approved by the Commission. Because the requisite considerations for anti-doping and racetrack safety are the most prescriptive, this section specifically addresses those standards and factors. The less prescriptive standards and factors must also be addressed, and the Commission provides for this in a less prescriptive rule, as discussed below.

1. Anti-Doping and Medication Control Program Considerations

When proposing a rule or modification to the horseracing anti-doping and medication control program, the Authority must explain how it considered the factors in Section 6 of the Act, 15 U.S.C. 3055, including the unique characteristics of a breed of horse made subject to the Act by election of a State racing commission or breed governing organization for such horse pursuant to Section 5(*l*) of the Act, 15 U.S.C. 3054(*l*), as required by Section 6(a)(2) of the Act, 15 U.S.C. 3055(a)(2). The Authority must explain how it considered the factors in Section 6(b) of the Act, 15 U.S.C. 3055(b), namely that: (1) Covered horses should compete only when they are free from the influence of medications, other foreign substances, and methods that affect their performance; (2) covered horses that are injured or unsound should not train or participate in covered races, and the use

of medications, other foreign substances, and treatment methods that mask or deaden pain in order to allow injured or unsound horses to train or race should be prohibited; (3) rules, standards, procedures, and protocols regulating medication and treatment methods for covered horses and covered races should be uniform and uniformly administered nationally; (4) to the extent consistent with chapter 57A of title 15, consideration should be given to international anti-doping and medication control standards of the International Federation of Horseracing Authorities and the Principles of Veterinary Medical Ethics of the American Veterinary Medical Association; (5) the administration of medications and treatment methods to covered horses should be based on an examination and diagnosis that identifies an issue requiring treatment for which the medication or method represents an appropriate component of treatment; (6) the amount of therapeutic medication a covered horse receives should be the minimum necessary to address the diagnosed health concerns identified during the examination and diagnostic process; and (7) the welfare of covered horses, the integrity of the sport, and the confidence of the betting public require full disclosure to regulatory authorities regarding the administration of medications and treatments to covered horses.

In addition, Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A), provides that certain baseline anti-doping and medication control rules must constitute the initial rules of the horseracing anti-doping and medication control program and, except as exempted pursuant to Section 6(e) and (f) of the Act, 15 U.S.C. 3055(e) and (f), remain in effect at all times after the program effective date. Such baseline anti-doping and medication control rules include: (1) The lists of permitted and prohibited substances (including drugs, medications, and naturally occurring substances and synthetically occurring substances) in effect for the International Federation of Horseracing Authorities, including the International Federation of Horseracing Authorities International Screening Limits for urine, dated May 2019, and the International Federation of Horseracing Authorities International Screening Limits for plasma, dated May 2019; (2) the World Anti-Doping Agency International Standard for Laboratories (version 10.0), dated November 12, 2019; (3) the Association of Racing Commissioners International out-of-competition testing standards, Model Rules of Racing (version 9.2); and (4) the Association of Racing Commissioners International penalty and multiple medication violation rules, Model Rules of Racing (version 6.2). In the case of a conflict among the rules, Section 6(g)(2)(B) of the Act, 15 U.S.C. 3055(g)(2)(B), provides that the most stringent rule shall apply. Accordingly, the Commission is requiring the Authority to state whether a proposed rule adopts the baseline standards identified in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A). If there is a conflict in any baseline standards identified in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A), the Authority must identify the conflict and state whether the standard it adopted is the most stringent standard. Under Section 6(g)(3)(C) of the Act, 15 U.S.C. 3055(g)(3)(C), ''[t]he Authority shall not approve any proposed modification that renders an anti-doping and medication control rule less stringent than the baseline anti-doping and medication control rules . . . without the approval of the anti-doping and medication control enforcement agency.'' Thus, for a proposed rule modification, the Authority must explain whether the modification renders an anti-doping and medication control rule less stringent than the baseline anti-doping and medication control rules described in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A), and state whether the anti-doping and medication control enforcement agency has approved of the change.

2. Racetrack Safety Program Considerations

Section 7 of the Act, 15 U.S.C. 3056, requires the Authority to consider certain factors when developing the racetrack safety program. Accordingly, when proposing a rule or modification to any rule regarding its racetrack safety program, the Authority must explain how the proposed rule or modification meets the requirements in Section 7(b) of the Act, 15 U.S.C. 3056(b), which provides that the horseracing safety program must include the following: (1) A set of training and racing safety standards and protocols taking into account regional differences and the character of differing racing facilities; (2) a uniform set of training and racing safety standards and protocols consistent with the humane treatment of covered horses, which may include lists of permitted and prohibited practices or methods (such as crop use); (3) a racing surface quality maintenance system that takes into account regional differences and the character of differing racing facilities (which may include requirements for track surface design and consistency and established standard operating procedures related to track surface, monitoring, and maintenance, such as standardized seasonal assessment, daily tracking, and measurement); (4) a uniform set of track safety standards and protocols, that may include rules governing oversight and movement of covered horses and human and equine injury reporting and prevention; (5) programs for injury and fatality data analysis, that may include pre- and post-training and race inspections, use of a veterinarian's list, and concussion protocols; (6) the undertaking of investigations at racetrack and non-racetrack facilities related to safety violations; (7) procedures for investigating, charging, and adjudicating violations and for the enforcement of civil sanctions for violations; (8) a schedule of civil sanctions for violations; (9) disciplinary hearings, which may include binding arbitration, civil sanctions, and research; (10) management of violation results; (11) programs relating to safety and performance research and education; and (12) an evaluation and accreditation program that ensures racetracks in the United States meet the standards described in the elements of the Horseracing Safety Program.

The Authority must also consider the safety standards in Section 7(a)(2) of the Act, 15 U.S.C. 3056(a)(2), which provide that in the development of the horseracing safety program for covered horses, covered persons, and covered horseraces, the Authority and the Commission must take into consideration existing safety standards, including the National Thoroughbred Racing Association Safety and Integrity Alliance Code of Standards, the International Federation of Horseracing Authority's International Agreement on Breeding, Racing, and Wagering, and the British Horseracing Authority's Equine Health and Welfare program. The Commission is therefore requiring the Authority to explain how it considered and whether it adopted any of the standards in Section 7(a)(2) of the Act,15 U.S.C. 3056(a)(2). If any horseracing safety standards in Section 7(a)(2) of the Act, 15 U.S.C. 3056(a)(2), were considered but not adopted or were modified, the Authority must explain why it decided not to adopt or why it decided to modify such standard.

3. Other Considerations

The Commission is incorporating the specific anti-doping and racetrack safety standards into this section because they are the most prescriptive and extensive, but this should not be read as an

invitation to dispense with the less-prescriptive guardrails set forth in the Act. To the extent the Act requires the Authority to consider any factors or standards not specifically referenced in this section, the Authority must explain whether and how it considered those factors when proposing a rule or modification. For instance, when proposing a civil sanctions rule or modification pursuant to Section 8(d)(1) of the Act, 15 U.S.C. 3057(d)(1), the Authority must explain how the rule or modification meets the requirements of Section 8(d)(2) of the Act, 15 U.S.C. 3057(d)(2).

B. Supporting Documentation

The Commission is requiring the Authority to submit any pertinent factual information it relied on in developing its proposed rule or modification. More specifically, the Authority's submission to the Commission must include a copy of existing standards used as a reference for the development of a proposed rule or modification and any scientific data, studies, or analysis underlying the development of the proposed rule or modification. The Commission anticipates receiving, for instance, a copy of the lists of permitted and prohibited substances in effect for the International Federation of Horseracing Authorities, including the International Federation of Horseracing Authorities International Screening Limits for urine, dated May 2019, and any other rules and standards referenced in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A) when the Authority's baseline rules for anti-doping are submitted. For organizational purposes, supporting documentation must be attached as exhibits, and each exhibit must clearly identify the proposed rule or modification it supports.

C. Redline Document for Proposed Rule Modification

To enable the Commission to quickly and easily identify the substance of a proposed rule modification, the Commission is requiring the Authority to provide a redline document of the existing rule, marked with the proposed changes.

D. Timing of Submission

Section 4(c)(1) of the Act, 15 U.S.C. 3053(c)(1) provides for a 60-day timeframe between the Commission's publication of the Authority's proposed rule or modification in the **Federal Register** for public comment and the date the Commission must approve or disapprove the Authority's proposed rule or modification. To ensure it has sufficient time for review, the Commission is requiring the Authority to provide the information it needs to evaluate the Authority's proposed rule or modification at least 90 days in advance of the date the Authority proposes having its proposed rule or modification published in the **Federal Register** for public comment. This will give the Commission additional time to evaluate the Authority's proposed rule or modification. It should be noted this 90-day timeframe serves as a minimum, not a maximum, timeframe. The Secretary may shorten the timeframe if the Authority demonstrates that a shorter timeframe is necessary to meet statutory deadlines.

E. Conclusory Statements and Failure To Provide Requisite Analysis

The Authority must provide an adequate basis for the Commission's review of its rules. The Commission seeks to understand the Authority's analysis of the information it relied on to determine whether a proposed rule or modification was warranted and if so, what provisions the rule should contain. To this end, the information required under this section must be sufficiently detailed and contain sufficient analysis to support a Commission finding that a proposed rule or modification satisfies the statutory requirements. A mere assertion or conclusory statement that a proposed rule or modification is consistent with the requirements of the Act, for instance, is insufficient. If the Authority fails to describe and justify the proposed rule or modification in the manner described in this section, or fails to submit the information required by this section, the Commission may not have sufficient information to make an affirmative finding that the proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission.

F. Public Comments

Section 4(d)(2) of the Act, 15 U.S.C. 3053(d)(2), provides the ''Commission shall publish in the **Federal Register** any [ ] proposed rule, standard, or procedure and provide an opportunity for public comment.'' However, the Act gives the Commission only a total of 60 days after publication to approve or disapprove a proposed rule or modification once it has been published in the **Federal Register**. Given that the Commission and the Authority will need time to review comments, the Act functionally provides for a much more limited comment period of approximately 30 days or less. To ensure the public has an adequate opportunity to review and understand the Authority's rules, ask questions, and provide comments, the Commission is encouraging the Authority to make its proposed rules publicly available and solicit public comments in advance of providing any submissions to the Commission. To avoid delays in Commission approval of its rules, the Authority should not wait until its proposed rule is published in the **Federal Register** to solicit its own public comments.

In a March 21, 2021 letter [2] to the Acting Chairwoman, Rebecca Kelly Slaughter, the Act's sponsors stated ''[t]he relationship between the [Commission] and the Authority is closely modeled on the enduring and effective relationship between the Securities and Exchange Commission (SEC) and Financial Industry Regulatory Authority (FINRA), a private self-regulatory organization.'' As part of its own rulemaking process, the FINRA Board of Governors may authorize the publication of its own Regulatory Notice soliciting comments on a rule proposal prior to its submission to the SEC.[3] If FINRA decides to issue a Regulatory Notice soliciting public comment on a proposal, the comment period typically is open for one to two months.[4] All comments become part of FINRA's ''official record'' of the rule proposal, and since December 1, 2003, FINRA has posted all comment letters on its website.[5] Depending on the comments received in response to the Regulatory Notice and any changes made to the proposal, FINRA staff will either return to the FINRA Board with a revised proposal or will file the rule proposal with the SEC for notice and comment.[6] Soliciting comments, as FINRA does, in advance of submitting any proposed rules or modifications to the Commission would benefit both the Authority, the regulated community, and the Commission. It would provide transparency and enable the Authority to resolve any issues with its rules prior to their submission to the Commission.

If public comments are solicited, the Commission is requiring the Authority to attach, as an exhibit to its submission under § 1.142, a copy of the comments. The Commission encourages the Authority to make such comments publicly available on its own website. In

[2] *See* Letter from Senator Mitch McConnell to Acting Chairwoman Rebecca Kelly Slaughter (Mar. 23, 2021) (on file with the Federal Trade Commission).

[3] *See* FINRA Rulemaking process, *https://www.finra.org/rules-guidance/rulemaking-process* (last visited July 9, 2021).

[4] *Id.*

[5] *Id.*

[6] *Id.*

addition, the Authority's draft **Federal Register** document must include a summary of the substance of all comments received and the Authority's written response to all significant issues raised in such comments. This advance resolution of comments will greatly facilitate the process of review of any proposed rules or modifications the Authority submits to the Commission.

IV. Section 1.143—Submissions to the Secretary

This section provides guidance for the Authority when submitting documents to the Secretary of the Commission.

All rule submissions made pursuant to § 1.142 and 15 U.S.C. 3053(a), rate increases which must be reported to the Commission under 15 U.S.C. 3052(f)(1)(C)(iv), or HISA Guidance which must be submitted to the Commission under 15 U.S.C. 3054(g)(2), must be emailed to the Secretary of the Commission at *electronicfilings@ftc.gov*. The subject line of the email must state: ''HISA Rule Submission,'' ''HISA Rate Increase Submission,'' or ''HISA Guidance Submission'' as applicable. This will enable the Secretary to easily identify submissions from the Authority and route them to the appropriate office.

To facilitate Commission review, documents must be organized and sent in a format that will facilitate the submission of documents to the Office of the Federal Register. Except for supporting documentation submitted pursuant to § 1.142(b) (existing standards used as a reference for the development of the proposed rule or modification, and scientific data, studies, or analysis underlying the development of the proposed rule or modification) and copies of public comments submitted pursuant to § 1.142(f), all documents submitted to the Secretary must be in a word processing format. This will enable the Commission to more easily make modifications to **Federal Register** documents, provide feedback on rule text, and draft orders. For organizational purposes, the Commission is requiring submissions with more than one attachment to contain a table of contents in the body of the email with a brief description of each item. The Authority must also provide the contact information for a person on the staff of the Authority responsible for responding to questions from the Commission. To facilitate submissions to the Office of the Federal Register, the Commission is requiring that the Authority's draft **Federal Register** documents follow the relevant format and editorial requirements for regulatory documents in the Office of **Federal Register**'s Document Drafting Handbook, 1 CFR parts 18, 21, and 22. Specifically, draft **Federal Register** documents must contain proper preamble captions and content; state the purpose of, and basis for, the proposed rule or modification; set forth regulatory text, headings, and authority citations; use correct numbering, structure, and amendatory language; and conform to style and formatting established by the Office of the Federal Register and Government Publishing Office (see, specifically, section 2.17 (proposed rules) of the Office of the Federal Register's Document Drafting Handbook).

If a document filed with the Secretary contains confidential information, the Secretary must be so informed, and a request for confidential treatment must be submitted in accordance with 16 CFR 4.9. Filings submitted electronically on or before 5:30 p.m. Eastern Time, on a business day, will be deemed filed on that business day, and all filings submitted after 5:30 p.m. Eastern Time, will be deemed filed on the next business day. This section also provides the Secretary of the Commission may reject a document for filing that fails to comply with the Commission's rules for filing in this section or § 1.142. Finally, if the conditions in this section and § 1.142 have been satisfied, the Commission will publish the proposed rules or modifications in the **Federal Register** for public comment.

V. Section 1.144—Approval or Disapproval of Proposed Rules or Modifications

Section 4(c)(1) of the Act, 15 U.S.C. 3053(c)(1) provides, ''Not later than 60 days after the date on which a proposed rule or modification is published in the **Federal Register**, the Commission shall approve or disapprove the proposed rule or modification.'' In addition, Section 4(c)(2) of the Act, 15 U.S.C. 3053(c)(2), provides ''[t]he Commission shall approve a proposed rule or modification if the Commission finds that the proposed rule or modification is consistent with [ ] this chapter; and [ ] applicable rules approved by the Commission.'' Accordingly, § 1.144 provides the Commission will approve or disapprove a proposed rule or modification by issuing an order within 60 days of the date the proposed rule or modification was published in the **Federal Register** for public comment. The Commission will approve a proposed rule or modification if it finds such proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission. Further, a proposed rule or modification will not take effect unless it has been approved by the Commission.

Because these rule revisions relate solely to agency procedure and practice, publication for notice and comment is not required under the Administrative Procedure Act. 5 U.S.C. 553(b).[7]

List of Subjects in 16 CFR Part 1

Administrative practice and procedure.

For the reasons set forth in the preamble, the Federal Trade Commission amends title 16, chapter I, subchapter A of the Code of Federal Regulations as follows:

PART 1—GENERAL PROCEDURES

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 46; 15 U.S.C. 57a; 5 U.S.C. 552; 5 U.S.C. 601 note.

■ 2. Add subpart S to read as follows:

Subpart S—Procedures for Submissions Under the Horseracing Integrity and Safety Act

Sec.

Authority: 15 U.S.C. 3053.

§ 1.140 Definitions.

When used in relation to the Horseracing Integrity and Safety Act, 15 U.S.C. 3051 through 3060, and this subpart—

Act means the Horseracing Integrity and Safety Act, 15 U.S.C. 3051 through 3060.

Breeder means a person who is in the business of breeding covered horses.

Commission means the Federal Trade Commission.

Covered horse means any Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State racing commission or the breed governing organization for such horse under 15 U.S.C. 3054(*l*), during the period—

(1) Beginning on the date of the horse's first timed and reported workout at a racetrack that participates in covered horseraces or at a training facility; and

[7] For this reason, the requirements of the Regulatory Flexibility Act are also inapplicable. 5 U.S.C. 601(2), 604(a). Likewise, the amendments do not modify any FTC collections of information within the meaning of the Paperwork Reduction Act. 44 U.S.C. 3501 *et seq.*

(2) Ending on the date on which the Authority receives written notice that the horse has been retired.

Covered horserace means any horserace involving covered horses that has a substantial relation to interstate commerce, including any Thoroughbred horserace that is the subject of interstate off-track or advance deposit wagers.

Covered persons means all trainers, owners, breeders, jockeys, racetracks, veterinarians, persons (legal and natural) licensed by a State racing commission and the agents, assigns, and employees of such persons and other horse support personnel who are engaged in the care, training, or racing of covered horses.

HISA Guidance means Horseracing Integrity and Safety Authority (Authority) guidance issued under 15 U.S.C. 3054(g)(1), which does not have the force of law.

Horseracing anti-doping and medication control program means the anti-doping and medication program established under 15 U.S.C. 3055(a).

Horseracing Integrity and Safety Authority or *Authority* means the private, independent, self-regulatory, nonprofit corporation recognized for purposes of developing and implementing a horseracing anti-doping and medication control program and a racetrack safety program for covered horses, covered persons, and covered horseraces.

Interstate off-track wager has the meaning given such term in Section 3 of the Interstate Horseracing Act of 1978, 15 U.S.C. 3002.

Jockey means a rider or driver of a covered horse in covered horseraces.

Owner means a person who holds an ownership interest in one or more covered horses.

Proposed rule means any rule proposed by the Authority pursuant to the Act.

Proposed rule modification or *modification* means:

(1) Any proposed modification to a rule or proposed rule change; or

(2) Any interpretation or statement of policy or practice relating to an existing rule of the Authority that is not HISA Guidance and would have the force of law if approved as a final rule.

Racetrack means an organization licensed by a State racing commission to conduct covered horseraces.

Racetrack safety program means the program established under 15 U.S.C. 3056(a).

State racing commission means an entity designated by State law or regulation that has jurisdiction over the conduct of horseracing within the applicable State.

Trainer means an individual engaged in the training of covered horses.

Training facility means a location that is not a racetrack licensed by a State racing commission that operates primarily to house covered horses and conduct official timed workouts.

Veterinarian means a licensed veterinarian who provides veterinary services to covered horses.

Workout means a timed running of a horse over a predetermined distance not associated with a race or its first qualifying race, if such race is made subject to the Act by election under 15 U.S.C. 3054(*l*) of the horse's breed governing organization or the applicable State racing commission.

§ 1.141 Required submissions.

The Authority must submit to the Commission any proposed rule, or proposed rule modification, of the Authority relating to—

(a) The bylaws of the Authority;

(b) A list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods;

(c) Laboratory standards for accreditation and protocols;

(d) Standards for racing surface quality maintenance;

(e) Racetrack safety standards and protocols;

(f) A program for injury and fatality data analysis;

(g) A program of research and education on safety, performance, and anti-doping and medication control;

(h) A description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons;

(i) A schedule of civil sanctions for violations;

(j) A process or procedures for disciplinary hearings;

(k) A formula or methodology for determining assessments described in 15 U.S.C. 3052(f); and

(l) Any other proposed rule or modification the Act requires the Authority to submit to the Commission for approval.

§ 1.142 Submission of proposed rule or modification.

(a) *Contents of submission.* In order for a submission to qualify as a proposed rule or proposed rule modification under 15 U.S.C. 3053(a), the Authority must submit to the Commission a complete draft of the **Federal Register** document for the proposed rule or proposed rule modification, which includes the text of the rule and a statement of the purpose of, and statutory basis for, the proposed rule or modification (''statement of basis and purpose''). The statement of basis and purpose must contain:

(1) The reasons for adopting the proposed rule or modification.

(2) Any problems the proposed rule or modification is intended to address and how the proposed rule or modification will resolve those problems.

(3) A description of any reasonable alternatives to the proposed rule or modification that may accomplish the stated objective and an explanation of the reasons the Authority chose the proposed rule or modification over its alternatives.

(4) How the proposed rule or modification will affect covered persons, covered horses, and covered horseraces.

(5) Why the proposed rule or modification is consistent with the requirements of the Act and any rules and regulations applicable to the Authority, including the following:

(i) *Anti-doping and medication control program.* When proposing a rule or modification to the horseracing anti-doping and medication control program, the Authority must explain how it considered the factors in 15 U.S.C. 3055, including:

(A) Under 15 U.S.C. 3055(a)(2), the unique characteristics of a breed of horse made subject to the Act by election of a State racing commission or breed governing organization for such horse pursuant to 15 U.S.C. 3054(*l*);

(B) The factors listed in 15 U.S.C. 3055(b); and

(C) The baseline anti-doping and medication control rules identified in 15 U.S.C. 3055(g)(2)(A). For a proposed rule, the Authority must state whether its proposed rule adopts the baseline standards identified in 15 U.S.C. 3055(g)(2)(A). If there is a conflict in any baseline standards identified in 15 U.S.C. 3055(g)(2)(A), the Authority must identify the conflict and state whether the standard it adopted is the most stringent standard. For a proposed rule modification, the Authority must explain whether the modification renders an anti-doping and medication control rule less stringent than the baseline anti-doping and medication control rules described in 15 U.S.C. 3055(g)(2)(A), and state whether the anti-doping and medication control enforcement agency has approved of the change.

(ii) *Racetrack safety program.* When proposing a rule or modification to any rule regarding the racetrack safety program required under 15 U.S.C. 3056(a)(1), the Authority must explain how the proposed rule or modification

meets the requirements in 15 U.S.C. 3056(b). The Authority must explain how it considered and whether it adopted the safety standards in 15 U.S.C. 3056(a)(2). If any horseracing safety standards in 15 U.S.C. 3056(a)(2) were considered but not adopted or were modified, the Authority must explain why it decided not to adopt or why it decided to modify such standard.

(iii) *Other rules.* To the extent the Act requires the Authority to consider any factors or standards not specifically referenced in this section, the Authority must explain whether and how it considered those factors when proposing a rule or modification. For instance, when proposing a civil sanctions rule or modification pursuant to 15 U.S.C. 3057(d)(1), the Authority must explain how the rule or modification meets the requirements of 15 U.S.C. 3057(d)(2).

(6) If written comments were solicited, the Authority's draft **Federal Register** document must include a summary of the substance of all comments received and the Authority's written response to all significant issues raised in such comments.

(7) The date that the Authority proposes for the **Federal Register** to publish its proposed rule or modification.

(b) *Supporting documentation.* The Authority's submission to the Commission required under paragraph (a) of this section must also include copies of the pertinent factual information underlying the Authority's development of the proposed rule or modification, including a copy of existing standards used as a reference for the development of the proposed rule or modification and scientific data, studies, or analysis underlying the development of the proposed rule or modification. Supporting documentation must be attached as exhibits, and each exhibit must clearly identify the proposed rule or modification it supports.

(c) *Redline document for proposed rule modification.* For proposed rule modifications, the Authority must also provide, in a document separate from the **Federal Register** document, a redline version of the existing rule that will enable the Commission to immediately identify any proposed changes.

(d) *Timing of submission.* To qualify as a proposed rule or proposed modification under 15 U.S.C. 3053(a), the Authority's submission must provide the information in paragraphs (a), (b), and (c) of this section at least 90 days in advance of the proposed date for the **Federal Register** to publish a proposed rule or modification for public comment pursuant to 15 U.S.C. 3053(b)(1). The Secretary may waive the 90-day requirement in this section if the Authority demonstrates such waiver is necessary to meet statutory deadlines.

(e) *Conclusory statements and failure to provide requisite analysis.* Information required to be submitted under this section must be sufficiently detailed and contain sufficient analysis to support a Commission finding that a proposed rule or modification satisfies the statutory requirements. For instance, a mere assertion or conclusory statement that a proposed rule or modification is consistent with the requirements of the Act is insufficient. Failure to describe and justify the proposed rule or modification in the manner described in this section or failure to submit the information required by this section may result in the Commission's having insufficient information to make an affirmative finding that the proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission.

(f) *Public comments.* The Authority is encouraged to solicit public comments on its proposed rule or modification in advance of making a submission to the Commission pursuant to this section. If the Authority solicits public comments, it must attach a copy of the comments as an exhibit to its submission. By soliciting public comments and addressing significant issues raised therein, the Authority facilitates the Commission's review and approval of the Authority's proposed rule or modification.

§ 1.143 Submissions to the Secretary.

(a) *Electronic submission.* All rule submissions under § 1.142 and 15 U.S.C. 3053(a), rate increases that must be reported to the Commission under 15 U.S.C. 3052(f)(1)(C)(iv), or HISA Guidance that must be submitted to the Commission under 15 U.S.C. 3054(g)(2) must be emailed to the Secretary of the Commission at *electronicfilings@ftc.gov*. The subject line of the email must state: ''HISA Rule Submission,'' ''HISA Rate Increase Submission,'' or ''HISA Guidance Submission,'' as applicable.

(b) *Format for submission of proposed rules or modifications*—(1) *Electronic format.* Except for supporting documentation submitted pursuant to § 1.142(b) and copies of comments submitted pursuant to § 1.142(f), all documents submitted to the Secretary must be in a word processing format.

(2) *Table of contents.* Submissions with more than one attachment must contain a table of contents in the body of the email with a brief description of each item.

(3) *Contact information.* The Authority must provide the name, telephone number, and email address of a person on the staff of the Authority responsible for responding to questions and comments on the submission in the body of the email.

(4) *Draft* ***Federal Register*** *documents.* Draft **Federal Register** documents must follow the relevant format and editorial requirements for regulatory documents under 1 CFR parts 18, 21, and 22 (see Office of Federal Register's Document Drafting Handbook). The Document Drafting Handbook specifies that draft **Federal Register** documents (see 1 CFR 15.10) must:

(i) Contain proper preamble captions and content;

(ii) State the purpose of, and basis for, the proposed rule or modification;

(iii) Set forth regulatory text, headings, and authority citations;

(iv) Use correct numbering, structure, and amendatory language; and

(v) Conform to the style and formatting established by the Office of the Federal Register and Government Publishing Office. (See, specifically, section 2.17 (proposed rules) of the Office of the Federal Register's Document Drafting Handbook.)

(c) *Confidential information.* If a document filed with the Secretary contains confidential information, the Secretary must be so informed, and a request for confidential treatment must be submitted in accordance with 16 CFR 4.9.

(d) *Date of filing.* If the conditions of this section are otherwise satisfied, all filings submitted electronically on or before 5:30 p.m. Eastern Time, on a business day, will be deemed filed on that business day, and all filings submitted after 5:30 p.m. Eastern Time, will be deemed filed on the next business day.

(e) *Authority to reject documents for filing.* The Secretary of the Commission may reject a document for filing that fails to comply with the Commission's rules for filing in this section or § 1.142.

(f) ***Federal Register*** *publication.* If the conditions in this section and § 1.142 have been satisfied, the Commission will publish the proposed rules or modifications in the **Federal Register** and request public comment on those proposed rules or modifications.

§ 1.144 Approval or disapproval of proposed rules and proposed rule modifications.

(a) *Commission decision.* The Commission will approve or disapprove

a proposed rule or modification by issuing an order within 60 days of the date the proposed rule or modification was published in the **Federal Register** for public comment.

(b) *Standard of review.* The Commission will approve a proposed rule or modification if the Commission finds that the proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission. If the Commission disapproves a rule or modification, it will make recommendations to the Authority to modify the proposed rule or modification within 30 days of such disapproval.

(c) *Effect.* A proposed rule or modification will not take effect unless it has been approved by the Commission.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2021–21306 Filed 10–4–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA–2018–N–0236]

RIN 0910–AH53

Medical Device De Novo Classification Process

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to establish requirements for the medical device De Novo classification process under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This final rule establishes procedures and criteria related to requests for De Novo classification (''De Novo request'') and provides a pathway to obtain marketing authorization as a class I or class II device and for certain combination products. These requirements are intended to ensure the most appropriate classification of devices consistent with the protection of the public health and the statutory scheme for device regulation. They are also intended to limit the unnecessary expenditure of FDA and industry resources that may occur if devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness are subject to premarket approval. The final rule implements the De Novo classification process under the FD&C Act, as enacted by the Food and Drug Administration Modernization Act of 1997 (FDAMA) and modified by the Food and Drug Administration Safety and Innovation Act (FDASIA) and the 21st Century Cures Act (Cures Act).

DATES: This rule is effective January 3, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Sergio de del Castillo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2431, Silver Spring, MD 20993, 301–796–6419.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

This rule establishes new regulations implementing the medical device De Novo classification process under the FD&C Act, which provides a pathway for certain new types of devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as a class III device, which would require premarket approval under the postamendments device classification section of the FD&C Act.

The De Novo classification process is intended to provide an efficient pathway to ensure the most appropriate classification of a device consistent with the protection of the public health and the statutory scheme for device regulation. When FDA classifies a device type as class I or II via the De Novo classification process, other manufacturers do not necessarily have to submit a De Novo request or premarket approval application (PMA) to legally market a device of the same type. Instead, manufacturers can use the less burdensome pathway of premarket notification (510(k)), when applicable, to legally market their device, because the device that was the subject of the original De Novo request can serve as a predicate device for a substantial equivalence determination.

B. Summary of the Major Provisions of the Final Rule

This rule establishes procedures and criteria for the submission and withdrawal of a De Novo request. It also establishes procedures and criteria for FDA to accept, review, grant, and/or decline a De Novo request. While several comments object to sections or subsections of the proposed rule, almost all comments voice support for the objective of the proposed rule: To establish regulations implementing the De Novo classification process. The rule provides that:

- A person may submit a De Novo request after submitting a 510(k) and receiving a not substantially equivalent (NSE) determination.
- A person may also submit a De Novo request without first submitting a 510(k), if the person determines that

there is no legally marketed device upon which to base a determination of substantial equivalence (SE).

- FDA will classify devices according to the classification criteria in the FD&C Act. FDA classifies devices into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to reasonably assure safety and effectiveness; into class II (special controls) if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval) if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.
- Devices will be classified by FDA by written order.
- A De Novo request includes administrative information, regulatory history, device description, classification summary information, benefits and risks of device use, and performance data to demonstrate reasonable assurance of safety and effectiveness.
- FDA may refuse to accept a De Novo request that is ineligible or that is not sufficiently complete to permit a substantive review.
- After a De Novo request is accepted, FDA will begin a substantive review of the De Novo request that may result in either FDA requesting additional information, issuing an order granting the request, or declining the De Novo request.
- FDA may decline a De Novo request if, among other things, the device is ineligible or insufficient information is provided to support De Novo classification.

The rule also describes our practices for the conditions under which the confidentiality of a De Novo file is maintained.

C. Legal Authority

This rule is being issued under the device definition provision of the FD&C Act, the combination products provision of the FD&C Act, the device classification section of the FD&C Act, the De Novo classification section of the FD&C Act, the general rulemaking section of the FD&C Act, and the inspection section of the FD&C Act.

D. Costs and Benefits

The final rule clarifies the De Novo classification process for certain medical devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as class III devices under the FD&C Act. A more transparent De Novo classification process could improve the efficiency of obtaining marketing authorization for certain novel medical devices. The medical device industry will incur one-time costs to read and understand this rule. Over 10 years, the annualized cost estimates a 7 percent discount rate range from $0.01 million to $0.17 million, with a primary estimate of $0.09 million. The annualized costs over 10 years at a 3 percent discount rate range from $0.1 million to $0.15 million, with a primary estimate of $0.08 million.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation or acronym	What it means
510(k)	Premarket Notification
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDAMA	Food and Drug Administration Modernization Act of 1997
FOIA	Freedom of Information Act
FR	Federal Register
GLP	Good Laboratory Practice
HDE	Humanitarian Device Exemption
IDE	Investigational Device Exemption
IC	Information Collection
ICR	Information Collection Request
NSE	Not Substantially Equivalent
OMB	Office of Management and Budget
PHI	Protected Health Information
PMA	Premarket Approval Application
PRA	Paperwork Reduction Act of 1995
Pub. L.	Public Law
QSR	Quality System Regulation
Ref.	Reference
RFD	Requests for Designation under 21 CFR 3.7 (§ 3.7)
SE	Substantially Equivalent
SSED	Summary of Safety and Effectiveness Data
U.S.C.	United States Code

III. Background

A. Need for the Regulation/History of This Rulemaking

In the **Federal Register** on December 7, 2018 (83 FR 63127), FDA issued a proposed rule entitled ''Medical Device De Novo Classification Process'' and requested comments on the proposed rule by March 7, 2019. This rule establishes procedures and criteria for the submission and withdrawal of a De Novo request. It also establishes procedures and criteria for FDA to accept, review, grant, and/or decline a De Novo request.

B. Summary of Comments to the Proposed Rule

FDA received comments on the proposed rule from several entities, including medical device associations; industry, medical and healthcare professional associations; public health

advocacy groups; law firms; and individuals. While several comments object to sections or subsections of the proposed rule, almost all comments voice support for the objective of the proposed rule: To establish regulations implementing the De Novo classification process. Comments raise concerns or request clarification regarding several issues, including:

- De Novo request information disclosure,
- facility inspections,
- devices that collect protected health information,
- training of FDA reviewers,
- the definitions,
- the De Novo request format,
- the De Novo request content,
- the criteria for accepting a De Novo request,
- the criteria for declining a De Novo request,
- the availability of the De Novo classification process for combination products, and
- the information needed to support FDA's determination to grant a De Novo classification request.

C. General Overview of Final Rule

FDA considered all comments received on the proposed rule and made changes, primarily for clarity and accuracy and to reduce burden in meeting regulatory requirements. On its own initiative, FDA is renumbering the sections to make them easier for De Novo requesters and the public to research and use. On its own initiative, FDA is also making minor technical changes to make the regulatory history, withdrawal, nonclinical studies, and classification summary provisions clearer. FDA also changed the word ''guidance'' to ''guidelines'' in the definition of Class II at § 860.3 (21 CFR 860.3) on its own initiative for consistency with the language used in section 513(a)(1)(B) of the FD&C Act (21 U.S.C. 360c (a)(1)(B)) and with § 860.123 (21 CFR 860.123) in the final rule. Finally, on its own initiative, FDA is adding requests for information regarding the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act, to the regulatory history information required to be included in a De Novo request under proposed § 860.234(a)(3) (21 CFR 860.234(a)(3)) (see § 860.220(a)(3) in the final rule). In the preamble of the proposed rule, FDA described section 513(g) requests for information as one of the submissions it was proposing to require requesters to identify as part of the regulatory history section of a De Novo request (see 83 FR 63127 at 63132). However, a reference to section 513(g) of the FD&C Act was inadvertently omitted from the proposed regulatory text included in the proposed rule. The changes from the proposed rule include the following revisions, additions, and removals.

- Renumber the proposed De Novo section numbers as follows:

TABLE 1—RENUMBERED SECTIONS

Proposed section No.	Renumbered section No.	Section name
860.201	860.200	Purpose and applicability.
860.223	860.210	De Novo request format.
860.234	860.220	De Novo request content.
860.245	860.230	Accepting a De Novo request.
860.256	860.240	Procedures for review of a De Novo request.
860.267	860.250	Withdrawal of a De Novo request.
860.289	860.260	Granting or declining a De Novo request.

- Revise the De Novo request confidentiality provision (§ 860.5(g)) to clarify that after an order granting a De Novo request is issued, data and information in the De Novo file that are not exempt from release under the Freedom of Information Act (FOIA) (5 U.S.C. 552) are immediately available for public disclosure; and to replace certain references to ''De Novo request'' with ''De Novo file.''
- Revise the De Novo format requirements as follows:
  - Remove the requirement to cite the volume number in the table of contents if the De Novo request consists of only one volume,
  - remove the requirement to provide a fax number when submitting a De Novo request, and
  - clarify that the De Novo request must be submitted as a single version in electronic format.
- Revise the De Novo content requirements as follows:
  - Add section 513(g) requests for information to the regulatory history requirement in proposed § 860.234(a)(3) (see § 860.220(a)(3)) and change the term ''use'' to ''device'' in the regulatory history requirement so the text more accurately refers to an application for ''humanitarian device exemption''.
  - Revise the order of the proposed requirements for the content of a De Novo request in proposed § 860.234(a)(9) through (11) (see § 860.220(a)(9) through (11) in the final rule).
  - Revise § 860.220(a)(7) and (a)(9) (this final rule renumbers proposed § 860.234(a)(7) as § 860.220(a)(7)) to clarify that the information required is that known to or that reasonably should be known to the requester.
  - Remove ''laboratory'' to clarify § 860.220(a)(13)(i) and (a)(15)(i) (this final rule renumbers proposed § 860.234(a)(13)(i) and (a)(15)(i) to § 860.220(a)(13)(i) and (a)(15)(i)) requires a summary of each nonclinical study.
  - Move the phrase, ''as appropriate,'' in § 860.220(a)(15)(i) to clarify that not all of the identified nonclinical studies may be applicable to the subject device.
  - Revise § 860.220(a)(15)(i) to clarify that a De Novo requester must include a protocol and complete test report for each nonclinical study.
  - Revise § 860.220(a)(15)(i) to clarify that a De Novo request must only include a statement regarding compliance with good laboratory practice (GLP) requirements in part 58 (21 CFR part 58) for nonclinical studies that are subject to part 58.
- Revise the provisions for withdrawal of a De Novo request to make minor technical changes.
- Revise the provisions for granting a De Novo request to specify that FDA will publish a notice of the classification order in the **Federal Register** within 30 days after granting the request.
- Revise the provisions for declining of a De Novo request to clarify that FDA will decline a De Novo request by written order and moves the grounds for which FDA may decline a De Novo request from § 860.260(b) into § 860.260(c).

IV. Legal Authority

The FD&C Act establishes a comprehensive system for the regulation of medical devices intended for human use. Among the provisions that provide authority for this final rule are sections 201(h), 503(g), 513(a) and (f), 701(a), and 704 of the FD&C Act (21 U.S.C. 321(h), 353(g), 360c(a) and (f), 371(a), and 374). This final rule establishes regulations to implement the De Novo classification process created by section 207 of FDAMA (Pub. L. 105–115) and amended by section 607 of FDASIA (Pub. L. 112–144) and section 3101 of the Cures Act (Pub. L. 114–255).

V. Comments on Proposed Rule and FDA Response

A. Introduction

We received several sets of comments on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from medical device associations, industry, medical and healthcare professional associations, public health advocacy groups, law firms, and individuals. We describe and respond to comments in sections V.B through V.K. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

Several comments made general remarks supporting the proposed rule without focusing on a particular proposed provision. Almost all comments supported the objective of the proposed rule: To establish regulations implementing the De Novo classification process. Several comments also requested that FDA make changes without focusing on a particular provision of the proposed rule. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) A commenter states that FDA should retain patient safety as its number one priority and integrate cybersecurity into the De Novo request process, and that science should support any decisions.

(Response 1) FDA agrees with this comment. As part of the cybersecurity review for premarket submissions for devices that contain software (including firmware) or programmable logic as well as software that is a medical device, FDA recommends that medical device manufacturers assess the impact of threats and vulnerabilities on device functionality and end users/patients as part of the cybersecurity review (Ref. 1).

(Comment 2) A commenter requests FDA to adopt an abbreviated procedure and a reduced user fee for De Novo requests when the requester believes that its device meets the criteria for classification in class I under section 513(a)(1)(A)(ii) of the FD&C Act, because the commenter believes that it would help provide more timely access to low-risk devices and conserve valuable FDA premarket review resources without compromising public health protection.

(Response 2) We do not agree that the procedure proposed by the commenter would be more efficient than the procedures described in FDA's proposed rule. The De Novo classification process provides a pathway for certain devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as class III under section 513(f)(1) of the FD&C Act. FDA makes the determination that a device is class I or class II under section 513(f)(2) of the FD&C Act using the criteria in section 513(a) of the FD&C Act. The process proposed by the commenter would require an abbreviated submission with only some of the information FDA proposed to require in a De Novo request when the requester believes that its device meets the criteria for classification as a class I device. The proposed process would also add a step to the Agency's review process for such devices by requiring FDA to determine within 15 days of receiving the request either that the device meets the criteria for classification into class I or that additional information is required to make the classification determination.

The FD&C Act provides 120 days for review of a De Novo request, regardless of the ultimate classification determination. In FDA's experience, 15 days is not a workable timeframe for the Agency to complete a substantive review of a submission for a new device type to determine that the device meets the criteria for classification into class I. Further, the commenter's suggested abbreviated initial submission omits information that is important for FDA's classification determinations, such as information on probable risks to health associated with use of the device. Therefore, under the commenter's proposed process, FDA would usually, if not always, need to require additional information within 15 days. In § 860.220(a) of this final rule, FDA has identified the required contents of a De Novo request taking into account the Agency's experience with the types of information needed to make a determination on a De Novo request. If a requester believes that some of the required information is not applicable to its device, the requester may submit a justification for omitting that information pursuant to § 860.220(c).

We also note that the proposed process does not appear to provide for any FDA action other than requesting additional information or classifying the device. Section 513(f)(2) of the FD&C Act provides for FDA to decline a De Novo request.

With respect to the user fees applicable to a De Novo request, the Medical Device User Fee Amendments of 2017 amended the FD&C Act to authorize FDA to collect user fees for certain premarket submissions received on or after October 1, 2017, including De Novo requests (see section 738 of the FD&C Act (21 U.S.C. 379j)). The fees are set by statute (section 738(a)(2)(A)(xi) of the FD&C Act) and therefore any changes to such fees are outside the scope of this rulemaking.

(Comment 3) A commenter concerned about the design of a remote monitoring system containing software states that as part of the De Novo request, a manufacturer should provide information on whether the device collects protected health information (PHI). The same commenter requests that the Health and Human Services' Office for Civil Rights should complete a review prior to the De Novo request being granted by FDA. A commenter states that a PHI pre-approval plan should be reviewed with the impact and patient experience included in the overall De Novo request grant.

(Response 3) Standards for the use and disclosure of protected health information by certain entities are set forth in regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 101–191), which are outside the scope of this rulemaking. To demonstrate a reasonable assurance of safety and effectiveness for software devices, documentation related to the requirements of the quality system regulation (QSR) (21 CFR part 820) is often a necessary part of the premarket submission. See also ''Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'' (Ref. 2). As part of QSR design controls, a manufacturer must ''establish and maintain procedures for validating the device design,'' which ''shall include software validation and risk analysis, where appropriate.'' (§ 820.30(g)). As part of the software validation and risk analysis required by § 820.30(g), software device manufacturers may need to establish a cybersecurity vulnerability and management approach, where appropriate. Such cybersecurity design controls help to ensure device security, including protection of health information.

(Comment 4) A comment recommends FDA provide additional training for FDA reviewers on De Novo classification to assist FDA reviewers in more thoroughly understanding the devices and how to review De Novo requests with the broader view of assessing the nature of the devices and their value to the patient.

(Response 4) FDA currently provides training to FDA staff on the De Novo classification process. With the publication of this final rule, FDA intends to update its current training to be reflective of the requirements of the final rule. FDA also understands that patient input can be an important consideration during FDA's review of a De Novo request, as reflected in our guidance for industry and FDA Staff, ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications'' (Ref. 3) and ''Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling'' (Ref. 4).

(Comment 5) A commenter proposes that unless required by the FD&C Act or the device is of high public health importance, FDA defer the identification of special controls for devices being granted De Novo classification until after the De Novo request is granted and FDA can make a general assessment of all class II devices. The same commenter also requests that FDA prioritize the identification of special controls for all class II devices.

(Response 5) Because special controls are necessary to assure the safety and effectiveness of class II devices, FDA does not agree with the commenter's proposal. FDA believes it is important to identify the appropriate special controls for class II devices at the time FDA grants the De Novo request. The granting of the De Novo request does several things: It allows the device to be marketed immediately, creates a classification regulation for devices of the type, and permits the device to serve as a predicate device (section 513(f)(2)(B) of the FD&C Act) (Ref. 5). Because these consequences flow from the grant of a De Novo request, and because special controls are necessary to reasonably assure the safety and effectiveness of a class II device, FDA will continue to identify special controls at the time that it grants a De Novo classification request.

The request that FDA prioritize the identification of special controls for all class II devices is outside the scope of this rulemaking.

(Comment 6) A comment recommends that medical device applicants be encouraged to perform and/or review studies that address the effect of the device on patient function, because the commenter states that, for all populations, the ability to function at work, at home, and with family is an important outcome.

(Response 6) Where relevant to the intended use of a device, FDA currently would take patient function into account in evaluating the safety and effectiveness of the device. As part of its initiative for patients to engage with FDA, FDA has incorporated patient perspectives into the total product life cycle, including in the premarket evaluation of devices (Refs. 4 and 6).

(Comment 7) A comment objects to the placement of all the De Novo request regulatory requirements in part 860 and suggests that the Center for Devices and Radiological Health (CDRH) separate requirements for the information needed to classify a device type from requirements for the information needed to authorize a specific low to moderate risk device for marketing by placing the latter in a separate regulation for ''Premarket Approval of Novel Class I and II Medical Devices.''

(Response 7) FDA disagrees with this comment. The De Novo classification provisions will be housed in part 860 of the CFR with the other device classification subparts. We recognize that, because the De Novo classification process includes a pathway to obtain marketing authorization for a specific device, placement of the De Novo classification regulations may not be as straightforward as the other classification regulations. FDA believes that part 860 is the most appropriate fit.

(Comment 8) A comment asserts that some devices, especially implantable devices, are inappropriately classified as class II instead of class III because these devices are ''potentially life-saving or life-threatening.'' The comment further indicates that the De Novo pathway should not replace the PMA pathway for implanted devices that are not eligible for 510(k) clearance and recommends that FDA document whether the increase in De Novo grants over the past few years indicates a movement from 510(k) clearance of devices to De Novo or from PMA review to the less stringent De Novo pathway before finalizing the proposed rule.

(Response 8) Altering the statutory standards for device classification and marketing authorization is outside the scope of this rulemaking. FDA classifies devices according to the statutory criteria set forth in section 513(a)(1) of the FD&C Act. Therefore, if FDA determines that general and special controls are sufficient to provide a reasonable assurance of safety and effectiveness for a potentially life-supporting device, FDA must classify that device into class II (see section 513(a)(1)(B) of the FD&C Act). Congress added section 513(f)(2) of the FD&C Act as part of FDAMA to limit unnecessary expenditure of FDA and industry resources that could occur if devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness were subject to premarket approval under section 515 of the FD&C Act (21 U.S.C. 360e). As enacted by FDAMA, to submit a De Novo request, a device first had to be found NSE to legally marketed predicate devices through a 510(k). Section 513(f)(2) of the FD&C Act was modified by section 607 of FDASIA, which created an alternative mechanism for submitting a De Novo request that does not require that a device be reviewed first under a 510(k) and found NSE prior to submission of a De Novo request. If a person believes their device is appropriate for classification into class I or class II and determines, based on currently available information, there is no legally marketed predicate device, they may submit a De Novo request without a preceding 510(k) and NSE.

(Comment 9) A comment objects to making De Novo devices immediately available as a predicate device because the commenter suggests that it puts patient safety at risk and does not reward innovation. The commenter proposes a ''safe harbor'' of several years where the De Novo device cannot be used as a predicate.

(Response 9) FDA disagrees with this comment. Section 513(f)(2) of the FD&C Act provides that any device classified through the De Novo pathway ''shall be a predicate device for determining substantial equivalence'' and does not impose a waiting period for such devices to be used as predicates.

C. Comments and FDA Response on Use of Advisory Committees and Bundling Devices

(Comment 10) A comment requests FDA to revise § 860.1 to limit the use of advisory committees to cases of high-risk, life-supporting, or life-sustaining devices, or to classification panels because the commenter states that referring a De Novo request to an advisory committee should be unusual, as the devices that are the subject of such requests generally present low to moderate risk.

(Response 10) We disagree with this proposed revision. This comment is directed specifically to the De Novo classification process, and § 860.1 applies to both premarket and postmarket classifications and reclassifications. In addition, we do not agree that the only time we should seek advice from an advisory committee is in cases of high-risk, life-supporting, or life-sustaining devices, or in a classification panel; FDA may refer a matter to an advisory committee because it chooses to do so at its own discretion (see our guidance ''Procedures for Meetings of the Medical Devices Advisory Committee'' (Ref. 7).) For example, the Agency may present a matter before an advisory committee if the matter is of significant public interest or there is additional or special expertise provided by the panel that could assist FDA in its decision making.

(Comment 11) A comment asks FDA to revise the De Novo ''Purpose and applicability'' provision (the final rule renumbers the proposed § 860.201(b) as § 860.200(b)) to clarify that a De Novo request may also be submitted for a group of related devices because a commenter states that, in some cases, more than one related device should be submitted for De Novo classification.

(Response 11) FDA disagrees with this comment. Generally, it is not appropriate to bundle multiple devices in a single De Novo request. For example, FDA would not grant a De Novo request that would require FDA to create more than one classification regulation. If an applicant feels that they have a situation where it makes logical sense to bundle multiple devices into one De Novo request, it would be advisable to discuss proactively with FDA in advance of submission of the De Novo request.

D. Comments and FDA Response on De Novo Request Information Disclosure

(Comment 12) A comment requests that FDA revise the De Novo file confidentiality provision in § 860.5(g) so that it follows the approach for PMAs concerning confidentiality because the commenter asserts requesters are entitled to maintain confidentiality for information submitted to FDA through the De Novo process even if some information relating to the De Novo request has been disclosed publicly. Another comment requests that FDA revise the provision regarding disclosure of the existence of a De Novo request before an order granting the request is issued to clarify that such disclosure is governed by the trade secrets and confidential commercial information provisions in § 20.61 (21 CFR 20.61). A different comment questions why CDRH could not disclose the existence of a De Novo request and the date of its acceptance for review or the date it was refused.

(Response 12) FDA is making minor revisions to refer to the ''De Novo file'' instead of the ''De Novo request'' in four places in § 860.5(g) for consistency with the language used in § 860.5(g)(1) and to align with similar language used in 21 CFR 814.9 regarding confidentiality of information in a PMA file. FDA otherwise disagrees with the comments requesting revision of the proposed De Novo request confidentiality requirements. The provisions in § 860.5(g)(2) and (3) provide that, before an order granting the De Novo request is issued, FDA may not publicly disclose the existence of or data and information contained in a De Novo file, unless such information has already been publicly disclosed or acknowledged by the De Novo requester. Therefore, if a requester publicly acknowledges only the date and existence of a De Novo request submission, that acknowledgment would not, by itself, make underlying data and information in the De Novo file publicly available for disclosure under § 860.5(g). Further, the requester cannot have confidentiality concerns about information it has already publicly disclosed. This approach is concordant with FDA's general public information regulations at § 20.61 and § 20.81 (21 CFR 20.81). Under § 20.61, information submitted to FDA that qualifies as trade secret or confidential commercial information is generally exempt from public disclosure, but § 20.81 provides that records otherwise exempt from disclosure are available for public disclosure to the extent that they ''contain data or information that have previously been disclosed in a lawful manner to any member of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy.''

Regarding why FDA will not disclose the existence of a De Novo request that has not been publicly disclosed or acknowledged, disclosing the existence of the De Novo request would disclose the requester's intent to market the device. Consistent with FDA's approach in other premarket programs, we generally consider an applicant's intent to market a device to be confidential commercial information where the applicant has kept that intent confidential. This approach is supported by the Supreme Court's recent decision in *Food Mktg. Inst.* v. *Argus Leader Media,* 139 S. Ct. 2356, 2363 (2019).

(Comment 13) Some comments requested more clarity on how and when data and information may be disclosed by FDA, and some comments suggested that the data and information disclosed after FDA issues an order granting a De Novo request should only be available following a FOIA request. A commenter also recommended changes to clarify that the requester would have an opportunity to review and redact trade secret information before the release of any data and information in the De Novo request. Another commenter recommended that CDRH draft and post on its website a summary of the information submitted to support FDA's classification determination and require De Novo requesters to prepare summaries of data and information submitted to support the safety and effectiveness of the specific device that could be posted in FDA's De Novo database to align with public disclosure of 510(k) and PMA summaries.

(Response 13) As discussed in response to the previous comment, prior to sending an order granting the De Novo request to the De Novo requester, FDA will not disclose the data or information contained in the De Novo file, unless the De Novo requester has publicly disclosed or acknowledged such information (§ 860.5(g)(3)). To provide more clarity and to help ensure that information exempt from release is appropriately protected, we are revising § 860.5(g)(4) to make clear that after FDA sends an order granting the De Novo request to the De Novo requester, FDA may immediately disclose any safety and effectiveness information and any other information in the De Novo file that is not exempt from release under FOIA.

FDA disagrees with the comments requesting FDA to limit the release of data and information contained in a granted De Novo request to situations in which the Agency has received a FOIA request for that information. FDA proactively discloses information of interest to the public on a regular basis. For example, granting a De Novo request allows marketing of the particular device that is the subject of the request, creates a classification regulation for devices of this type, and permits the device to serve as a predicate device (section 513(f)(2) of the FD&C Act; Ref. 5). FDA believes that information regarding granted De Novo requests and summaries of safety and effectiveness information that formed the basis of FDA's granting decisions should be publicly posted without waiting to receive a FOIA request for that

information. With respect to affording requesters an opportunity to review and redact records that may contain trade secret information before they are disclosed, FDA will follow its existing pre-disclosure notification requirements in § 20.61.

Since 2010, FDA has posted on its website classification orders and redacted decision summary documents for devices classified through the De Novo classification process. This approach is analogous to our current approach for other marketing authorization pathways: summaries of safety and effectiveness information that formed the basis of FDA's decisions are posted on FDA's website for PMA approvals, available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm*; and for 510(k) clearances, 510(k) summaries are available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.* We believe the comment suggesting that FDA require a De Novo requester to prepare a summary of safety and effectiveness information for public posting to align with PMA and 510(k) procedures confuses the requirement for a PMA to include a summary that allows the reader to gain a general understanding of the data and information in the application (§ 814.20 (21 CFR 814.20(b)(3))) with the publicly posted detailed summary of safety and effectiveness data (SSED) on which an approval or denial decision is based for a PMA. Although some PMA applicants may submit draft SSEDs, the final SSEDs posted online are FDA documents. The De Novo decision summary is intended to present an objective and balanced summary of the scientific evidence that served as the basis for the decision to grant a De Novo request. Because the Agency already prepares such documents and determines what information supports its decision to grant the De Novo request, FDA is not revising the final rule to require requesters to prepare a similar summary, as this commenter requests. We believe the information that the commenter indicates would be of interest to healthcare providers and patients is already made publicly available through FDA's current approach.

E. Comments and FDA Response on Facility Inspections

(Comment 14) A comment supported facility inspection prior to granting or declining a De Novo request because the commenter states that it is essential for safety in the case of novel medical devices. Several comments wanted to delete either all of subsection § 860.240(c) (this final rule renumbers proposed § 860.256(c) as § 860.240(c)) or paragraph § 860.240(c)(2) (this final rule renumbers proposed § 860.256(c)(2) as § 860.240(c)(2)) or revise subsection § 860.240(c) because the commenters state these provisions are unduly burdensome or that FDA lacks statutory authority to require facility inspections to assess implementation of the QSR (part 820).

(Response 14) Several comments objected to proposed § 860.256(c) (this final rule renumbers proposed § 860.256(c) as § 860.240(c)), which relates to the inspection of relevant facilities prior to granting or declining a De Novo request and argued that the FD&C Act does not give FDA this inspection authority. FDA disagrees with the comments, and, as described below, is finalizing the provision with clarifying changes. The inspection would be done only in the two circumstances specified in the regulation. Based on past experience, inspections in these circumstances should arise with a small percentage of De Novo requests.

1. Clinical and Nonclinical Data

As explained in the proposed rule preamble, an inspection prior to its De Novo decision is used to help FDA determine whether clinical or nonclinical data were collected in a manner that ensures the data accurately represents the risks and benefits of the device, in accordance with section 513(a)(1)(C) of the FD&C Act. FDA has been conducting such inspections when data integrity and quality concerns arise during its review of a De Novo request, and information from these inspections has been critically important to the Agency's De Novo determination. For example, based on review of the clinical data provided in the De Novo request, FDA may determine that the results of a clinical investigation are clinically or physiologically improbable. An inspection may be conducted to verify the integrity of the data.

In another example, FDA may receive a whistleblower complaint alleging misconduct at one or more clinical investigational sites, and the results from the clinical investigation are used to support a De Novo request. Our assessment of the subject device is dependent on the veracity of the complaint. FDA inspections of one or more investigational sites to assess the veracity of the complaint would help determine whether evidence submitted in support of the De Novo request (*e.g.,* data from a particular site) needs to be excluded from FDA's consideration.

2. Quality System Regulation and Current Good Manufacturing Practices

For certain devices with critical and/or novel manufacturing processes that may impact the safety and effectiveness of the device, FDA also believes that an inspection may be necessary for FDA to determine whether general controls, including the QSR (part 820) for devices and current good manufacturing practices (21 CFR part 4, subpart A) for combination products, are adequate to provide a reasonable assurance of safety and effectiveness of the device, or whether special controls to mitigate risks must be developed. Such inspections are not for the purpose of reviewing for compliance with the QSR. Rather, the purpose of such an inspection is to gather information on critical and/or novel manufacturing processes, the methods and procedures used, and such additional information as may be necessary to assess the safety and effectiveness of a drug or biologic constituent part of a combination product. Such information will help classify the device type by providing an understanding of critical and/or novel manufacturing processes to determine if the device type is of low to moderate risk, to determine if general controls and special controls can effectively mitigate the probable risks to health, and to determine if the product specifications can reasonably be met. In some circumstances, this information can only be obtained by an inspection—and not any other means, such as through review of standard operating procedures—because it requires a detailed understanding of how manufacturers, in practice, carry out complex and/or safety critical processes, methods, or procedures. In these situations, the information obtained from an inspection would be necessary for FDA to make a De Novo determination.

For example, FDA may receive a De Novo request for a permanent implant with a coating that contains the same active ingredient that is in a new drug application (NDA) approved drug product. The combination product is intended to reduce the risk of surgical site infections. The safety and effectiveness of the combination product is linked to the ability of the manufacturer to ensure consistent levels of drug coating and drug release batch-to-batch. Probable risks associated with inconsistent coating or inconsistent drug release may include local/systemic toxicity, reproductive/genotoxicity, antibiotic resistance, and infection. An inspection would help assess the sampling methodology and laboratory

controls used by the manufacturer to ensure consistent levels of drug coating and drug release batch-to-batch. Such information would be critical to FDA in its De Novo determination because assessment of the sampling methodology and laboratory controls at the manufacturing facility would aid in FDA's determination that the product has consistent levels of drug coating and drug release batch-to-batch. This information would enable FDA to determine whether the proposed special controls are sufficient to reasonably assure safety and effectiveness or if additional controls are needed.

In another example, FDA may receive a De Novo request for a device that is provided sterile using a novel sterilization method for which there is little or no published information and limited or no history of FDA evaluation of sterilization development and/or validation data. Probable risks associated with inadequate sterilization may include risk of infection or contamination. An inspection of the facility where the device is sterilized would be critical to determining if special controls regarding sterilization validation are sufficient to mitigate the device's probable risks, verify that the novel sterilization method can feasibly be carried out, and determine if additional controls are needed to mitigate the risks associated with inadequate sterilization to reasonably assure the device's safety.

One commenter objected to inspections used to assess whether QSRs are adequate to ensure that critical and/or novel manufacturing processes that may impact the safety and effectiveness of the device are controlled on the grounds that such inspections require either a warrant or specific statutory authorization under the Constitution. Section 704(a)(1) of the FD&C Act grants FDA authority to enter and inspect ''any factory, warehouse, or establishment in which food, drugs, or devices are manufactured, processed, packed, or held for the introduction into interstate commerce or after such introduction.'' 21 U.S.C. 374. In addition, FDA intends to undertake inspections only in limited circumstances when the inspection is to help determine whether to grant a De Novo request from a firm and determine whether the proposed special controls are sufficient to reasonably assure safety and effectiveness or if additional controls are needed under section 513(f)(2) of the FD&C Act.

F. Comments and FDA Response on Definitions

(Comment 15) A comment proposed several changes to the ''Supplemental data sheet'' definition because not all implanted devices are class III, and another comment recommended changes to Form FDA 3429 (General Device Classification Questionnaire).

(Response 15) These comments are moot because, in a separate rulemaking (see 83 FR 64443 at 64454 through 64456, December 17, 2018, effective March 18, 2019), the definitions for the terms ''Supplemental data sheet'' and ''Classification questionnaire'' were removed from § 860.3 and the prior requirements to provide Form FDA 3427 (Supplemental Data Sheet) and Form FDA 3429 (General Device Classification Questionnaire) were removed from §§ 860.84 and 860.123.

(Comment 16) A comment requests that FDA keep the individual paragraph designations in the definitions section (§ 860.3) because the commenter states it is helpful to industry to be able to cite a specific term by paragraph designation.

(Response 16) FDA disagrees with this comment. FDA believes it would be easier for industry to locate definitions listed alphabetically. FDA has taken a similar approach in its labeling and unique device identification regulations (see 21 CFR 801.3 and 830.3). FDA further believes that it is not difficult to cite to alphabetical definitions within § 860.3.

G. Comments and FDA Response on De Novo Request Format

(Comment 17) A comment asks FDA to revise the proposed De Novo request format requirements to clarify that the application can be a single version in electronic format, conforming it to FDA's proposed rule, ''Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Allowed in Electronic Format'' (83 FR 46444, September 13, 2018).

(Response 17) FDA agrees that a De Novo request may be submitted as a single version in electronic format, which is currently eCopy and, in the future, may be a different electronic format. De Novo requests currently must be submitted as a single eCopy, in accordance with section 745A(b)(1) of the FD&C Act (21 U.S.C. 379k–1(b)(1)) and FDA's guidance, ''eCopy Program for Medical Device Submissions,'' issued April 27, 2020 (Ref. 8). Section 745A(b)(3) of the FD&C Act requires the presubmission and submission types enumerated in section 745A(b)(1) (including De Novo requests), any supplements to such presubmissions or submissions for devices, and any appeals of action taken with respect to such presubmissions or submissions, including devices under the Public Health Service Act, to be submitted solely in electronic format as specified by FDA in guidance. Once FDA issues guidance under section 745A(b)(3) of the FD&C Act, the Agency can require De Novo request submissions in electronic formats other than eCopy. We are revising paragraph § 860.210(a) (this final rule renumbers proposed § 860.223(a) as § 860.210(a)) to require submission of a De Novo request as a single version in electronic format).

(Comment 18) A commenter states it is overly prescriptive to require a specific format for a De Novo request.

(Response 18) We do not agree that the format FDA is requiring is overly prescriptive. Section 860.210 (this final rule renumbers proposed § 860.223 as § 860.210), the format section, requires that the De Novo request be signed by the requester or an authorized representative, be designated as a ''De Novo request,'' and be written or translated into English. FDA believes it is easier for FDA reviewers to find required information if the De Novo request information is provided in a specific format, thereby facilitating more efficient review and processing of the request.

(Comment 19) Because a De Novo request may contain only one volume, a comment asks FDA to revise the De Novo request format paragraph to qualify that the table of contents of a De Novo request reference a volume number only if the De Novo request contains more than one volume.

(Response 19) FDA agrees that it is unnecessary to cite the volume if the De Novo request does not contain more than one volume. We are revising paragraph § 860.220(a)(1) (this final rule renumbers proposed § 860.234(a)(1) as § 860.220(a)(1)) accordingly.

H. Comments and FDA Response on De Novo Request Content

(Comment 20) Some comments request FDA to revise the ''Device description'' provision at § 860.220(a)(6)(ii) ((this final rule renumbers proposed § 860.234(a)(6)(ii) as § 860.220(a)(6)(ii)) because the commenters state some of the terminology is more typically used to describe drugs than devices. The commenters suggest that ''component'' is more applicable to devices than ''ingredient,'' and that some components may not be ''functional'' but may still be important to a De Novo

classification decision. A commenter states the term ''principal components'' is appropriate because it signals that the submitter should identify the device's primary components but need not identify every component. Another commenter similarly suggests the term ''major components'' would be appropriate.

(Response 20) FDA disagrees that ingredient is an atypical term for a device. For example, in vitro diagnostic device labels generally are required to include the quantity, proportion, or concentration of each reactive ingredient for a reagent (21 CFR 809.10(a)(3)).

In addition, FDA does not agree with requiring only a device's principal or major components to be described in a De Novo request. FDA is requesting identification of all functional components or ingredients that comprise the subject device or combination product so that FDA has sufficient understanding of the device to evaluate whether general controls or general and special controls are sufficient to provide reasonable assurance of safety and effectiveness. We would consider any component of the device relating to how the device operates be a functional component. It was not our intent to limit the identification of the components or ingredients of the device or combination product. To that end, we disagree with the commenters' proposed edits to require identification of only major or principal components.

(Comment 21) Comments on the summary of studies (this final rule renumbers proposed § 860.234(a)(13)(ii) as § 860.220(a)(13)(ii)), the technical sections (this final rule renumbers proposed § 860.234(a)(15)(i) and (iii) as § 860.220(a)(15)(i) and (iii)), and the bibliography (this final rule renumbers proposed § 860.234(a)(16)(i) as § 860.220(a)(16)(i)) that are part of the required content of a De Novo request ask that FDA limit the required information to that ''necessary to determine the classification of the device.'' The commenter states that it is necessary to clarify that data unrelated to classification of the device (*e.g.,* for other indications) do not need to be submitted and that the focus of the application is to determine the classification of the device.

(Response 21) FDA does not agree with these comments and does not believe the requested clarifications are necessary. Under the FD&C Act, FDA determines the classification of a device that is the subject of a De Novo request (section 513(f)(2) of the FD&C Act). The requirements for the content of a De Novo request reflect the information that, in FDA's experience, generally is necessary to determine if general or general and special controls are sufficient to provide a reasonable assurance of safety and effectiveness of the device that is the subject of the De Novo request. To the extent the requester believes that certain required content for a De Novo request is not applicable to its device, the requester has the option under § 860.220(c) (this final rule renumbers proposed § 860.234(c) to § 860.220(c)) to omit that information and submit a statement that specifies the omitted information and justifies the omission. FDA will notify the requester if it does not accept the justification.

Further, § 860.220(a)(15) (this final rule renumbers proposed § 860.234(a)(15) as § 860.220(a)(15)) already specifies that the required technical sections must include data and information ''in sufficient detail to permit FDA to determine whether to grant or decline the De Novo request.'' Therefore, we believe it is already clear the information required in the technical sections under § 860.220(a)(15)(i) and (iii) (the final rule renumbers proposed § 860.234(a)(15)(i) and (iii) as § 860.220(a)(15)(i) and (iii)) and the related summary of studies under § 860.220(a)(13) (the final rule renumbers proposed § 860.234(a)(13) as § 860.220(a)(13)) is information focused on FDA's classification determination. In addition, the bibliography of published reports required under § 860.220(a)(16)(i) (the final rule renumbers proposed § 860.234(a)(16)(i) as § 860.220(a)(16)(i)) is limited to reports ''that concern the safety or effectiveness of the device.'' Published reports concerning the safety or effectiveness of the device that is the subject of the De Novo request would be useful to FDA's evaluation of the request.

(Comment 22) Some comments object that FDA's proposed requirements for the data and information submitted in a De Novo request are overly broad or potentially confusing. One commenter supports requirements for a thorough review of existing data but requests that the requirement to submit '' 'all' available data . . . should be clarified to indicate that which is reasonably attainable by'' the De Novo requester. Other commenters request that FDA change the phrase ''known or reasonably known'' in certain provisions of § 860.220(a) (this final rule renumbers proposed § 860.234(a) to § 860.220(a)) to ''known or reasonably available to'' the requester. These commenters indicate that the ''known or reasonably known'' standard does not clarify to whom the required information is known or reasonably known. A commenter also indicates that the proposed language could lead FDA reviewers to decide a De Novo requester is ''hiding something'' if the submission lacks information known to the reviewer but not the requester. Another commenter states that use of the term ''reasonably available'' instead would ''impl[y] that the sponsor must engage in reasonable effort to obtain the relevant information.''

(Response 22) FDA did not include provisions in the proposed rule using the phrase ''all available data'' as one comment suggests, but we believe limiting all of the required information for a De Novo request to that ''reasonably attainable by'' the requester is inappropriate. In some cases, for example, a requester may know of studies or reports concerning the safety or effectiveness of the device but be unable to obtain them for some reason (*e.g.,* the requester must pay to gain access to a registry containing the relevant data). In these cases, it is still useful to provide to FDA the information about such studies or reports that is known or reasonably should be known to the requester, even if complete information about or copies of such studies or reports is unavailable to the requester. For example, FDA may have a greater ability to access a publication with more complete information.

In response to these comments, FDA is revising § 860.220(a)(7) and (9) (this final rule renumbers proposed § 860.234(a)(7) as § 860.220(a)(7) and renumbers § 860.234(a)(11) as § 860.220(a)(9)) to clarify that the information required is that known to or that reasonably should be known to the requester. The intent of requiring a De Novo request to include information that is known or reasonably known to the requester is to ensure that the requester engages in a reasonable effort to provide relevant information and does not omit information important to FDA's determination to grant or decline the De Novo request because of a failure to conduct reasonable searches for such information. As explained in the proposed rule, for example, the summary of known or reasonably known probable risks to health associated with the use of the device required in the De Novo request under § 860.220(a)(9) ''should be based on the best available information at the time of submission of the De Novo request.'' (83 FR 63127 at 63133) These requirements help ensure that FDA's evaluation of a

De Novo request is based on complete and quality information and minimize review staff's need to request additional information. We believe the term ''should reasonably be known'' appropriately captures the intent of these requirements.

(Comment 23) A comment requests that FDA provide more flexibility in the standard for valid scientific evidence for De Novo devices as a way to address lower risk devices, rather than requiring only less-detailed summary information for some components of a complete De Novo request.

(Response 23) FDA disagrees with the comment. As in other device classification processes, FDA relies upon valid scientific evidence in determining the safety and effectiveness of a device that is the subject of a De Novo request (§ 860.260(e) (this final rule renumbers proposed § 860.289(d) as § 860.260(e)). This is unchanged by the requirement to provide summaries of certain information as part of a De Novo request. In addition, the required content of a De Novo request must include, in addition to such summaries, technical sections containing nonclinical study results, software information and testing, and clinical investigation results with sufficient detail to allow FDA to make a determination on the De Novo request.

Regarding the commenter's request for ''flexibility'' in the standard for valid scientific evidence, FDA does not believe any change is necessary. FDA's regulatory definition of valid scientific evidence already makes clear that ''[t]he evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use'' (§ 860.7(c)(2)). FDA has also issued guidance explaining its approach to making benefit-risk determinations in the context of De Novo requests, which is a flexible, patient-centric approach tailored to the type and intended use of the device. See our guidances ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications'' (Ref. 3) and ''Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions'' (Ref. 9).

(Comment 24) A commenter states FDA should focus on device design to improve device safety. The same commenter asserts that all premarket applications (PMA, 510(k), and De Novo requests) should include a design and development plan, design input, output, design reviews, verification, validation, transfer, and all design changes.

(Response 24) FDA agrees that device design is important to device safety. Manufacturers are already required under part 820 (QSR) to focus on device design (§ 820.30, Design controls). Additionally, FDA may require additional verification or validation information for specific design features or inspect relevant facilities, where appropriate (§ 860.240, this final rule renumbers proposed § 860.256 as § 860.240).

(Comment 25) Because a commenter notes that ''manufacturer'' is used elsewhere in the proposed rule and because some commenters state that many companies no longer use Fax machines, the comments request that FDA revise the ''Administrative information'' provision of the De Novo request content section to add a reference to ''manufacturer,'' in addition to owners and operators, and to remove the reference to Fax machines from § 860.220(a)(2) (this final rule renumbers proposed § 860.234(a)(2) as § 860.220(a)(2)).

(Response 25) FDA agrees to remove the reference to Fax machines and is revising paragraph § 860.220(a)(2) (this final rule renumbers proposed § 860.234(a)(2) as § 860.220(a)(2)) accordingly. However, we do not agree that it is necessary to add a reference to ''manufacturer'' in this provision. In the final rule, § 860.220(a)(2) requires that the De Novo request include the establishment registration number of the owner or operator submitting the De Novo request, if applicable, because certain ''owners or operators,'' as defined in 21 CFR 807.3(f), are the entities required to register and submit listing information under 21 CFR part 807. Use of the terms ''owner'' and ''operator'' in § 860.220(a)(2) does not mean that a device manufacturer is unable to submit a De Novo request. The registration and listing requirements apply to owners or operators of establishments who are ''engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use,'' unless they are exempt under 510(g) of the FD&C Act or FDA regulations (see 21 CFR 807.20).

(Comment 26) A comment requests FDA revise the indications for use paragraph (§ 860.220(a)(5), this final rule renumbers the proposed § 860.234(a)(5) as § 860.220(a)(5)) in the De Novo request content section to include references to intended use and the meaning of that term for the purpose of determining substantial equivalence because intended use will be relevant to 510(k) submissions made after FDA grants a De Novo request. The commenter also suggests the revisions would align more closely with the PMA requirements in § 814.20(b)(3).

(Response 26) FDA does not agree with this comment and believes that the indications for use requirement is aligned with § 814.20(b)(3)(i) and the definitions in Appendix D of FDA's guidance, ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'' (Ref. 10).

(Comment 27) A few commenters state it is unnecessary and places a potentially unrealistic burden on the De Novo requester to provide a ''complete'' device description; the comments request FDA require a ''device description.''

(Response 27) FDA disagrees with these comments and is retaining the word ''complete'' in § 860.220(a)(6) (this final rule renumbers the proposed § 860.234(a)(6) as § 860.220(a)(6)). The word ''complete'' is appropriate in this context and not overly burdensome. FDA does not expect an excessively detailed description of the device, but there must be sufficient detail to describe the aspects of the device that could affect safety or effectiveness. A complete device description is necessary for FDA to classify a device.

(Comment 28) Comments on the requirement to describe alternative practices (§ 860.220(a)(7), this final rule renumbers proposed § 860.234(a)(7) as § 860.220(a)(7)) either support the requirement as facilitating classification and improving transparency, or request revisions to reduce the burden of describing known or reasonably known alternative practices and procedures. The comments suggest revising the provision to instead ask for a summary related to the standard of care for a disease or condition for which the device is indicated as it bears on the device's proposed classification or assessment of probable benefits and risks.

(Response 28) FDA disagrees with the comments to limit the description of alternative practices. We do not believe this requirement requires extensive unnecessary efforts, as some of the commenters suggest. As explained in the proposed rule, this requirement is intended to capture alternative biologic, device, or drug practices or procedures. An understanding of available alternative practices or procedures that are used to diagnose, treat, prevent, cure, or mitigate the disease or condition for which the device is

intended or that similarly affect the structure or function of the body is one of the factors FDA considers in its benefit-risk assessments to determine the appropriate classification for a device. For example, for a device indicated to treat a rare condition for which there are no alternative treatments, FDA may accept greater uncertainty in the evidence regarding the device's probable benefits and probable risks. Furthermore, FDA does not agree with the assumption that a standard of care exists for all diseases or conditions for which a device is intended.

(Comment 29) Comments request that FDA rearrange the order of the provisions in proposed § 860.234(a)(9) through (11) (this final rule renumbers proposed § 860.234(a)(9) as § 860.220(a)(11) and this final rule renumbers proposed § 860.234(a)(11) as § 860.220(a)(9)). Commenters suggest that the risks and mitigations form the basis for the classification recommendation and accordingly request that the *Summary of risks and mitigations* provision (proposed § 860.234(a)(11) precede the *Classification recommendation* provision (proposed § 860.234(a)(9)). Commenters further suggest that the *Proposed special controls* provision (proposed § 860.234(a)(10)) should immediately follow the *Summary of risks and mitigations* provision to demonstrate whether specific mitigations are general and/or special controls.

(Response 29) The order in proposed § 860.234(a)(9) through (11) follows the order in which section 513(f)(2)(A)(v) of the FD&C Act discusses corresponding items. However, we believe the commenters' proposed changes make sense. Accordingly, we are revising the order of the paragraphs as follows:

- § 860.220(a)(9) *Summary of risks and mitigations*;
- § 860.220(a)(10) *Proposed special controls;* and
- § 860.220(a)(11) *Classification recommendation.*

(Comment 30) A comment supports the requirement for a summary of known or reasonably known probable risks, while another comment suggests that the De Novo request include both a summary and a discussion of the probable risks and mitigations identified through a formal risk analysis.

(Response 30) FDA agrees with the comment supporting the requirement for a De Novo request to include a summary of known or reasonably known probable risks, but FDA believes that requiring both a summary and a discussion of these probable risks and proposed mitigations is unnecessary. The De Novo request will be required to summarize probable risks to health associated with use of the device that are known or should reasonably be known to the requester and the proposed mitigations. For each mitigation measure that involves specific performance testing or labeling, the request must reference the associated section or pages of the supporting information, such as supporting protocols and/or testing data. FDA believes such information is sufficient to assist the Agency in identifying the probable risks to health and in evaluating the proposed risk mitigation measures to determine whether general controls or general and special controls can provide reasonable assurance of safety and effectiveness. Furthermore, FDA requires a related discussion demonstrating that the probable benefit to health outweighs the probable risks of the De Novo device in § 860.220(a)(14) (this final rule renumbers the proposed § 860.234(a)(14) as § 860.220(a)(14)).

(Comment 31) A comment requests that FDA revise the standards paragraph to clarify that De Novo requesters are not required to declare conformity to standards referenced in the De Novo request.

(Response 31) The standards paragraph at § 860.220(a)(12) (this final rule renumbers the proposed § 860.234(a)(12) as § 860.220(a)(12)) does not require that De Novo requesters submit a declaration of conformity to the referenced standard, so the requested clarification is not necessary. See our guidance, ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices'' (Ref. 11) for additional information on how to use consensus standards in premarket submissions, including information for those choosing to rely on a consensus standard in a declaration of conformity to meet a premarket submission requirement.

(Comment 32) A commenter states that the bibliography of all published reports concerning the safety or effectiveness of the device not submitted under the technical sections of the De Novo request (§ 860.220(a)(16)(i), this final rule renumbers proposed § 860.234(a)(16)(i) as § 860.220(a)(16)(i)) and the identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device (§ 860.220(a)(16)(ii), this final rule renumbers proposed § 860.234(a)(16)(ii) as § 860.220(a)(16)(ii)) should be provided to FDA for consideration.

(Response 32) FDA agrees with the comment and believes that providing a bibliography of all published reports concerning the safety or effectiveness of the device not submitted under the technical sections of the De Novo request, as required by § 860.220(a)(16)(i), and the information on other data, information, or reports relevant to an evaluation of the safety and effectiveness of the device required under § 860.220(a)(16)(ii) will be useful to FDA's assessment of safety and effectiveness.

(Comment 33) A comment opposed authorizing implanted medical devices for marketing through the De Novo pathway without long-term controlled clinical trials because the commenter states patients deserve long-term safety and effectiveness data. A comment further recommends FDA require information about changes to the research protocol and statistical methodology in the summary of studies submitted in the De Novo request because the commenter states the information is important for evaluating the quality of the study.

(Response 33) FDA disagrees that long-term controlled clinical trials must be required across all implanted medical devices. In reviewing a De Novo classification request, studies other than long-term controlled clinical trials may also constitute valid scientific evidence that FDA can rely upon in making a benefit-risk determination for an implanted device, as discussed in our guidance ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications'' (Ref. 3). ''Valid scientific evidence'' is defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2). Valid scientific evidence, as discussed in § 860.7(c)(2), includes ''partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device.'' FDA does not believe long-term, controlled clinical studies are necessary to demonstrate that general controls or general and special controls will provide a reasonable assurance of safety and effectiveness for all implantable devices reviewed through the De Novo pathway. For example, some devices are intended to be implanted for a relatively short period of time (*e.g.,* 30 days) and then removed from the body; longer term clinical data therefore may not be needed to assess

the safety and effectiveness of these devices when used as intended.

Requiring these studies for all implantable devices is also inconsistent with FDA's least burdensome approach to medical device regulation, which is intended to eliminate unnecessary burdens that may delay the marketing of beneficial new products, while maintaining the statutory requirements for marketing authorization. As discussed in FDA's guidance, ''The Least Burdensome Provisions: Concept and Principles'' (Ref. 12), FDA typically follows a stepwise analytical process when requesting additional information to make a decision on a marketing submission to ensure the information requested reflects the least burdensome approach. FDA typically requests clinical data when analytical or nonclinical bench performance testing data, or nonclinical animal [1] and/or biocompatibility studies are insufficient, or available scientific methods are not acceptable, *e.g.,* the scientific methods are deemed unacceptable because they are not clinically validated or are not supported by a valid scientific rationale.

We do not believe any changes are necessary to address the comment's request that FDA require information about changes to the research protocol and statistical methodology. In addition to the summary of studies required under § 860.220(a)(13) (this final rule renumbers proposed § 860.234(a)(13) as § 860.220(a)(13)), the technical sections of the De Novo request must include, among other things, protocols, investigation design, results of statistical analyses, and any other appropriate information, for each clinical investigation used to support the De Novo request (§ 860.220(a)(15), this final rule renumbers proposed § 860.234(a)(15) as § 860.220(a)(15)). Therefore, the required contents of the technical section would already capture information regarding significant changes made to the protocol or to the statistical methodology that would be important for evaluating the results of the study.

(Comment 34) A few comments propose revisions to the human subject study summaries provision at § 860.220(a)(13)(ii) (this final rule renumbers proposed § 860.234(a)(13)(ii) as § 860.220(a)(13)(ii)) to require that this section of the De Novo request include a summary of ''any clinical data'' known by or reasonably available to the requester submitted in the De Novo request instead of a summary of ''each clinical investigation'' submitted in the De Novo request. The commenters suggest that the language in the proposed rule appeared to assume that the requester's only source of clinical data would be clinical investigations that the requester initiated and note that there may be other sources of clinical data, such as studies described in literature or conducted by others, or in marketing data from other countries. They also recommend limiting the information about such clinical data required in the summary to that ''known or reasonably available'' to the requester because it would clarify that when complete data are not available, they are not required.

(Response 34) FDA agrees that sources of clinical data other than clinical investigations initiated by the requester may be available to the requester; however, we do not agree that the proposed requirement for the De Novo request to include a summary of studies limits the types of clinical data that may be submitted in a De Novo request. Under § 860.220(a)(13), (this final rule renumbers proposed § 860.234(a)(13) as § 860.220(a)(13)), the De Novo request must include an abstract of any information or report described in the De Novo request under § 860.220(a)(16)(ii) (this final rule renumbers proposed § 860.234(a)(16)(ii) as § 860.220(a)(16)(ii)) and a summary of the results of technical data submitted under § 860.220(a)(15) (this final rule renumbers proposed § 860.234(a)(15) as § 860.220(a)(15)). The information required under § 860.220(a)(16)(ii) includes ''information derived from investigations other than those in the request and from commercial marketing experience.'' Therefore, clinical data derived from other sources, such as marketing experience in other countries, are among the types of data that would be summarized under § 860.220(a)(13). The particular paragraph of § 860.220(a)(13) that the commenters suggest revising sets forth additional information that summaries must discuss for those clinical investigations involving human subjects that are submitted in the De Novo request.

FDA also disagrees that it is necessary to limit the information required under § 860.220(a)(13)(ii) (this final rule renumbers proposed § 860.234(a)(13)(ii) as § 860.220(a)(13)(ii)) to that known or reasonably available to the requester. The requester should be able to provide the information required under § 860.220(a)(13)(ii) for clinical investigations submitted in the technical sections in support of the De Novo request. To the extent certain elements required for the summary of such clinical investigations are not included in the De Novo request because they are not reasonably available to the requester, the requester should address why they are not available. Therefore, we are not revising § 860.220(a)(13)(ii) in response to these comments.

(Comment 35) A comment requests FDA to qualify the requirement for a De Novo request to provide a discussion demonstrating that the data and information in the request constitute valid scientific evidence, with the phrase, ''if applicable,'' because a De Novo request for a low-risk device may present de minimis valid scientific evidence.

(Response 35) FDA disagrees with this comment. As part of the De Novo classification process, FDA must determine that the device is of low to moderate risk (21 U.S.C. 360c(f)(2)(A)(iv)). FDA relies upon valid scientific evidence in determining the safety and effectiveness of a device for purposes of classification, as explained in our response to Comment 23. Therefore, adding the phrase ''if applicable'' as the commenter suggests would not be appropriate.

As discussed in FDA's guidance, ''Factors to Consider When Making Benefit-Risk Determinations Medical Device Premarket Approval and De Novo Classifications'' (Ref. 3), FDA assesses the benefits and risks of a device that is the subject of a De Novo request to determine if general or general and special controls are sufficient to provide reasonable assurance of safety and effectiveness (see § 860.7(d)(1) and (e)(1)). While low-risk devices may not need to show as substantial a benefit to patients to have a favorable benefit-risk profile, FDA's classification determination must still be based on valid scientific evidence.

(Comment 36) A comment requests FDA to clarify that, where relevant, requirements for data and information in the technical sections in § 860.220(a)(15) (this final rule renumbers proposed § 860.234(a)(15) as § 860.220(a)(15)) may be satisfied by cross-referencing data and information submitted in satisfaction of the summary of studies provision (§ 860.220(a)(13), this final rule renumbers proposed § 860.234(a)(13) as § 860.220(a)(13)) to avoid requiring a requester to repeat information provided earlier in the De Novo request. A comment also requests that FDA remove the list of specific items that must be

[1] FDA supports the principles of the ''3Rs,'' to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if it they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

included in the summary of each clinical investigation under § 860.220(a)(13)(ii) (this final rule renumbers proposed § 860.234(a)(13)(ii) as § 860.220(a)(13)(ii)) because the commenter asserts it is unnecessarily restrictive and repetitive to require this information in the summary when the same information is also required in the technical sections of the De Novo request under § 860.220(a)(15)(iii) (this final rule renumbers proposed § 860.234(a)(15)(iii) as § 860.220(a)(15)(iii)).

(Response 36) FDA does not agree with this comment. The summary of technical data required under § 860.220(a)(13) is intended to be analogous to an executive summary of each study used to support the De Novo request and would typically include less information than that submitted in the technical sections. The information required in the technical sections (§ 860.220(a)(15)) is the more detailed and complete information regarding each study. While it may be appropriate to cross reference the information from the summary section (§ 860.220(a)(13)), FDA does not believe cross referencing the information in the summary required under § 860.220(a)(13) would be sufficient to provide all of the required technical information to support marketing authorization. Because the summary information required for clinical investigations submitted in the De Novo request may include information other than the specific items listed in § 860.220(a)(13)(ii) and because it is intended to be a higher level summary of the data in the technical sections, we do not believe the required summary is unnecessarily restrictive or repetitive.

(Comment 37) A few comments ask FDA to revise the nonclinical testing paragraph (§ 860.220(a)(15)(i), this final rule renumbers proposed (§ 860.234(a)(15)(i) as (§ 860.220(a)(15)(i)) by moving the ''as appropriate'' qualifier forward in the sentence.

(Response 37) FDA agrees that moving the words ''as appropriate'' forward in the sentence would clarify the requirement. We are revising paragraph § 860.220(a)(15)(i) accordingly.

(Comment 38) A few comments ask FDA to revise the requirements for a summary of studies and the technical sections in a De Novo request to clarify that a statement regarding compliance with part 58 is only necessary for studies that are required to comply with part 58 because the commenters state that many nonclinical studies are outside the scope of part 58 if they do not involve the use of animals or other test systems.

(Response 38) FDA agrees that some nonclinical studies that may be submitted to support a De Novo request, such as certain electromagnetic compatibility testing, are not subject to part 58. In response to these comments, FDA is revising § 860.220(a)(15)(i) (this final rule renumbers proposed § 860.234(a)(15)(i) as § 860.220(a)(15)(i)) to clarify that a statement of compliance with part 58 (or a brief statement of the reason for noncompliance) is required only for nonclinical studies subject to part 58.

(Comment 39) A comment asks FDA to revise the requirements for submitting results of clinical investigations involving human subjects (§ 860.220(a)(15)(iii), this final rule renumbers proposed § 860.234(a)(15)(iii) as § 860.220(a)(15)(iii)) to clarify that clinical investigations are not required in all cases to support the De Novo classification decision. Comments also requested revisions to this provision to clarify that some clinical investigations submitted in the De Novo request may be ongoing (*e.g.,* clinical investigations that are ongoing but for which all subjects have reached the primary endpoint). These comments also ask FDA to revise the proposed regulatory text to refer to ''records'' instead of copies of individual subject report forms because the commenters assert that many clinical investigations are carried out with validated electronic data capture systems and individual human subject forms are not used.

(Response 39) FDA agrees that clinical evidence may not always be required in a De Novo request to support a determination that general controls or general and special controls provide a reasonable assurance of safety and effectiveness of the device and device type. However, we believe no clarification is needed regarding whether a clinical investigation involving human subjects is required because that determination will be specific to the De Novo request. If the requester believes that information regarding clinical investigations required under § 860.220(a)(15)(iii) (this final rule renumbers proposed § 860.234(a)(15)(iii) as § 860.220(a)(15)(iii)), or other information required under § 860.220(a)(15)(i) (this final rule renumbers proposed § 860.234(a)(15)(i) as § 860.220(a)(15)(i)), is not applicable to its device, then the requester may include a justification for omitting that information from the De Novo request in accordance with § 860.220(c) (this final rule renumbers proposed § 860.234(c) as § 860.220(c)). If De Novo requesters have questions about the process for submission and review of a De Novo request for their device, we recommend that they consult FDA's guidance, ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' (Ref. 5) and request a meeting with FDA through the Q-submission program. Meetings between the requester and FDA allow for an open discussion and exchange of technical, scientific, and regulatory information that can help build a common understanding of FDA's initial expectations regarding clinical studies and nonclinical studies related to the De Novo request (Ref. 13).

FDA recognizes that some De Novo requests include results from clinical investigations that remain ongoing, such as a study that has a pre-specified interim analysis of safety or effectiveness data. However, FDA believes the regulatory text in § 860.220(a)(15)(iii) would already permit inclusion of such results and does not believe a revision to the regulatory text is necessary.

We also recognize that some comments raise a concern that individual subject forms are not used in many clinical investigations. While the commenters do not object to providing individual subject information for those subjects who died during a clinical investigation or who did not complete the investigation, the commenters suggest that the term ''records'' would better reflect electronic source data instead of the term ''copies of such forms.'' We agree with the comments that data capture and collection methods used in clinical investigations have evolved over time. FDA has published guidance, ''Use of Electronic Health Record Data in Clinical Investigations,'' addressing data capture in clinical investigations that do not use paper case report forms (Ref. 14). FDA interprets the term ''individual subject form,'' as used in this rule, to include the different electronic or paper formats used to capture individual subject data. Therefore, we do not believe that using the term ''record'' is necessary.

(Comment 40) A comment asks FDA to require that the technical sections of a De Novo request include a protocol and a report for all clinical investigations and laboratory studies to make the requirements for the technical sections more consistent and less confusing.

(Response 40) We agree that additional clarity regarding technical sections requirements for nonclinical studies would be helpful. Protocols and complete test reports generally are necessary to provide sufficient detail

regarding the results of a nonclinical study to permit FDA to determine whether to grant or decline the De Novo request. However, we are revising § 860.220(a)(15)(i) (this final rule renumbers proposed § 860.234(a)(15)(i) as § 860.220(a)(15)(i)) to state expressly that these materials must be provided for each nonclinical study submitted in the technical sections of the request. FDA's guidance, ''Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions'' (Ref. 15) discusses the information that should typically be included in test protocols and complete test reports for nonclinical bench performance testing provided in a premarket submission. We note that in cases where a requester is appropriately declaring conformity with a voluntary consensus standard that FDA has recognized pursuant to section 514(c) of the FD&C Act (21 U.S.C. 360d(c)) to meet applicable requirements, it may not be necessary to submit complete test reports with respect to those requirements. In these cases, the requester may submit a statement of omission for this information in the De Novo request in accordance with § 860.220(c). However, consistent with section 514(c)(3)(B) of the FD&C Act, FDA may request, at any time, the data or information relied on by a person to make a declaration of conformity with respect to a recognized standard. See FDA's guidance ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices'' (Ref. 11) for more information regarding use of declarations of conformity in premarket submissions.

FDA disagrees with modifying § 860.220(a)(15)(iii) to specifically require submission of a clinical investigation report. This provision already describes the supporting information required regarding the results of each clinical investigation, and in our experience, there can be significant variability in the types of information included in ''reports'' prepared for clinical investigations. If some or all of the information required under § 860.220(a)(15)(iii) is included in a separate clinical investigation report, the requester may include the report in its De Novo request to satisfy those requirements.

(Comment 41) A comment asks FDA to revise the ''other information'' provision (§ 860.220(a)(16), this final rule renumbers proposed § 860.234(a)(16) as § 860.220(a)(16)) to limit the information required in the bibliography of all published reports not submitted under the technical sections of the De Novo request (§ 860.220(a)(15), this final rule renumbers proposed § 860.234(a)(15) as § 860.220(a)(15)) to those ''necessary to support the safety or effectiveness of the device'' because the commenter asserts such reports should be limited to those needed to establish the device's proposed classification, its probable risk, and its probable benefit.

(Response 41) We do not agree with limiting the bibliography required under § 860.220(a)(16) to that information necessary to support the device's safety or effectiveness. Paragraph § 860.220(a)(16)(i) (this final rule renumbers proposed § 860.234(a)(16)(i) as § 860.220(a)(16)(i)) requires that the requester submit a bibliography of all adverse or supportive published reports, other than those submitted in greater detail in the technical sections of the De Novo request, that are known to or should reasonably be known to the requester and that concern the safety and effectiveness of the device. The commenter's proposed revision would eliminate the requirement to include adverse published reports that may call into question the safety or effectiveness of the device at issue. However, such adverse reports may be important to FDA's assessment of the probable benefits and risks of the device and affect the Agency's classification determination.

(Comment 42) A comment supports the requirement to provide a sample of the device, if requested by FDA (§ 860.220(a)(17), this final rule renumbers proposed § 860.234(a)(17) as § 860.220(a)(17)) because it improves transparency. Other comments request that FDA eliminate the language indicating that the Agency may ''test'' one or more of the devices because FDA has traditionally relied on testing by the manufacturer. Another commenter indicated that while providing samples may be appropriate for a high-risk device likely to be reviewed in a PMA, it is unclear that samples are necessary for devices reviewed through the De Novo pathway.

(Response 42) FDA disagrees with the comments that suggest limiting the sample requirement and agrees with the comment that the request for samples improves transparency. In many cases, FDA relies on descriptions of a device and testing performed by manufacturers to evaluate safety and effectiveness. However, there are some situations in which FDA would request a sample of a device reviewed through the De Novo pathway because FDA needs to see or test the device to understand the device and determine if general or general and special controls are sufficient to reasonably assure safety and effectiveness of the device and device type. Examples of the situations where a device sample may be requested by FDA for examination or testing include devices intended for use by a lay person that previously have been marketed for use by a physician or other experienced healthcare professional, and devices with novel, complex designs that are difficult to assess solely through written description and/or engineering drawings.

(Comment 43) A comment supports the proposed requirement that a De Novo request include ''[l]abels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use'' (§ 860.220(a)(18), this final rule renumbers proposed § 860.234(a)(18) as § 860.220(a)(18)) because this requirement improves transparency. Other commenters propose limiting the requirement to not include advertisements because the commenters state advertisements are outside the scope of a class I and class II device review.

(Response 43) FDA agrees that the requirement to submit labels, labeling, and advertisements improves transparency. FDA disagrees that review of advertisements is outside the scope of De Novo request review. Under the proposed provision, only labels, labeling, and advertisements ''sufficient to describe the device, its intended use, and the directions for its use'' are required, and such information is necessary to determine the device's intended use and its safety and effectiveness for the purposes of classification. See, *e.g.,* § 860.7(b)(2).

(Comment 44) A comment supports the requirement for a requester to provide a list of any required information that is omitted from the De Novo request and a justification for any omission because the commenter states it would ensure completeness of the applicant's research and pre-application evaluations.

(Response 44) FDA agrees that it is beneficial for the requester to provide a statement identifying and justifying the omission of any information required under § 860.220(a) (this final rule renumbers proposed § 860.234(a) as § 860.220(a)) and is finalizing the requirement to provide such a statement in § 860.220(c) (this final rule renumbers proposed § 860.234(c) as § 860.220(c)). However, we wish to clarify that the omissions statement is not required to be in the format of a list, as the comment suggests.

(Comment 45) A comment requests FDA to revise the requirements for incorporation of information in FDA files by reference (§ 860.220(b), this final

rule renumbers proposed § 860.234(b) as § 860.220(b)) to permit the requester to file a general authorization allowing another person to submit additional pertinent information. According to the commenter, this would allow De Novo requesters to avoid the need for case-by-case authorization.

(Response 45) FDA disagrees with this comment and believes the commenter misunderstands the circumstances in which FDA requires an authorization. The provision in § 860.220(b) addresses situations in which a De Novo request references information in FDA's files that was submitted by someone other than the requester. For FDA to consider that information as part of the De Novo request, we require a written authorization from the person originally submitting that information to FDA that authorizes the use of the information in the De Novo request. Because the authorizer determines the scope of the authorization, it can be as broad or as limited as the authorizer wants the authorization to be. The comment seems to suggest that the requester should be able to provide authorization for the De Novo request to reference information in FDA's files submitted by others, but the submitters of the data are the ones in a position to authorize references to it.

(Comment 46) A few comments request FDA to revise the requirement to update a pending De Novo request with new information from ongoing or completed studies that may reasonably affect an evaluation of the safety and effectiveness of the device as it becomes available (§ 860.220(d), this final rule renumbers proposed § 860.234(d) as § 860.220(d)) because the commenters assert FDA should allow time for data aggregation and assessment. The comments suggest that FDA should require such information as agreed upon with the De Novo requester or as specified in a protocol.

(Response 46) FDA disagrees with these comments. The comments assume incorrectly that for each ongoing or completed nonclinical and/or clinical study, there exists a protocol that has timeframes for reporting new safety and effectiveness information to FDA or an agreement specifying when new safety and effectiveness information must be submitted to update a pending De Novo request. FDA is also concerned that specifying a set time period for updating the De Novo request would be problematic because the importance of the data required to be reported may vary. For example, FDA would be particularly interested in receiving quickly information that concerns the death of a human subject. Updating a De Novo request in accordance with pre-set periods in a protocol or agreement could also result in FDA making a decision on a De Novo request without key, available safety and effectiveness information. For example, an unplanned review of the safety data could have implications on the statistical validity of a study.

I. Comments and FDA Response on Criteria for Accepting a De Novo Request

(Comment 47) A comment states the requirements in § 860.230 (this final rule renumbers proposed § 860.245 as § 860.230)) should be moved to FDA's guidance, ''Acceptance Review for De Novo Classification Requests'' (FDA draft guidance published October 30, 2017). Another comment recommends finalizing FDA's guidance, ''Acceptance Review for De Novo Classification Requests,'' concurrently with finalizing the rule.

(Response 47) FDA disagrees with this comment because FDA's requirements are based on its statutes and regulations. FDA guidance provides non-binding recommendations. Regulations are necessary because they allow the Agency to enforce the requirements therein. For this reason, we decline to remove the accepting a De Novo request requirements, including those in § 860.230, from this regulation.

FDA's ''Acceptance Review for De Novo Classification Requests'' guidance was finalized on September 9, 2019 (84 FR 47310) (Ref. 16), so the comment requesting concurrent publication is moot.

(Comment 48) A comment requests FDA to clarify that references to ''15 days'' signify calendar days because it will enhance De Novo requester planning.

(Response 48) FDA declines to clarify in the codified but confirms that it interprets ''15 days'' to mean ''15 calendar days.'' This interpretation is consistent with FDA's final guidance entitled, ''Acceptance Review for De Novo Classification Requests'' (Ref. 16), which explains that the 15 days are calendar days. It is also consistent with our interpretation of ''days'' as used in analogous regulations for PMAs and 510(k)s.

J. Comments and FDA Response on Granting or Declining a De Novo Request

(Comment 49) A comment objects to developing a new lexicon for De Novo requests (*i.e.,* grant or decline) and asks FDA to use the term ''approval'' because the commenter asserts that CDRH approves both ''De Novo devices'' and ''PMA devices'' for marketing based on a determination that they are safe and effective for their intended use.

(Response 49) We disagree with this comment. The term ''decline'' is language from section 513(f)(2) of the FD&C Act, and FDA believes the term ''grant'' is appropriate, given that section 513(f)(2) of the FD&C Act addresses a ''request for classification.'' In addition, FDA does not make identical determinations when approving a PMA or granting a De Novo request. The statutory standards for approval of a PMA include a showing of reasonable assurance that the device is safe and effective (see section 515(d) of the FD&C Act). FDA will grant a De Novo request and classify the device as either class I or class II when the request demonstrates that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness (see section 513(a) and (f)(2) of the FD&C Act).

(Comment 50) To be consistent with section 513(f)(2)(C) of the FD&C Act, a few comments requested that FDA revise the provision regarding publication in the **Federal Register** of the notice announcing the classification of the device to state that the publication will occur within 30 days of granting the request.

(Response 50) FDA agrees to revise § 860.260(a)(2) (this final rule renumbers proposed § 860.289(a)(2) as § 860.260(a)(2)) to reflect the statutory timeframe for publishing a notice in the **Federal Register** announcing the classification of a device under section 513(f)(2)(C) of the FD&C Act. We are revising § 860.260(a)(2) accordingly to add the phrase ''within 30 days after the issuance of an order granting the De Novo request.'' We note that the classification of a device, including any special controls, is effective on the date the order letter is issued granting the De Novo request. Once the De Novo request is granted, the device may serve as a predicate device to which another device can claim substantial equivalence. FDA places copies of such orders on its website.

(Comment 51) A comment on the proposed provisions for declining a De Novo request notes that stating FDA ''may issue written notice'' declining a request suggests there is an alternative to issuing a written notice and asks FDA to describe the alternative.

(Response 51) FDA intended to outline the grounds for which FDA may decline a De Novo request in proposed § 860.289(b) (this final rule renumbers proposed § 860.289(b) as § 860.260(c) and moves the grounds for which FDA may decline a De Novo request into

§ 860.260(c)). FDA explained in the preamble to the proposed rule that it was proposing to ''decline a De Novo request by issuing a written order to the requester'' (83 FR 63127 at 63137). However, FDA is revising paragraph § 860.260(b) and (c) accordingly to clarify this point.

(Comment 52) A comment asks FDA to delete the entire paragraph § 860.260(c) (this final rule renumbers proposed § 860.289(b) as § 860.260(c) and moves the grounds for which FDA may decline a De Novo request into § 860.260(c)) on declining a De Novo request because the commenter states the paragraph exceeds the appropriate bases for denial of a De Novo request, which the commenter identifies as the device is inappropriate for classification into class I or class II, or there is a legally marketed predicate device.

(Response 52) FDA disagrees with this comment. Section 860.260(c)) (this final rule renumbers proposed § 860.289(b) as § 860.260(b) and moves the grounds for which FDA may decline a De Novo request into § 860.260(c)) explains FDA's interpretation and implementation of the statutory grounds for declining a De Novo request, which does not rely upon only section 513(f)(2)(A)(iv) of the FD&C Act. For example, if a product is not a device within the meaning of section 201(h) of the FD&C Act or a combination product as defined at § 3.2(e) (21 CFR 3.2(e)), then FDA may decline to grant the De Novo request.

As noted in the proposed rule (83 FR 63127 at 63137), FDA generally intends to decline a De Novo request for a combination product that does not have a device primary mode of action—(see § 3.2(m)). However, a De Novo request may be appropriate, for example, for the device constituent part of such a combination product if the constituent parts of the combination product are to be distributed separately (see § 3.2(e)(3) through (4)), and the other constituent part (drug or biological product) of the combination product is to be marketed under its own, separate application (*i.e.,* abbreviated new drug application, NDA, or biologics license application).

(Comment 53) A few comments request that FDA delete the entire paragraph on declining a De Novo request because the device labeling does not comply with parts 801 and 809 (21 CFR parts 801 and 809) because the commenters state it is outside the scope of the De Novo classification process to deny classification based on the device's labeling.

(Response 53) FDA disagrees with these comments. Parts 801 and 809 are general controls, and whether the device complies with general controls is necessary to determine whether it is of low to moderate risk for the purposes of classification. FDA may decline a De Novo request if it determines that the device submitted is not of low to moderate risk, or that general controls would be inadequate to control the risk and special controls to mitigate the risks cannot be developed. Whether the device's labeling complies with the requirements in parts 801 and 809 is necessary to determine which regulatory controls are appropriate for the new device type class. The device's labeling compliance with parts 801 and 809 is also necessary to determine the device's safety and effectiveness for the purposes of classification.

(Comment 54) A comment requests FDA to revise the basis for declining a De Novo request set forth in § 860.260(c)(8) (this final rule renumbers proposed § 860.289(b)(8) as § 860.260(c)(8)) to specify that a request may only be declined when certain nonclinical studies within the scope of part 58 are not conducted in compliance with those regulations. The commenter asserts that many nonclinical studies are outside the scope of part 58.

(Response 54) FDA agrees that a De Novo request may include nonclinical studies that are not subject to part 58, as we explained in Response 38. FDA would not decline a De Novo request on the basis that a nonclinical study failed to comply with part 58, if that study did not fall within the scope of studies that are subject to part 58. However, FDA is revising § 860.260(c)(8) to make this clearer.

(Comment 55) A comment requests that FDA revise the paragraph on declining a De Novo request (§ 860.260(c)(10)(i), this final rule renumbers proposed § 860.289(b)(10)(i) as § 860.260(c)(10)(i)) because the commenter states that failure to follow a protocol is not, per se, a reason to decline a De Novo request.

(Response 55) FDA disagrees with the commenter's suggestion to revise the provision on declining a De Novo request so that it does not include failure to follow a protocol. The failure to follow a protocol may cause the resulting data to be incomplete, invalid, or otherwise unreliable, and may be a sufficient reason to decline a De Novo request. Protocols typically discuss the objectives, design, methodology, and organization of a clinical or nonclinical study. Significant deviations from a study protocol may lead to a study that, as conducted, does not produce valid scientific evidence. Alternatively, data from a study that was terminated early may not provide sufficient information to support a reasonable assurance of safety or effectiveness.

(Comment 56) A comment objects to the placement of the paragraph on determining safety and effectiveness as one of the last paragraphs in subpart D because the commenter states FDA should do both a classification determination and a determination of the device's safety and effectiveness.

(Response 56) FDA does not agree with the comment's premise that the location of the paragraph in subpart D is an indication of the paragraph's importance. The FD&C Act provides that the De Novo process is both a classification and a marketing authorization grant for the particular device (section 513(f)(2) of the FD&C Act). The classification determination and ''determination of safety and effectiveness'' are necessary to make a determination regarding the device which is the subject of the De Novo request.

K. Comments and FDA Response on Availability of the De Novo Classification Process for Combination Products

(Comment 57) A comment requests that FDA clarify that for the summary of risk and mitigations and the risk-benefit discussion required to be submitted in the De Novo request, the summary and the risk-benefit discussion should describe the incremental risk and benefits posed by a combination product because the commenter states the content requirements should reflect that the De Novo classification process is available for combination products.

(Response 57) FDA believes that inclusion of this language is unnecessary as we consider section 503(g)(3) of the FD&C Act to be clear regarding its applicability to combination products that include an approved constituent part as defined in section 503(g)(3) of the FD&C Act. In addition, the statute is clear that these considerations apply to such combination products submitted under sections 515, 510(k), and 513(f)(2) of the FD&C Act. We do not believe inclusion of this language is necessary to provide further clarity beyond what is stated in the statute. Combination products have distinct premarket review and approvability considerations arising from combining a drug, device, and/or biological product, which retain their regulatory identities when they become constituent parts of combination products. Combination products are also a separate legal category of medical products, distinct from biological products, devices, and drugs. General principles of premarket review and

regulation for combination products include application of a risk-based approach and coordination among Centers for their review and regulation. Review of combination products in a De Novo classification request would consider safety and effectiveness questions relating to the combination product as a whole, each constituent part, interactions between them, and user/patient interaction with the product.

(Comment 58) A comment asks FDA to clarify that while a De Novo request may be appropriate for the device constituent part of a combination product where the constituent parts of the combination product are distributed separately (*e.g.,* § 3.2(e)(3) through (4)), and the non-device (drug or biologic) constituent part is to be marketed under its own, separate application, the non-device constituent part must be appropriately labeled for use with the device constituent part (*i.e.,* approved at doses, concentrations, routes of administration, indications, and adequate instructions for use). The commenter notes that if the non-device constituent part is not appropriately labeled for use with the device constituent part, then FDA would cause the non-device constituent party to be adulterated or misbranded.

(Response 58) FDA does not agree that clarification is necessary. Per § 3.2(e), the labeling of the constituent parts of such ''cross-labeled'' combination products specify use only with the other approved individually specified constituent part(s), which are required to achieve the intended use, indication, or effect. The labeling for the combination product is comprised of the labeling for each constituent part.

(Comment 59) A comment requests that FDA consider ''co-packaged'' combination products (per § 3.2(e)(2)) that have a device primary mode of action as eligible for the De Novo classification process.

(Response 59) Regarding inclusion of co-packaged combination products as defined in § 3.2(e)(2) that have a device primary mode of action, FDA does not believe further clarification is warranted in the codified because § 860.260 (this final rule renumbers proposed § 860.289 as § 860.260) explains that we are using the definition of combination products in § 3.2(e)(1) through (4). Co-packaged combination products as defined in § 3.2(e)(2) that have a device primary mode of action are part of this definition and eligible for the De Novo classification process.

VI. Effective Date

This final rule will become effective 90 days after the date of publication in the **Federal Register**.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small entities affected by this final rule would incur very low one-time costs to read and understand the rule, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

The final rule will clarify the De Novo classification process for certain medical devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as class III devices under the FD&C Act. In addition, the final rule will clarify and create a more efficient De Novo classification process by specifying: (1) What medical devices are eligible for the De Novo classification process; (2) what information manufacturers must provide in De Novo requests; and (3) how to organize this information. By clarifying and making the process more efficient, the final rule could reduce the time and costs associated with reviewing De Novo requests. Moreover, the final rule will allow us to refuse to accept inappropriate and deficient De Novo requests and require us to protect the confidentiality of certain data and information submitted with a request until we issue an order granting the request.

Industry will incur costs to read and understand this final rule. We estimate that the annualized costs over 10 years would range from $0.01 million to $0.17 million at a 7 percent discount rate, with a primary estimate of $0.09 million. We estimate that the annualized costs over 10 years at a 3 percent discount rate would range from $0.01 million to $0.15 million, with a primary estimate of $0.08 million.

TABLE 2—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF THE FINAL RULE

[$ millions]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Benefits:							
Annualized				2019	7	10	
Monetized $millions/year				2019	3	10	
Annualized Quantified				2019	7	10	
				2019	3	10	

TABLE 2—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF THE FINAL RULE—Continued
[$ millions]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Qualitative							Clarification of the De Novo process for requesters. Potentially fewer incomplete submissions and faster introduction of medical devices.
Costs:							
Annualized Monetized $millions/year	$0.09	$0.01	$0.17	2019	7	10	
	0.08	0.01	0.15	2019	3	10	
Annualized Quantified				2019	7	10	
				2019	3	10	
Qualitative.							
Transfers:							
Federal Annualized Monetized $millions/year.				2019	7	10	
				2019	3	10	
	From:			To:			
Other Annualized Monetized $millions/year.				2019	7	10	
				2019	3	10	
	From:			To:			
Effects:							
State, Local or Tribal Government: None.							
Small Business: A small one-time administrative burden of up to $300 per year on each affected small entity.							
Wages: None.							
Growth: None.							

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 20) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) and (f) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Medical Device De Novo Classification Process (OMB Control Number 0910–0844)—Revision.

Description: This final rule implements the medical device De Novo classification process under section 513(f)(2) of the FD&C Act, which provides a pathway for certain new types of devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as a class III device, which would require premarket approval under the postamendments device classification section of the FD&C Act (section 513(f)(1)).

On October 30, 2017, FDA issued a final guidance (De Novo Program guidance) (Ref. 5) to provide recommendations on the process for the submission and review of a De Novo request. The information collections associated with the guidance are approved under OMB control number 0910–0844. We provide below a revised burden estimate for the De Novo classification process as described in this final rule.

Section 860.200 (this final rule renumbers proposed § 860.201 as § 860.200) explains the purpose of the De Novo Classification regulations and provides the applicability of a De Novo request submission. Sections 860.210 and 860.220 (this final rule renumbers proposed § 860.223 and § 860.234 as § 860.210 and § 860.220) describe the format and content, respectively, of a De Novo request. Section 860.230 (this final rule renumbers proposed § 860.245 as § 860.230) describes the conditions under which FDA may refuse to accept a De Novo request. Section 860.240(b) (this final rule renumbers proposed § 860.256(b) as § 860.240(b)) provides for supplemental, amendatory, or additional information for a pending De Novo request. Section 860.250(a)(4) (this final rule renumbers proposed § 860.267(a)(4) as § 860.250(a)(4)) provides that a requester may submit a written notice to FDA that the De Novo request has been withdrawn.

Description of Respondents: Respondents to the information collection are medical device manufacturers seeking to market medical device products that have been automatically designated as class III under section 513(f)(1) of the FD&C Act.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
De Novo request—860.200, 860.210, 860.220, 860.230, 860.240(b).	68	1	68	182	12,376	$88
Written notice of withdrawal—860.250(a)(4).	5	1	5	0.17 (10 minutes)	1	7
Total					12,377	95

[1] Numbers have been rounded.

The information collection request (ICR) previously approved for the De Novo classification process (OMB control number 0910–0844), includes separate information collections (ICs) for De Novo requests submitted under section 513(f)(2)(i) of the FD&C Act (estimated 100-hour burden per response) and those submitted under section 513(f)(2)(ii) (estimated 180-hour burden per response), with burden estimates further separated by those sent to CDRH and those sent to the Center for Biologics Evaluation and Research.

For administrative efficiency, in this ICR revision, we are consolidating the separate ICs for requests submitted under section 513(f)(2)(i) or (ii) of the FD&C Act into a single IC for all De Novo requests submitted to FDA. Therefore, this final rule simply provides a burden estimate for all De Novo requests without distinguishing between those submitted under 513(f)(2)(i) or (ii) of the FD&C Act. This estimate includes estimated burdens associated with the initial request (purpose and applicability in § 860.200), format and content (§ 860.210 and § 860.220), supplements and amendments (§ 860.240(b)), and time to ensure that all the format and content requirements are met before submission (§ 860.230). Based on our recent experience with the De Novo Program, FDA estimates that the average burden per response for a De Novo request is 182 hours. Additionally, we adjusted the estimated number of respondents based on updated data.

The estimated burden for § 860.230 includes 2 hours per response for manufacturers to review their De Novo request for compliance with the acceptance criteria listed in § 860.230 to determine if it is complete and to complete the checklists recommended in the guidance ''Acceptance Review for De Novo Classification Requests'' (Ref.16). The information collections contained in the guidance, including 2 hours for review of the De Novo request for completeness and the checklists, were approved by OMB since publication of the proposed rule.

We estimate that the average burden per response for written notice of withdrawal of a De Novo request, as described in § 860.250(a)(4), is 10 minutes (0.17 hours). The burden table in the proposed rule erroneously listed 10 hours, rather than 10 minutes, for the average burden per response. We have corrected the error. The average burden per response is based on estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a De Novo request (and related materials), have consulted and advised manufacturers on submissions, and have reviewed the documentation submitted. We expect that we will receive approximately five notices of withdrawal per year. There is no change to the currently approved burden estimate for withdrawal of a De Novo request.

These adjustments resulted in a 1,647-hour increase to the previously approved total burden estimate.

We received several comments related to the proposed rule. Descriptions of the comments on the proposed rule and FDA's responses are provided in section V of this final rule. Comments and responses related to the provisions that underlie the information collection are described in the following sections: section V.B, regarding general comments; section V.D, De Novo request information disclosure; section V.F, regarding definitions; section V.G, regarding De Novo request format; section V.H, regarding De Novo request content; section V.I, regarding criteria for accepting a De Novo request; section V.J, regarding criteria for granting or declining a De Novo request; and section V.K, regarding availability of the De Novo classification process for combination products. We have not made changes to the estimated burden as a result of the comments.

The estimate of the annual reporting burden provided in the proposed rule included printing and shipping for the complete paper submission and eCopy. Under § 860.210 of the final rule, each De Novo request must be provided as a single version in electronic format. Therefore, we have adjusted the operating and maintenance cost in the final rule to include the cost of the eCopy and shipping of the eCopy.

The cost per eCopy (CDs, DVDs, and flash drives) ranges from $0.25 to $2.50 per eCopy. All forms of eCopy media cost roughly $0.22 to ship. We estimate the average cost per eCopy, plus shipping, for a De Novo request or a request for withdrawal to be $1.30 per submission.

The annual cost estimate for De Novo requests is $88 (68 submissions × $1.30) (rounded). The annual cost estimate for requests for withdrawal is $7 (5 requests × $1.30) (rounded). Therefore, we estimate the total annual operating and maintenance costs of this information collection to be $95. This is a decrease of $7,188 to the currently approved total annual operating and maintenance cost estimate.

This final rule also refers to previously approved collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in the guidance entitled ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' (Ref. 5) have been approved under OMB control number 0910–0844; the collections of information in the guidance entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program—Guidance for Industry and Food and Drug Administration Staff'' (Ref. 13) have been approved under OMB control number 0910–0756; the collections of information in the guidances entitled ''Guidance for Industry and Food and Drug Administration Staff—User Fees

for 513(g) Requests for Information'' (Ref. 17) and ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act—Guidance for Industry and Food and Drug Administration Staff'' (Ref. 18) have been approved under OMB control number 0910–0705; and the collections of information in the guidance entitled ''Emergency Use Authorization of Medical Products and Related Authorities'' (Ref. 19) have been approved under OMB control number 0910–0595. The collections of information in Title 21 of the Code of Federal Regulations (CFR) are approved under the following OMB control numbers: part 3 under 0910–0523; parts 50 and 56 under 0910–0130; part 54 under 0910–0396; part 58 under 0910–0119; parts 801 and 809 under 0910–0485; part 807, subpart E, under 0910–0120; part 812 under 0910–0078; part 814, subparts A through E under 0910–0231; part 814, subpart H under 0910–0332; part 820 under 0910–0073; part 860, subpart C under 0910–0138.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices.*
2. FDA, ''Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices.*
3. FDA, ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de.*
4. FDA, ''Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-preference-information-voluntary-submission-review-premarket-approval-applications.*
5. FDA, ''De Novo Classification Process (Evaluation of Automatic Class III Designation),'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/de-novo-classification-process-evaluation-automatic-class-iii-designation.*
6. FDA, CDRH Patient Engagement web page, available at *https://www.fda.gov/about-fda/about-center-devices-and-radiological-health/cdrh-patient-engagement.*
7. FDA, ''Procedures for Meetings of the Medical Devices Advisory Committee,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-meetings-medical-devices-advisory-committee.*
8. FDA, ''eCopy Program for Medical Device Submissions,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.*
9. FDA, ''Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-uncertainty-making-benefit-risk-determinations-medical-device-premarket-approvals-de.*
10. FDA, ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)],'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.*
11. FDA, ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.*
12. FDA, ''The Least Burdensome Provisions: Concept and Principles,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.*
13. FDA, ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.*
14. FDA, ''Use of Electronic Health Record Data in Clinical Investigations,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-industry.*
15. FDA, ''Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket.*
16. FDA, ''Acceptance Review for De Novo Classification Requests,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-*

documents/acceptance-review-de-novo-classification-requests.

17. FDA's guidance ''Guidance for Industry and Food and Drug Administration Staff—User Fees for 513(g) Requests for Information,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information.*
18. FDA's guidance ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic.*
19. ''Emergency Use Authorization of Medical Products and Related Authorities,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.*
20. FDA's full analysis of economic impacts is available in the Docket No. FDA–2018–N–0236 for this rule and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 860

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 860 is amended as follows:

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

■ 1. The authority citation for part 860 is revised to read as follows:

Authority: 21 U.S.C. 321(h), 353(g), 360c, 360d, 360e, 360i, 360j, 371, 374.

■ 2. In part 860, remove all references to ''the act'' and add in their place ''the Federal Food, Drug, and Cosmetic Act''.

■ 3. Amend § 860.1 by revising paragraph (b) to read as follows:

§ 860.1 Scope.

* * * * *

(b) This part prescribes the criteria and procedures to be used by advisory committees, including classification panels, where applicable, in making their recommendations, and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices. Supplementing the general Food and Drug Administration procedures governing advisory committees (part 14 of this chapter), this part also provides procedures for manufacturers, importers, and other interested persons to participate in proceedings to classify and reclassify devices. This part also describes the type of data required for determination of the safety and effectiveness of a device, and the circumstances under which information submitted to advisory committees, including classification panels, or to the Commissioner in connection with classification and reclassification proceedings, will be available to the public.

■ 4. Revise § 860.3 to read as follows:

§ 860.3 Definitions.

For the purposes of this part:

Class means one of the three categories of regulatory control for medical devices, defined as follows:

Class I means the class of devices that are subject only to the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the Federal Food, Drug, and Cosmetic Act. A device is in class I if:

(1) General controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or

(2) There is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury.

Class II means the class of devices that is or eventually will be subject to special controls. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, which are necessary to provide adequate assurance of safety and effectiveness, and describe how such controls provide such assurance.

Class III means the class of devices for which premarket approval is or will be required in accordance with section 515 of the Federal Food, Drug, and Cosmetic Act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness, or that application of special controls described in the definition of ''*Class II*'' in this section in addition to general controls, would provide such assurance, and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

Classification panel means one of the several advisory committees established by the Commissioner under section 513 of the Federal Food, Drug, and Cosmetic Act and part 14 of this chapter for the purpose of making recommendations to the Commissioner on the classification and reclassification of devices and for other purposes prescribed by the Federal Food, Drug, and Cosmetic Act or by the Commissioner.

Classification regulation means a section under parts 862 through 892 of this chapter that contains the identification (general description and intended use) and classification (class I, II or III) of a single device type or more than one related device type(s).

Commissioner means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health and Human Services, or the Commissioner's designee.

De Novo request means any submission under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act for a medical device, requesting classification into class I or class II, including all information submitted with or incorporated by reference therein.

FDA means the Food and Drug Administration.

General controls mean the controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration, listing, and premarket notification), 516 (banned devices), 518 (notification and other remedies), 519 (records, reports, and unique device identification), and 520 (general provisions) of the Federal Food, Drug, and Cosmetic Act.

Generic type of device means a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

Implant means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise to protect human health.

Life-supporting or life-sustaining device means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Petition means a submission seeking reclassification of a device in accordance with § 860.123.

Special controls mean the controls necessary to provide reasonable assurance of safety and effectiveness for a generic type of device that is class II. Special controls include performance standards, performance testing, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act), recommendations, and other appropriate actions, as the Commissioner deems necessary to provide such assurance.

■ 5. Amend § 860.5 by adding paragraph (g) to read as follows:

§ 860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.

* * * * *

(g) Confidentiality of data and information in a De Novo file is as follows:

(1) A ''De Novo file'' includes all data and information from the requester submitted with or incorporated by reference in the De Novo request, any De Novo supplement, or any other related submission relevant to the administrative file, as defined in § 10.3(a) of this chapter. Any record in the De Novo file will be available for public disclosure in accordance with the provisions of this section and part 20 of this chapter.

(2) The existence of a De Novo file may not be disclosed by FDA before an order granting the De Novo request is issued unless it previously has been publicly disclosed or acknowledged by the De Novo requester.

(3) Before an order granting the De Novo request is issued, data or information contained in the De Novo file is not available for public disclosure, except to the extent the existence of the De Novo file is disclosable under paragraph (g)(2) of this section and such data or information has been publicly disclosed or acknowledged by the De Novo requester.

(4) After FDA issues an order granting a De Novo request, the data and information in the De Novo file that are not exempt from release under the Freedom of Information Act, 5 U.S.C. 552, are immediately available for public disclosure.

■ 6. Add subpart D, consisting of §§ 860.200 through 860.260, to read as follows:

Subpart D—De Novo Classification

Sec.

Subpart D—De Novo Classification

§ 860.200 Purpose and applicability.

(a) The purpose of this part is to establish an efficient, transparent, and thorough process to facilitate De Novo classification into class I or class II for devices for which there is no legally marketed device on which to base a review of substantial equivalence and which meet the definition of class I or class II as described in section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act and § 860.3.

(b) De Novo requests can be submitted for a single device type:

(1) After receiving a not substantially equivalent determination in response to a premarket notification (510(k)), or

(2) If a person determines there is no legally marketed device upon which to base a determination of substantial equivalence.

§ 860.210 De Novo request format.

(a) Each De Novo request or information related to a De Novo request pursuant to this part must be formatted in accordance with this section. Each De Novo request must be provided as a single version in electronic format. These materials must:

(1)(i) For devices regulated by the Center for Devices and Radiological Health, be sent to the current address displayed on the website *https://www.fda.gov/cdrhsubmissionaddress.*

(ii) For devices regulated by the Center for Biologics Evaluation and Research, be sent to the current address displayed on the website *https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper.*

(2) Be signed by the requester or an authorized representative.

(3) Be designated ''De Novo Request'' in the cover letter.

(4) Have all content used to support the request written in, or translated into, English.

§ 860.220 De Novo request content.

(a) Unless the requester justifies an omission in accordance with paragraph (c) of this section, a De Novo request must include:

(1) *Table of contents.* A table of contents that specifies the volume (if the De Novo request contains more than one volume) and page number for each item.

(2) *Administrative information.* The name, address, phone, and email address of the requester and U.S. representative, if applicable. The establishment registration number, if applicable, of the owner or operator submitting the De Novo request.

(3) *Regulatory history.* Identify any prior submissions to FDA for the device, including, but not limited to, any premarket notifications (510(k)s) submitted under part 807 of this chapter; applications for premarket approval (PMAs) submitted under part 814 of this chapter; applications for humanitarian device exemption (HDE) submitted under part 814 of this chapter; applications for investigational device exemption (IDEs) submitted under part 812 of this chapter; requests for designation (RFD) under § 3.7 of this chapter; requests for information under section 513(g) of the Federal Food, Drug, and Cosmetic Act; applications for emergency use authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act; pre-submissions, or previously submitted De Novo requests; or state that there have been no prior submissions.

(4) *Device name.* The generic name of the device as well as any proprietary name or trade name.

(5) *Indications for use.* A general description of the disease or condition the device is intended to diagnose, treat, prevent, cure or mitigate, or affect the structure or function of the body, including a description of the patient

population for which the device is intended. The indications for use include all the labeled patient uses of the device, including if it is prescription or over-the-counter.

(6) *Device description.* A complete description of:

(i) The device, including, where applicable, pictorial representations, device specifications, and engineering drawings;

(ii) Each of the functional components or ingredients of the device, if the device consists of more than one physical component or ingredient;

(iii) The properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition and/or the effect of the device on the structure or function of the body;

(iv) The principles of operation of the device; and

(v) The relevant FDA assigned reference number(s) for any medical devices (such as accessories or components) that are intended to be used with the device and that are already legally marketed.

(7) *Alternative practices and procedures.* A description of existing alternative practices or procedures that are used in diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended or which similarly affect the structure or function of the body and that are known or should reasonably be known to the requester.

(8) *Classification summary.* (i) For devices not the subject of a previous submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act, a complete description of:

(A) The searches used to establish that no legally marketed device of the same type exists.

(B) A list of classification regulations, PMAs, HDEs, premarket notifications (510(k)s), EUAs, and/or product codes regarding devices that are potentially similar to the subject device.

(C) A rationale explaining how the device that is the subject of the De Novo request is different from the devices covered by the classification regulations, PMAs, HDEs, 510(k)s, EUAs, and/or product codes identified in paragraph (a)(8)(i)(B) of this section.

(ii) For devices which were the subject of a previous submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act that were determined not substantially equivalent (NSE), the relevant 510(k) number, along with a summary of the search performed to confirm the device has not been classified or reclassified since the date the NSE order was issued by FDA pursuant to § 807.100(a) of this chapter.

(9) *Summary of risks and mitigations.* A summary of probable risks to health associated with use of the device that are known or should reasonably be known to the requester and the proposed mitigations, including general controls and, if the classification recommendation from paragraph (a)(11) of this section is class II, special controls for each risk. For each mitigation measure that involves specific performance testing or labeling, the De Novo request must provide a reference to the associated section or pages for the supporting information in the De Novo request.

(10) *Proposed special controls.* If the classification recommendation from paragraph (a)(11) of this section is class II, then the summary must include an initial draft proposal for applicable special controls and a description of how those special controls provide reasonable assurance of safety and effectiveness.

(11) *Classification recommendation.* The recommended class (I or II) must be identified and must be supported by a description of why general controls, or general and special controls, are adequate to provide reasonable assurance of safety and effectiveness.

(12) *Standards.* Reference to any published voluntary consensus standards that are relevant to any aspect of the safety or effectiveness of the device and that are known or should reasonably be known to the requester. Such standards include voluntary consensus standards whether recognized or not yet recognized under section 514(c) of the Federal Food, Drug, and Cosmetic Act. Provide adequate information to demonstrate how the device meets, or justify any deviation from, the referenced standard.

(13) *Summary of studies.* An abstract of any information or report described in the De Novo request under paragraph (a)(16)(ii) of this section and a summary of the results of technical data submitted under paragraph (a)(15) of this section. Each such study summary must include a description of the objective of the study, a description of the experimental design of the study, a brief description of how the data were collected and analyzed, and a brief description of the results, whether positive, negative, or inconclusive. This section must also include the following:

(i) A summary of each nonclinical study submitted in the De Novo request;

(ii) A summary of each clinical investigation involving human subjects submitted in the De Novo request, including a discussion of investigation design, subject selection and exclusion criteria, investigation population, investigation period, safety and effectiveness data, adverse reactions and complications, subject discontinuation, subject complaints, device failures (including unexpected software events, if applicable) and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate. Any investigation conducted under an investigational device exemption (IDE) under part 812 of this chapter must be identified as such.

(14) *Benefit and risk considerations.* A discussion demonstrating that:

(i) The data and information in the De Novo request constitute valid scientific evidence within the meaning of § 860.7(c) and

(ii) Pursuant to § 860.7, when subject to general controls, or general and special controls, the probable benefit to health from use of the device outweighs any probable injury or illness from such use.

(15) *Technical sections.* The following technical sections, which must contain data and information in sufficient detail to permit FDA to determine whether to grant or decline the De Novo request:

(i) A section containing the results of the nonclinical studies of the device, including, as appropriate, microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, electrical safety, electromagnetic compatibility, and other laboratory or animal tests. Information on nonclinical studies must include protocols and complete test reports for each study. For those nonclinical studies subject to part 58 of this chapter, this section must include a statement that each such study was conducted in compliance with such regulations, or, if the study was not conducted in compliance with part 58 of this chapter, a brief statement of the reason for the noncompliance.

(ii) For all devices that incorporate software, a section containing all relevant software information and testing, including, but not limited to, appropriate device hazard analysis, hardware, and system information.

(iii) A section containing results of each clinical investigation of the device involving human subjects, including clinical protocols, number of investigators and subjects per investigator, investigation design, subject selection and exclusion criteria, investigation population, investigation period, safety and effectiveness data, adverse reactions and complications,

subject discontinuation, subject complaints, device failures (including unexpected software events if applicable) and replacements, tabulations of data from all individual subject report forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, results of statistical analyses of the results of the clinical investigations, contraindications, warnings, precautions, and other limiting statements relevant to the use of the device type, and any other appropriate information from the clinical investigations. Any investigation conducted under an IDE under part 812 of this chapter must be identified as such. Information on clinical investigations involving human subjects must include the following:

(A) For clinical investigations conducted in the United States, a statement with respect to each investigation that it either was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to the regulations under § 56.104 or § 56.105 of this chapter, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter; or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(B) For clinical investigations conducted in the United States, a statement that each investigation was conducted in compliance with part 812 of this chapter concerning sponsors of clinical investigations and clinical investigators, or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(C) For clinical investigations conducted outside the United States that are intended to support the De Novo request, the requirements under § 812.28 of this chapter apply. If any such investigation was not conducted in accordance with good clinical practice (GCP) as described in § 812.28(a) of this chapter, include either a waiver request in accordance with § 812.28(c) of this chapter or a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(D) A statement that each investigation has been completed per the protocol or a summary of any protocol deviations.

(E) A financial certification or disclosure statement or both as required by part 54 of this chapter.

(F) For a De Novo request that relies primarily on data from a single investigator at one investigation site, a justification showing that these data and other information are sufficient to reasonably demonstrate the safety and effectiveness of the device when subject to general controls or general and special controls, and to ensure that the results from a site are applicable to the intended population.

(G) A discussion of how the investigation data represent clinically significant results, pursuant to § 860.7(e).

(16) *Other information.* (i) A bibliography of all published reports not submitted under paragraph (a)(15) of this section, whether adverse or supportive, known to or that should reasonably be known to the requester and that concern the safety or effectiveness of the device.

(ii) An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the requester from any source, foreign or domestic, including information derived from investigations other than those in the request and from commercial marketing experience.

(iii) Copies of such published reports or unpublished information in the possession of or reasonably obtainable by the requester, if requested by FDA.

(17) *Samples.* If requested by FDA, one or more samples of the device and its components. If it is impractical to submit a requested sample of the device, the requester must name the location at which FDA may examine and test one or more of the devices.

(18) *Labeling and advertisements.* Labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings must be supplied.

(19) *Other information.* Such other information as is necessary to determine whether general controls or general and special controls provide reasonable assurance of safety and effectiveness of the device.

(b) Pertinent information in FDA files specifically referred to by a requester may be incorporated into a De Novo request by reference. Information submitted to FDA by a person other than the requester will not be considered part of a De Novo request unless such reference is authorized in writing by the person who submitted the information.

(c) If the requester believes that certain information required under paragraph (a) of this section to be in a De Novo request is not applicable to the device that is the subject of the De Novo request, and omits any such information from the De Novo request, the requester must submit a statement that specifies the omitted information and justifies the omission. The statement must be submitted as a separate section in the De Novo request and listed in the table of contents. If the justification for the omission is not accepted by FDA, FDA will so notify the requester.

(d) The requester must update the pending De Novo request with new safety and effectiveness information learned about the device from ongoing or completed studies and investigations that may reasonably affect an evaluation of the safety or effectiveness of the device as such information becomes available.

§ 860.230 Accepting a De Novo request.

(a) The acceptance of a De Novo request means that FDA has made a threshold determination that the De Novo request contains the information necessary to permit a substantive review. Within 15 days after a De Novo request is received by FDA, FDA will notify the requester whether the De Novo request has been accepted.

(b) If FDA does not find that any of the reasons in paragraph (c)(1) of this section for refusing to accept the De Novo request apply or FDA fails to complete the acceptance review within 15 days, FDA will accept the De Novo request for review and will notify the requester. The notice will include the De Novo request reference number and the date FDA accepted the De Novo request. The date of acceptance is the date that an accepted De Novo request was received by FDA.

(c)(1) FDA may refuse to accept a De Novo request if any of the following applies:

(i) The requester has an open or pending premarket submission or reclassification petition for the device;

(ii) The De Novo request is incomplete because it does not on its face contain all the information required

under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act or does not contain each of the items required under this part, or a justification for omission of any item;

(iii) The De Novo request is not formatted as required under § 860.210;

(iv) The De Novo request is for multiple devices and those devices are of more than one type; or

(v) The requester has not responded to, or has failed to provide a rationale for not responding to, deficiencies identified by FDA in previous submissions for the same device, including those submissions described in § 860.220(a)(3).

(2) If FDA refuses to accept a De Novo request, FDA will notify the requester of the reasons for the refusal. The notice will identify the deficiencies in the De Novo request that prevent accepting and will include the De Novo request reference number.

(3) If FDA refuses to accept a De Novo request, the requester may submit the additional information necessary to comply with the requirements of section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act and this part. The additional information must include the De Novo request reference number of the original submission. If the De Novo request is subsequently accepted, the date of acceptance is the date FDA receives the additional information.

§ 860.240 Procedures for review of a De Novo request.

(a) FDA will begin substantive review of a De Novo request after the De Novo request is accepted under § 860.230. Within 120 days after receipt of a De Novo request or receipt of additional information that results in the De Novo request being accepted under § 860.230, FDA will review the De Novo request and send the requester an order granting the De Novo request under § 860.260(a) or an order declining the De Novo request under 860.260(b).

(b) A requester may supplement or amend a pending De Novo request to revise existing information or provide additional information.

(1) FDA may require additional information regarding the device that is necessary for FDA to complete the review of the De Novo request.

(2) Additional information submitted to FDA must include the reference number assigned to the original De Novo request and, if submitted on the requester's own initiative, the reason for submitting the additional information.

(c) Prior to granting or declining a De Novo request, FDA may inspect relevant facilities to help determine:

(1) That clinical or nonclinical data were collected in a manner that ensures that the data accurately represents the benefits and risks of the device; or

(2) That implementation of Quality System Regulation (part 820 of this chapter) requirements, in addition to other general controls and any specified special controls, provide adequate assurance that critical and/or novel manufacturing processes produce devices that meet specifications necessary to ensure reasonable assurance of safety and effectiveness.

§ 860.250 Withdrawal of a De Novo request.

(a) FDA considers a De Novo request to have been withdrawn if:

(1) The requester fails to provide a complete response to a request for additional information pursuant to § 860.240(b)(1) within 180 days after the date FDA issues such request;

(2) The requester fails to provide a complete response to the deficiencies identified by FDA pursuant to § 860.230(c)(2) within 180 days of the date notification was issued by FDA;

(3) The requester does not permit an authorized FDA employee an opportunity to inspect the facilities, pursuant to § 860.240(c), at a reasonable time and in a reasonable manner, and to have access to copy and verify all records pertinent to the De Novo request; or

(4) The requester submits a written notice to FDA that the De Novo request has been withdrawn.

(b) If a De Novo request is withdrawn, the Agency will notify the requester. The notice will include the De Novo request reference number and the date FDA considered the De Novo request withdrawn.

§ 860.260 Granting or declining a De Novo request.

(a)(1) FDA will issue to the requester an order granting a De Novo request if none of the reasons in paragraph (c) of this section for declining the De Novo request applies.

(2) If FDA grants a De Novo request, within 30 days after the issuance of an order granting the De Novo request, FDA will publish in the **Federal Register** a notice of the classification order, including any special controls.

(b) If FDA declines a De Novo request, FDA will issue a written order to the requester.

(c) FDA may decline a De Novo request if the requester fails to follow the requirements of this part or if, upon the basis of the information submitted in the De Novo request or any other information before FDA, FDA determines:

(1) The device does not meet the criteria under section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act and § 860.3 for classification into class I or II;

(2) The De Novo request contains a false statement of material fact or there is a material omission;

(3) The device's labeling does not comply with the requirements in parts 801 and 809 of this chapter, as applicable;

(4) The product described in the De Novo request does not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act and is not a combination product as defined at § 3.2(e) of this chapter;

(5) The device is of a type which has already been approved in existing applications for premarket approval (PMAs) submitted under part 814 of this chapter;

(6) The device is of a type that has already been classified into class I, class II, or class III;

(7) An inspection of a relevant facility under § 860.240(c) results in a determination that general or general and special controls would not provide reasonable assurance of safety and effectiveness;

(8) A nonclinical study subject to part 58 of this chapter that is described in the De Novo request, and that is essential to show there is reasonable assurance of safety, was not conducted in compliance with part 58 of this chapter and no reason for the noncompliance is provided or, if a reason is provided, the practices used in conducting the study do not support the validity of the study;

(9) A clinical investigation described in the De Novo request involving human subjects that is subject to the institutional review board regulations in part 56 of this chapter, informed consent regulations in part 50 of this chapter, or GCP described in § 812.28(a) of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable;

(10) A clinical or nonclinical study necessary to demonstrate that general controls or general and special controls provide reasonable assurance of safety and effectiveness:

(i) Has not been completed per the study protocol, or

(ii) Deficiencies related to the investigation and identified in any request for additional information under § 860.240(b)(1) have not been adequately addressed; or

(11) After a De Novo request is accepted for review under § 860.230(b), the requester makes significant unsolicited changes to the device's:

(i) Indications for use; or

(ii) Technological characteristics.

(d) An order declining a De Novo request will inform the requester of the deficiencies in the De Novo request, including each applicable ground for declining the De Novo request.

(e) FDA will use the criteria specified in § 860.7 to determine the safety and effectiveness of a device in deciding whether to grant or decline a De Novo request. FDA may use information other than that submitted by the requester in making such determination.

Dated: September 30, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2021–21677 Filed 10–4–21; 8:45 am]

BILLING CODE 4164–01–P

FEDERAL MEDIATION AND CONCILIATION SERVICE

29 CFR Part 1400

RIN 3076–AA19

Outside Employment, Business Activities, or Interests Regulation

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Final rule; rescission of regulation.

SUMMARY: On August 7, 1992, the Office of Government Ethics (OGE) published a final rule entitled ''Supplemental Agency Regulations'' requiring Federal agencies creating supplemental ethics regulations to submit such regulations to OGE for concurrence and joint issuance within their regulations. In accordance with ''Supplemental Agency Regulations,'' this final rule rescinds the current Federal Mediation and Conciliation Service (FMCS) supplemental ethics regulation ''Outside employment, business activities, or interests''.

DATES: This final rule is effective October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Alisa Silverman, Attorney-Advisor, Office of General Counsel, Federal Mediation and Conciliation Service, 250 E St. SW, Washington, DC 20427; Office/Fax/Mobile 202–606–5488; *asilverman@fmcs.gov*.

SUPPLEMENTARY INFORMATION:

I. Discussion

On April 13, 1968, at 33 FR 5765, the Federal Mediation and Conciliation Service (FMCS) published a final rule entitled ''Outside employment, business activities, and interests.'' This final rule implemented ethics regulations concerning outside activities.

On August 7, 1992, at 57 FR 35042, the Office of Government Ethics (OGE) published a rule ''Supplemental Agency Regulations'' requiring Federal agencies creating supplemental ethics regulations to submit such regulations to OGE for concurrence and joint issuance within title 5 of the Code of Federal Regulations.

In accordance with 5 CFR 2635.105, FMCS is working jointly with OGE to develop new supplemental agency regulations to be published by OGE within title 5 of the Code of Federal Regulations. Therefore, FMCS is issuing this final rule, which rescinds the current rule on outside employment, business activities, and interests within title 29 of the Code of Federal Regulations.

II. Final Rule

FMCS has determined that this rule is suitable for final rulemaking. The revisions to FMCS' policies and requirements surrounding outside activities are purely internal matters of agency management, as well as the agency's procedure, and practice. Accordingly, FMCS is not required to engage in a notice and comment process to issue this rule under the Administrative Procedures Act, See U.S.C. 553(a)(2), 553(b)(A). Furthermore, because this rule is procedural rather than substantive, the normal requirement of 5 U.S.C. 553(d) that a rule not be effective until at least 30 days after publication in the **Federal Register** is inapplicable. FMCS also finds good cause to provide an immediate effective date for this rule because it imposes no obligations on parties outside the Federal Government and therefore no advance notice is required to enable employers or other private parties to come into compliance.

List of Subjects in 29 CFR Part 1400

Administrative practice and procedure.

For the reasons discussed in the preamble, and under the authority 29 U.S.C. 172 of Taft Harley Act of 1947, and 5 U.S.C. 7301, FMCS amends 29 CFR chapter XII as follows:

PART 1400—STANDARDS OF CONDUCT, RESPONSIBILITIES, AND DISCIPLINE

■ 1. The authority citation for part 1400 continues to read as follows:

Authority: E.O. 11222, 30 FR 6469, 3 CFR, 1965 Supp.; 5 CFR 735.104.

§ 1400.735–12 [Removed]

■ 2. Remove § 1400.735–12.

Issued in Washington, DC.

Sarah Cudahy,

General Counsel.

[FR Doc. 2021–21716 Filed 10–4–21; 8:45 am]

BILLING CODE 6732–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2020–0647]

RIN 1625–AA09

Drawbridge Operation Regulation; New Jersey Intracoastal Waterway, Point Pleasant, NJ; Correction

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Correcting amendments.

SUMMARY: The Coast Guard published a final rule in the **Federal Register** on August 23, 2021, which was effective on September 22, 2021, announcing changes to the Route 88 (Veterans Memorial) Bridge and Route 13 (Lovelandtown) Bridge across the NJICW at Point Pleasant Canal, mile 3.0 and 3.9, respectively at Point Pleasant, NJ. The amendatory instruction within that final rule was incorrect and the changes could not be incorporated into the CFR. This correcting amendment incorporates those changes into the CFR.

DATES: The correction is effective on October 5, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0647. In the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Mickey Sanders, Bridge Administration Branch, Fifth District, U.S. Coast Guard, telephone (757) 398–6587, email *Mickey.D.Sanders2@uscg.mil*.

SUPPLEMENTARY INFORMATION:

Correction

On August 23, 2021, the Coast Guard published a final rule titled ''Drawbridge Operation Regulation; New

Jersey Intracoastal Waterway, Point Pleasant, NJ'' (86 FR 46966). This final rule amended 33 CFR 117.733. However, amendatory instruction number 2.c. incorrectly redesignated seven paragraphs into only six paragraphs.

List of Subjects in 33 CFR Part 117

Bridges.

Accordingly, 33 CFR part 117 is corrected by making the following correcting amendments:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 117.733 by:

■ a. Removing paragraphs (i) and (j);

■ b. Redesignating paragraphs (b) through (h) as (d) through (j); and

■ c. Adding new paragraphs (b) and (c).

The additions read as follows:

§ 117.733 New Jersey Intracoastal Waterway.

* * * * *

(b) The draw of the Route 88 Bridge, mile 3.0, across Point Pleasant Canal at Point Pleasant, shall operate as follows:

(1) From 7 a.m. to 11 p.m. the draw shall open on signal.

(2) From 11:01 p.m. to 6:59 a.m. the draw shall open on signal, if at least four hours advance notice is given.

(c) The draw of the Route 13 Bridge, mile 3.9, across Point Pleasant Canal at Point Pleasant, shall operate as follows:

(1) From 7 a.m. to 11 p.m. the draw shall open on signal.

(2) From 11:01 p.m. to 6:59 a.m. the draw shall open on signal, if at least four hours advance notice is given.

* * * * *

Dated: September 29, 2021.

M.T. Cunningham,

Chief, Office of Regulations and Administrative Law, U.S. Coast Guard.

[FR Doc. 2021–21628 Filed 10–4–21; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 73, and 74

[AU Docket No. 21–284; DA 21–1176; FR ID 50840]

Auction of Construction Permits for Low Power Television and TV Translator Stations; Notice and Filing Requirements, Minimum Opening Bids, Upfront Payments, and Other Procedures for Auction 111

AGENCY: Federal Communications Commission.

ACTION: Final action; requirements and procedures.

SUMMARY: This document summarizes the procedures, deadlines, and upfront payment and minimum opening bid amounts for the upcoming auction of construction permits for new or modified low power television and TV translator stations. The *Auction 111 Procedures Public Notice* summarized here is intended to familiarize potential applicants with details of the procedures, terms, and conditions governing participation in Auction 111, as well as an overview of the post-auction application and payment process.

DATES: Applications to participate in Auction 111 must be submitted before 6 p.m. Eastern Time (ET) on November 9, 2021. Upfront payments for Auction 111 must be received by 6 p.m. ET on January 25, 2022. Bidding in Auction 111 is scheduled to start on February 23, 2022.

FOR FURTHER INFORMATION CONTACT:

General Auction 111 Information: FCC Auctions Hotline at 888–225–5322, option two; or 717–338–2868.

Auction 111 Legal Information: Lyndsey Grunewald or Scott Mackoul at (202) 418–0660.

Licensing Information: Shaun Maher at (202) 418–2324 or Mark Colombo at (202) 418–7611.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, *Auction 111 Procedures Public Notice,* in AU Docket No. 21–284; DA 21–1176, released on September 21, 2021. The complete text of this document, including attachments and any related document, is available on the Commission's website at *http://www.fcc.gov/auction/111* or by using the search function for on the Commission's Electronic Comment Filing System (ECFS) web page at *www.fcc.gov/ecfs.* Alternative formats are available to persons with disabilities by sending an email to *FCC504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

I. General Information

A. Introduction

1. By the *Auction 111 Procedures Public Notice,* the Office of Economics and Analytics (OEA) and the Media Bureau (MB) establish the procedures to be used for Auction 111, a closed auction of construction permits for new or modified low power television (LPTV) stations and TV translator stations (collectively referred to as LPTV/translator stations). Auction 111 is a closed auction; only those parties listed in Attachment A to the *Auction 111 Procedures Public Notice* are eligible to file applications to participate in Auction 111 and to complete the remaining steps to become qualified to bid.

B. Background and Relevant Authority

2. Auction 111 will resolve groups of pending mutually exclusive (MX) engineering proposals for up to 17 new or modified LPTV/translator station construction permits. The MX groups and engineering proposals listed in Attachment A to the *Auction 111 Procedures Public Notice* consist of applications for new LPTV/translator stations, or major changes to existing stations, that were accepted on a first-come, first-served basis (*i.e.,* rolling one-day windows), pursuant to 47 CFR 74.787(a)(3) and displacement relief applications filed pursuant to a special filing window for eligible LPTV/translator stations displaced by the broadcast television spectrum incentive auction (Auction 1000). Any LPTV/translator station applications for new facilities, major changes to existing facilities, or displacement relief that are mutually exclusive with one another must be resolved via the Commission's part 1 and part 73 competitive bidding rules.

3. In 2009, MB began accepting applications for new rural digital LPTV/translator stations on a limited basis and then later froze those filings. All but one of the MX groups listed in Attachment A to the *Auction 111 Procedures Public Notice* consist of applications for new or modified rural digital LPTV/translator stations that were submitted on the first day that MB began accepting such applications. The remaining MX group listed in Attachment A to the *Auction 111 Procedures Public Notice* consists of two displacement relief applications filed pursuant to a special displacement application filing window opened in

2018 by the Incentive Auction Task Force and MB for eligible licensees and permittees of LPTV/translator stations displaced by Auction 1000.

4. In order to facilitate resolution of pending mutually exclusive LPTV/translator station applications before initiating competitive bidding procedures, and given the passage of time since the applications were filed, MB announced that it would withhold action on certain MX applications for new or modified LPTV/translator stations, including each application listed in Attachment A to the *Auction 111 Procedures Public Notice,* from June 1, 2020 to July 31, 2020, in order to provide applicants with an opportunity to resolve mutual exclusivity through settlement or technical modification of their engineering proposals. MB advised each applicant that, absent resolution of its mutual exclusivity, its application would be subject to the Commission's competitive bidding procedures.

5. On July 9, 2021, OEA and MB released the *Auction 111 Comment Public Notice,* 86 FR 37972, July 19, 2021, seeking comment on competitive bidding procedures to be used in Auction 111 to resolve the applications that remained MX after this settlement period. OEA and MB received no comments in response to the *Auction 111 Comment Public Notice.* In the *Auction 111 Procedures Public Notice,* OEA and MB resolved all open issues raised in the *Auction 111 Comment Public Notice.* Auction 111 will proceed pursuant to the procedures described in the *Auction 111 Procedures Public Notice.*

6. Other Commission rules and decisions provide the underlying authority for the procedures OEA and MB adopted for Auction 111. Among other things, prospective applicants should familiarize themselves with the Commission's general competitive bidding rules, including recent amendments and clarifications thereto, as well as Commission decisions regarding competitive bidding procedures, application requirements, and obligations of Commission licensees. Applicants should also familiarize themselves with the Commission's rules relating to the LPTV and TV translator services, as well as Commission orders concerning competitive bidding for broadcast construction permits. Applicants must also be thoroughly familiar with the procedures, terms and conditions contained in the *Auction 111 Procedures Public Notice* and any future public notices that may be released in this proceeding or that relate to the construction permits being offered in Auction 111 or the LPTV/translator services.

7. The terms contained in the Commission's rules, relevant orders, and public notices are not negotiable. The Commission may amend or supplement the information contained in its public notices at any time and will issue public notices to convey any new or supplemental information to applicants. Pursuant to the Commission's rules, OEA and MB also retain the authority to implement further procedures during the course of this auction. It is the responsibility of all applicants to remain current with all Commission rules and with all public notices pertaining to Auction 111.

C. Construction Permits and Parties Eligible To Participate in Auction 111

8. Attachment A to the *Auction 111 Procedures Public Notice* lists the pending applications for LPTV/translator station construction permits that will be assigned through Auction 111 unless the applicants resolve their mutual exclusivity by entering into settlement agreements or making minor amendments to their pending applications before the deadline for filing an application to participate in the auction (FCC Form 175), referred to as a short-form application. Only the LPTV/translator station applicants listed in Attachment A to the *Auction 111 Procedures Public Notice* are eligible to file a short-form application for Auction 111. An applicant listed in Attachment A to the *Auction 111 Procedures Public Notice* may become qualified to bid in Auction 111 only if it complies with the auction filing, qualification, and payment requirements described in the *Auction 111 Procedures Public Notice,* and otherwise complies with applicable rules, policies, and procedures. Each listed applicant may become a qualified bidder only for those construction permits specified for that applicant in Attachment A to the *Auction 111 Procedures Public Notice.* As noted in the *Auction 111 Comment Public Notice,* each of the engineering proposals within each MX group are directly mutually exclusive with one another; therefore, no more than one construction permit will be awarded through Auction 111 for each MX group identified in Attachment A to the *Auction 111 Procedures Public Notice.*

9. A copy of the *Auction 111 Procedures Public Notice* has been sent by email and overnight delivery to the contact address listed on each LPTV/translator station application listed in Attachment A of the *Auction 111 Procedures Public Notice.* Future public notices in this proceeding may be provided directly to each applicant listed in Attachment A at this contact address as well. Each applicant is obligated to maintain the accuracy of this information pursuant to 47 CFR 1.65. Each party that is eligible to file a short-form application in Auction 111 should make sure that the contact address provided in its LPTV/translator station application is accurate and is a location capable of accepting packages. After the deadline for filing short-form applications (FCC Form 175) to participate in Auction 111, Auction 111-related materials will be sent to auction applicants at the contact addresses in their short-form applications. These addresses should also be locations that are capable of accepting packages that require signatures.

10. Section 73.3572(b) of the Commission's rules prohibits the transfer or assignment of an application for a new LPTV/translator station construction permit. Any change in ownership to an applicant for a new LPTV/translator station construction permit listed in Attachment A to the *Auction 111 Procedures Public Notice* that has resulted in a change in control of the applicant, or a situation where the original party or parties to the application do not retain more than 50 percent ownership interest in the application as originally filed, is considered a major amendment to the application and will result in the application being considered newly filed. If the LPTV/translator station application is considered newly-filed, the applicant will not be eligible to file a short-form application for Auction 111 and its pending application will be dismissed.

11. In accordance with the Commission's rules, the LPTV/translator station applicants listed in Attachment A to the *Auction 111 Procedures Public Notice* may withdraw or make minor amendments to their pending LPTV/translator station applications or enter into legal or engineering settlement agreements until 6:00 p.m. ET on November 9, 2021, the deadline for filing short-form applications in Auction 111. As mentioned in the *Auction 111 Comment Public Notice,* if such actions (1) are submitted prior to the short-form application filing deadline, (2) are fully in accordance with the Communications Act of 1934, as amended (the Act) and the Commission's rules, as determined by Commission staff, and (3) completely resolve the mutual exclusivity, then the subject MX group will be removed from Auction 111 and the remaining engineering proposal(s) will be processed under standard licensing

procedures. Additional details regarding making filings to resolve mutual exclusivity prior to the short-form application filing deadline are provided below.

12. Shortly after the short-form application filing deadline, OEA and MB will release a public notice identifying the remaining mutually exclusive applications that will be resolved through competitive bidding in Auction 111. As provided in 47 CFR 73.5002(d), these mutually exclusive applicants will then be given one final limited opportunity to resolve mutual exclusivity by the filing of technical amendments, dismissal requests, and requests for approval of universal settlements. Due to the prohibited communications rule, which starts at the short-form application filing deadline, applicants in Auction 111 will not be able to communicate with each other for the purpose of resolving conflicts outside of this limited settlement period. As noted in the *Auction 111 Comment Public Notice,* under the Commission's established precedent, once two or more short-form applications are accepted for an MX group, mutual exclusivity exists for the relevant construction permit for auction purposes. Unless the mutual exclusivity is resolved during this limited settlement opportunity, an applicant in Auction 111 cannot obtain a construction permit without placing a bid, even if no other auction applicant for that particular construction permit becomes qualified to bid or in fact places a bid.

II. Applying To Participate in Auction 111

A. Resolving Mutual Exclusivity Prior to the Short-Form Application Filing Deadline

13. The parties listed in Attachment A to the *Auction 111 Procedures Public Notice* may avoid resolving their mutual exclusivity through competitive bidding by instead resolving their mutual exclusivity, prior to the short-form application filing deadline, by means of requests to dismiss the pending LPTV/translator station applications, unilateral engineering amendments to such applications, legal settlement, or engineering settlement. Any unilateral amendments or amendments pursuant to a settlement agreement made to the pending LPTV/translator station applications must be minor, as defined by the applicable rules, and must not create new mutual exclusivities or application conflicts. Any legal or engineering settlement agreements must be filed with the Commission for approval and must include the documentation required by 47 CFR 73.3525. All amendments to pending applications and any requests for approval of settlement agreements, as well as accompanying documentation, must be submitted by filing an amended FCC Form 2100—Schedule C in the Media Bureau's Licensing and Management System (LMS) by 6:00 p.m. ET on November 9, 2021. OEA and MB encourage the parties listed in Attachment A to the *Auction 111 Procedures Public Notice* that are interested in resolving their mutual exclusivity to initiate and complete negotiations, and make any necessary filings, well ahead of the short-form application filing deadline. Applicants, however, should avoid both entering into a settlement agreement for a construction permit prior to the short-form application deadline and filing a short-form application covering that same construction permit. Such a situation could raise issues with regard to the applicant's compliance with the prohibited communications rule.

14. As mentioned above, if a unilateral engineering amendment or legal or engineering settlement (1) is submitted for approval in accordance with the procedures described above by 6:00 p.m. ET on November 9, 2021, (2) is fully in accordance with the Act and the Commission's rules, as determined by Commission staff, and (3) completely resolves the mutual exclusivity, then the subject MX group will be removed from Auction 111 and the remaining engineering proposal(s) will be processed under standard licensing procedures. If no such filing is made, and therefore the engineering proposals in an MX group remain mutually exclusive as of the short-form application filing deadline, then each applicant in that MX group must timely file a short-form application in order to avoid dismissal of its pending LPTV/translator station application. Specifically, MB will dismiss the mutually exclusive long-form application of any party eligible to participate in Auction 111 that fails to submit a short-form application. Accordingly, if only one member of an MX group submits a short-form application, and thus all other long-form applications in that MX group are dismissed, that short-form application is not mutually exclusive for auction purposes and the relevant construction permit will not be included in Auction 111. In that case, the engineering proposal of the party that submitted a short-form application will be treated as a singleton and processed under standard licensing procedures. OEA and MB note that, if an applicant forgoes filing a short-form application pursuant to an agreement with mutually exclusive applicants, such settlement agreement must be submitted to MB for approval. If a party to a settlement agreement files a short-form application, that settlement agreement may need to be disclosed in its short-form application pursuant to 47 CFR 1.2105(a)(2)(viii) or may be a prohibited joint bidding agreement pursuant to 47 CFR 1.2105(a)(2)(ix).

B. General Information Regarding Short-Form Applications

15. A short-form application, or FCC Form 175, provides information that the Commission uses to determine whether the applicant has the legal, technical, and financial qualifications to participate in a Commission auction for licenses or permits. The short-form application is the first part of the Commission's two-phased auction application process. In the first phase, a party seeking to participate in Auction 111 must file a short-form application in which it certifies, under penalty of perjury, that it is qualified to participate. Eligibility to participate in Auction 111 is determined based on an applicant's short-form application and certifications and on the applicant's upfront payment. After bidding closes, in the second phase of the process, each winning bidder in Auction 111 must file an amendment to its pending long-form application listed in Attachment A to the *Auction 111 Procedures Public Notice* for each permit it wins in the auction.

16. A party seeking to participate in Auction 111 must file an FCC Form 175 electronically via the Auction Application System prior to 6:00 p.m. ET on November 9, 2021, following the procedures prescribed in the FCC Form 175 Instructions. If an applicant claims eligibility for a bidding credit, then the information provided in its FCC Form 175 will be used to determine whether the applicant is eligible for the claimed bidding credit. The *Auction 111 Procedures Public Notice* describes more fully the information disclosures and certifications required in the short-form application. An applicant that files an FCC Form 175 for Auction 111 will be subject to the Commission's rule prohibiting certain communications. An applicant is subject to the prohibition beginning at the deadline for filing short-form applications—6:00 p.m. ET on November 9, 2021.

17. An Auction 111 applicant bears full responsibility for submitting an accurate, complete, and timely short-

form application. Pursuant to the Commission's competitive bidding rules, you must make a series of certifications under penalty of perjury on your FCC Form 175 related to the information provided in your application and your participation in the auction, and you must confirm that you are legally, technically, financially, and otherwise qualified to hold a license. If you fail to make the required certifications in your FCC Form 175 by the filing deadline, then your application will be deemed unacceptable for filing and cannot be corrected after the filing deadline.

18. Submitting an FCC Form 175 (and any amendments thereto) constitutes a representation by the certifying official that you are an authorized representative of the applicant with authority to bind the applicant, that you have read the form's instructions and certifications, and that the contents of the application, its certifications, and any attachments are true and correct. Submitting a false certification to the Commission may result in penalties, including monetary forfeitures, license forfeitures, ineligibility to participate in future auctions, and/or criminal prosecution.

19. Applicants are cautioned that requests for confidential treatment of required information submitted in FCC Form 175 will not be routinely granted because this information bears on each applicant's qualifications. The Commission generally has held that it may publicly release confidential business information where the party has put that information at issue in a Commission proceeding or where the Commission has identified a compelling public interest in disclosing the information. In this regard, the Commission specifically has held that information submitted in support of receiving bidding credits in auction proceedings should be made available to the public.

20. No individual or entity may file more than one short-form application or have a controlling interest in more than one short-form application. If a party submits multiple short-form applications for an auction, then only one application may form the basis for that party to become qualified to bid in that auction.

21. Similarly, and consistent with the Commission's general prohibition on joint bidding agreements, a party generally is permitted to participate in a Commission auction only through a single bidding entity. Accordingly, the filing of applications in Auction 111 by multiple entities controlled by the same individual or set of individuals generally will not be permitted. This restriction applies across all applications, without regard to the construction permits selected. As noted by the Commission in adopting the prohibition on applications by commonly controlled entities, this rule, in conjunction with the prohibition against joint bidding agreements, protects the competitiveness of the Commission's auctions.

22. Additional details regarding certain information required to be submitted in the FCC Form 175 are provided in the *Auction 111 Procedures Public Notice.* You should also consult the Commission's rules to ensure that all required information is included in your short-form application. To the extent the information in the *Auction 111 Procedures Public Notice* does not address your specific operating structure, or if you need additional information or guidance concerning the described disclosure requirements, you should review the educational materials for Auction 111 (see the Education section of the Auction 111 website at *www.fcc.gov/auction/111*) and use the contact information provided in the *Auction 111 Procedures Public Notice* to consult with Commission staff to better understand the information you must submit in your short-form application.

C. Authorized Bidders

23. An applicant must designate at least one authorized bidder, and no more than three, in its FCC Form 175. The Commission's rules prohibit an individual from serving as an authorized bidder for more than one auction applicant or being listed as an authorized bidder in more than one FCC Form 175 application.

D. Permit Selection

24. Only those parties listed in Attachment A to the *Auction 111 Procedures Public Notice* are eligible to submit short-form applications and only with regard to the construction permit(s) covered by the party's pending, long-form application(s) listed in Attachment A to the *Auction 111 Procedures Public Notice.* For each eligible party, the Auction Application System will only display on your FCC Form 175 the construction permits for which you are eligible to apply to bid. You must, however, affirmatively select on your FCC Form 175 the construction permit(s) on which you want to bid. You should carefully review and verify your construction permit selections before the deadline for submitting your FCC Form 175, because permit selections cannot be changed after the initial auction application filing deadline. The FCC auction bidding system will not accept bids on construction permits that were not selected on the bidder's FCC Form 175.

E. Disclosure of Agreements and Bidding Arrangements

25. An applicant must provide in its FCC Form 175 a brief description of, and identify each party to, any partnerships, joint ventures, consortia or agreements, arrangements, or understandings of any kind relating to the LPTV/TV translator station construction permits being auctioned, including any agreements that address or communicate directly or indirectly bids (including specific prices), bidding strategies (including the specific licenses on which to bid or not to bid), or the post-auction market structure, to which the applicant, or any party that controls or is controlled by the applicant, is a party. In most circumstances, if a party filing a short-form application has entered into a settlement agreement regarding a construction permit listed in Attachment A to the *Auction 111 Procedures Public Notice,* regardless of whether the party has selected that construction permit on its short-form application or not, that settlement agreement should be identified and briefly described in its FCC Form 175. In connection with the agreement disclosure requirement, the applicant must certify under penalty of perjury in its FCC Form 175 that it has described, and identified each party to, any such agreements, arrangements, or understandings to which it (or any party that controls it or that it controls) is a party. If, after the FCC Form 175 filing deadline, an auction applicant enters into any agreement relating to the licenses being auctioned, then it is subject to these same disclosure obligations. Each applicant must maintain the accuracy and completeness of the information in its pending auction application.

26. For purposes of making the required agreement disclosures on the FCC Form 175, if parties agree in principle on all material terms prior to the application filing deadline, then each party to the agreement that is submitting an auction application must provide a brief description of, and identify the other party or parties to, the agreement on its respective FCC Form 175, even if the agreement has not been reduced to writing. Parties that have not agreed in principle by the FCC Form 175 filing deadline should not describe, or include the names of parties to, the discussions on their applications.

27. The Commission's rules generally prohibit joint bidding and other arrangements involving auction applicants (including any party that controls or is controlled by such applicants). For purposes of the prohibition, a joint bidding arrangement includes any arrangement relating to the construction permits being auctioned that addresses or communicates, directly or indirectly, bidding at the auction, bidding strategies, including arrangements regarding price or the specific construction permits on which to bid, and any such arrangement relating to the post-auction market structure. The general prohibition on joint bidding arrangements excludes certain agreements, including those that are solely operational in nature, as defined in 47 CFR 1.2105(a)(2)(ix)(A)–(C).

28. To implement the prohibition on joint bidding arrangements, the Commission's rules require each applicant to certify in its short-form application that it has disclosed any arrangements or understandings of any kind relating to the licenses being auctioned to which it (or any party that controls or is controlled by it) is a party. The applicant must also certify that it (or any party that controls or is controlled by it) has not entered and will not enter into any arrangement or understanding of any kind relating directly or indirectly to bidding at auction with, among others, any other applicant.

29. Although the Commission's rules do not prohibit auction applicants from communicating about matters that are within the scope of an excepted agreement that has been disclosed in an FCC Form 175, the Commission reminds applicants that certain discussions or exchanges could nonetheless touch upon impermissible subject matters, and that compliance with the Commission's rules will not insulate a party from enforcement of the antitrust laws.

30. Applicants should bear in mind that a winning bidder will be required to disclose in its post-auction amendment to its pending long-form application the specific terms, conditions, and parties involved in any agreement relating to the licenses being auctioned into which it had entered prior to the time bidding was completed. This applies to any settlement agreement, joint venture, partnership, or other agreement, arrangement, or understanding of any kind entered into relating to the competitive bidding process, including any agreements relating to the permits being auctioned that address or communicate directly or indirectly bids (including specific prices), bidding strategies (including the specific permits on which to bid or not to bid), or the post-auction market structure, to which the applicant, or any party that controls or is controlled by the applicant, is a party.

F. Ownership Disclosure Requirements

31. Each applicant must comply with the ownership disclosure requirements and provide information required by 47 CFR 1.2105 and 1.2112. Specifically, in completing FCC Form 175, an applicant must fully disclose information regarding the real party or parties-in-interest in the applicant or application and the ownership structure of the applicant, including both direct and indirect ownership interests of 10% or more, as prescribed in 47 CFR 1.2105 and 1.2112. These interest holders may differ from the types of attributable interest holders that are required to be reported by broadcast applicants under part 73 of the Commission's rules in conjunction with licensing and assignment and transfer of facilities or reporting of ownership information, such as insulated interest holders and holders of non-voting stock/equity in the applicant. Each applicant is responsible for ensuring that information submitted in its short-form application is complete and accurate.

32. In certain circumstances, an applicant may have previously filed an FCC Form 602 ownership disclosure information report or filed an auction application for a previous auction in which ownership information was disclosed. The most current ownership information contained in any FCC Form 602 or previous auction application on file with the Commission that used the same FCC Registration Number (FRN) the applicant is using to submit its FCC Form 175 will automatically be pre-filled into certain ownership sections on the applicant's FCC Form 175, if such information is in an electronic format compatible with FCC Form 175. Each applicant must carefully review any ownership information automatically entered into its FCC Form 175, including any ownership attachments, to confirm that all information supplied on FCC Form 175 is complete and accurate as of the application filing deadline. Any information that needs to be corrected or updated must be changed directly in FCC Form 175.

G. Foreign Ownership Disclosure Requirements

33. Section 310 of the Act requires the Commission to review foreign investment in radio station licenses and imposes specific restrictions on who may hold certain types of radio licenses. In completing FCC Form 175, an applicant is required to disclose information concerning foreign ownership of the applicant. If an applicant has foreign ownership interests in excess of the applicable limit or benchmark set forth in 47 U.S.C. 310(b), then it may seek to participate in Auction 111 only if it has filed a petition for declaratory ruling with the Media Bureau prior to the FCC Form 175 filing deadline. An applicant must certify in its FCC Form 175 that, as of the deadline for filing its application to participate in the auction, the applicant either is in compliance with the foreign ownership provisions of 47 U.S.C. 310 or has filed a petition for declaratory ruling requesting Commission approval to exceed the applicable foreign ownership limit or benchmark in 47 U.S.C. 310(b) that is pending before, or has been granted by, the Commission.

H. Prohibited Communications and Compliance With Antitrust Laws

34. The rules prohibiting certain communications set forth in 47 CFR 1.2105(c) and 73.5002(d) and (e) apply to each applicant that files an FCC Form 175 in Auction 111. Section 1.2105(c)(1) of the Commission's rules provides that, subject to specified exceptions, after the deadline for filing a short-form application, all applicants are prohibited from cooperating or collaborating with respect to, communicating with or disclosing, to each other in any manner the substance of their own, or each other's, or any other applicant's bids or bidding strategies (including post-auction market structure), or discussing or negotiating settlement agreements, until after the down payment deadline.

1. Entities Subject to § 1.2105(c)

35. An applicant for purposes of this rule includes the officers and directors of the applicant, all controlling interests in the entity submitting the FCC Form 175, as well as all holders of interests amounting to 10% or more of that entity. A party that submits an application becomes an applicant under the rule at the short-form application filing deadline, and that status does not change based on later developments, including failure to become a qualified bidder.

2. Prohibition Applies Until Down Payment Deadline

36. The prohibition in 47 CFR 1.2105(c) on certain communications begins at an auction's short-form application filing deadline and ends at the auction's down payment deadline

after the auction closes, which will be announced in a future public notice.

37. After the short-form application filing deadline, OEA and MB will announce a limited settlement period of no more than two weeks during which this prohibition may be partially suspended for the purpose of resolving mutual exclusivity through settlements. Outside of this limited settlement period, and until this limited settlement period is announced, the prohibition on certain communications remains in effect.

3. Scope of Prohibition on Certain Communications; Prohibition on Joint Bidding Agreements

38. Section 1.2105(c) of the Commission's rules prohibits certain communications between auction applicants, regardless of whether the applicants seek permits in the same geographic area or market. The rule also prohibits any joint bidding arrangement, including arrangements relating to the permits being auctioned that address or communicate, directly or indirectly, bidding at the auction, bidding strategies, including arrangements regarding price or the specific permits on which to bid, and any such arrangements relating to the post-auction market structure. The rule allows for limited exceptions for communications within the scope of any arrangement consistent with the exclusion from the Commission's rule prohibiting joint bidding, provided such arrangement is disclosed on the applicant's auction application. An applicant may communicate pursuant to any pre-existing agreements, arrangements, or understandings relating to the licenses being auctioned that are solely operational or that provide for the transfer or assignment of licenses, provided that such agreements, arrangements, or understandings are disclosed on its application and do not both relate to the permits at auction and address or communicate bids (including amounts), bidding strategies, or the particular permits or licenses on which to bid or the post-auction market structure.

39. In addition to express statements of bids and bidding strategies, the prohibition against communicating in any manner includes public disclosures as well as private communications and indirect or implicit communications. Consequently, an applicant must take care to determine whether its auction-related communications may reach another applicant.

40. Parties subject to 47 CFR 1.2105(c) should take special care in circumstances where their officers, directors, and employees may receive information directly or indirectly relating to any applicant's bids or bidding strategies. Such information may be deemed to have been received by the applicant under certain circumstances. For example, Commission staff have determined that, where an individual serves as an officer or director for two or more applicants, the bids and bidding strategies of one applicant are presumed to be conveyed to the other applicant through the shared officer or director, which creates an apparent violation of the rule.

41. Subject to the limited exceptions described above, 47 CFR 1.2105(c)(1) prohibits applicants from discussing or negotiating settlement agreements and from communicating with specified other parties only with respect to their own, or each other's, or any other applicant's bids or bidding strategies. Moreover, a communication conveying bids or bidding strategies (including post-auction market structure) must also relate to the licenses being auctioned in order to be covered by the prohibition. Thus, the prohibition is limited in scope and does not apply to all communications between or among the specified parties. The Commission consistently has made clear that application of the rule prohibiting communications has never required total suspension of essential ongoing business. Entities subject to the prohibition may negotiate agreements, other than settlement agreements, during the prohibition period, provided that the communications involved do not relate to both: (1) The licenses or permits being auctioned and (2) bids or bidding strategies or post-auction market structure.

42. Accordingly, business discussions and negotiations that are unrelated to settlement agreements for the construction permits in Auction 111 or bidding in Auction 111 and that do not convey information about the bids or bidding strategies of an applicant, including the post-auction market structure, are not prohibited by the rule. Moreover, not all auction-related information is covered by the prohibition. For example, communicating merely whether a party has or has not applied to participate in Auction 111 will not violate the rule. In contrast, communicating, among other things, how a party will participate, including whether or not a party plans to submit an upfront payment and the upfront payment amount, specific bid amounts, and/or whether or not the party is placing bids, would convey bids or bidding strategies and would be prohibited.

43. While 47 CFR 1.2105(c) does not prohibit business discussions and negotiations among auction applicants that are unrelated to the auction, each applicant must remain vigilant not to communicate, directly or indirectly, information that affects, or could affect, bids or bidding strategies. Certain discussions might touch upon subject matters that could convey price or geographic information related to bidding strategies. Such subject areas include, but are not limited to, management, sales, local marketing agreements, and other transactional agreements.

44. OEA and MB caution applicants that bids or bidding strategies may be communicated outside of situations that involve one party subject to the prohibition communicating privately and directly with another such party. For example, the Commission has warned that prohibited communications concerning bids and bidding strategies may include communications regarding capital calls or requests for additional funds in support of bids or bidding strategies to the extent such communications convey information concerning the bids and bidding strategies directly or indirectly. Moreover, the Commission found a violation of the rule against prohibited communications when an applicant used the Commission's bidding system to disclose its bidding strategy in a manner that explicitly invited other auction participants to cooperate and collaborate in specific markets, and it has placed auction participants on notice that the use of its bidding system to disclose market information to competitors will not be tolerated and will subject bidders to sanctions.

45. Likewise, when completing a short-form application, each applicant should avoid any statements or disclosures that may violate 47 CFR 1.2105(c). Applicants also should be mindful that communicating non-public application or bidding information publicly or privately to another applicant may violate 47 CFR 1.2105(c) even though that information subsequently may be made public during later periods of the application or bidding processes.

4. Communicating With Third Parties

46. Section 1.2105(c) does not prohibit an applicant from communicating bids or bidding strategies to a third party, such as a consultant or consulting firm, counsel, or lender. The applicant should take appropriate steps, however, to ensure that any third party it employs for advice pertaining to its bids or bidding

strategies does not become a conduit for prohibited communications to other specified parties, as that would violate the rule. For example, an applicant might require a third party, such as a lender, to sign a non-disclosure agreement before the applicant communicates any information regarding bids or bidding strategy to the third party. Within third-party firms, separate individual employees, such as attorneys or auction consultants, may advise individual applicants on bids or bidding strategies, as long as such firms implement firewalls and other compliance procedures that prevent such individuals from communicating the bids or bidding strategies of one applicant to other individuals representing separate applicants. Although firewalls and/or other procedures should be used, their existence is not an absolute defense to liability if a violation of the rule has occurred.

47. As the Commission has noted in other broadcast auctions, in the case of an individual, the objective precautionary measure of a firewall is not available. As a result, an individual that is privy to bids or bidding information of more than one applicant presents a greater risk of becoming a conduit for a prohibited communication. Whether a prohibited communication has taken place in a given case will depend on all the facts pertaining to the case, including who possessed what information, what information was conveyed to whom, and the course of bidding in the auction.

48. Applicants may discuss the short-form application or bids for specific permits with the counsel, consultant, or expert of their choice before the short-form application deadline. Furthermore, the same third-party individual could continue to give advice to multiple applicants regarding their applications after the short-form application deadline, provided that no information pertaining to bids or bidding strategies is conveyed to that individual from any of the applicants the individual advises. No person may serve as an authorized bidder for more than one applicant in Auction 111.

49. Applicants also should use caution in their dealings with other parties, such as members of the press, financial analysts, or others who might become conduits for the communication of prohibited bidding information. For example, even though communicating that it has applied to participate in this auction will not violate the rule, an applicant's statement to the press that it intends to stop bidding in an auction could give rise to a finding of a violation of 47 CFR 1.2105. Similarly, an FCC Form 175 applicant's public statement of intent not to place bids during bidding in Auction 111 could also violate the rule.

5. Section 1.2105(c) Certifications

50. By electronically submitting its FCC Form 175, each applicant in Auction 111 certifies its compliance with 47 CFR 1.2105(c) and 73.5002(d). The mere filing of a certifying statement as part of an application, however, will not outweigh specific evidence that a prohibited communication has occurred, nor will it preclude the initiation of an investigation when warranted. Any applicant found to have violated these communication prohibitions may be subject to sanctions.

6. Duty To Report Prohibited Communications

51. Section 1.2105(c)(4) requires that any applicant that makes or receives a communication that appears to violate 47 CFR 1.2105(c) must report such communication in writing to the Commission immediately, and in no case later than five business days after the communication occurs. Each applicant's obligation to report any such communication continues beyond the five-day period after the communication is made, even if the report is not made within the five-day period.

7. Procedures for Reporting Prohibited Communications

52. A party reporting any information or communication pursuant to 47 CFR 1.65, 1.2105(a)(2), or 1.2105(c)(4) must take care to ensure that any report of a prohibited communication does not itself give rise to a violation of 47 CFR 1.2105(c). For example, reporting a prohibited communication through ECFS or another Commission filing system that allows public access to filed materials could violate the rule by communicating prohibited information to other parties covered by the rule.

53. An applicant must file only a single report concerning a prohibited communication and must file that report with the Commission personnel expressly charged with administering the Commission's auctions. This rule is designed to minimize the risk of inadvertent dissemination of information in such reports. Any reports required by 47 CFR 1.2105(c) must be filed consistent with the instructions set forth in the *Auction 111 Procedures Public Notice.* For Auction 111, such reports must be filed with the Chief of the Auctions Division, OEA, by the most expeditious means available. Any such report should be submitted by email to the Auctions Division Chief at the following email address: *auction111@fcc.gov.* If you choose instead to submit a report in hard copy, contact Auctions Division staff at *auction111@fcc.gov* or (202) 418–0660 for guidance.

54. Given the potential competitive sensitivity of information in such a report, a party seeking to report a prohibited communication should consider submitting its report with a request that the report or portions of the submission be withheld from public inspection by following the procedures specified in 47 CFR 0.459. Such parties should coordinate with the Auctions Division staff about the procedures for submitting reports of prohibited communications.

8. Winning Bidders Must Disclose Terms of Agreements

55. Each applicant that is a winning bidder will be required to provide, as part of its amendment to its long-form application, any agreement or arrangement relating to the competitive bidding process that it has entered into and a summary of the specific terms, conditions, and parties involved in that agreement. Such agreements must have been entered into prior to the filing deadline for short-form applications. This disclosure requirement applies to any settlement agreement, bidding consortia, joint venture, partnership, or agreement, understanding, or other arrangement entered into relating to the competitive bidding process, including any agreement relating to the post-auction market structure. Failure to comply with the Commission's rules can result in enforcement action.

9. Antitrust Laws

56. Regardless of compliance with the Commission's rules, applicants remain subject to the antitrust laws, which are designed to prevent anticompetitive behavior in the marketplace. Compliance with the disclosure requirements of 47 CFR 1.2105(c)(4) will not insulate a party from enforcement of the antitrust laws. For instance, a violation of the antitrust laws could arise out of actions taking place well before any party submits a short-form application. The Commission has cited a number of examples of potentially anticompetitive actions that would be prohibited under antitrust laws: For example, actual or potential competitors may not agree to divide territories in order to minimize competition, regardless of whether they split a market in which they both do business, or whether they merely reserve one market for one and another market for the other.

57. To the extent the Commission becomes aware of specific allegations that suggest that violations of the federal antitrust laws may have occurred, the Commission may refer such allegations to the United States Department of Justice for investigation. If an applicant is found to have violated the antitrust laws or the Commission's rules in connection with its participation in the competitive bidding process, then it may be subject to a forfeiture and may be prohibited from participating further in Auction 111 and in future auctions, among other sanctions.

I. New Entrant Bidding Credit

58. To promote the objectives of 47 U.S.C. 309(j) and further its long-standing commitment to the diversification of broadcast facility ownership, the Commission provides a tiered new entrant bidding credit for broadcast auction applicants with no, or very few, other media interests.

59. Applicants that qualify for the new entrant bidding credit are eligible for a bidding credit in this auction that represents the amount by which a bidder's winning bid is discounted. Eligibility for the new entrant bidding credit must be specified in an applicant's short-form application, which establishes that applicant's maximum bidding credit eligibility for Auction 111. The size of a new entrant bidding credit depends on the number of ownership interests in other media of mass communications that are attributable to the bidder-entity and its attributable interest-holders. A 35% bidding credit will be given to a winning bidder if it, and/or any individual or entity with an attributable interest in the winning bidder, has no attributable interest in any other media of mass communications, as defined in 47 CFR 73.5008. A 25% bidding credit will be given to a winning bidder if it, and/or any individual or entity with an attributable interest in the winning bidder, has an attributable interest in no more than three mass media facilities, as defined in 47 CFR 73.5008. No bidding credit will be given if any of the commonly owned mass media facilities serve the same area as the broadcast permit proposed in the auction, as defined in 47 CFR 73.5007(b), or if the winning bidder, and/or any individual or entity with an attributable interest in the winning bidder, has attributable interests in more than three mass media facilities.

60. Bidding credits are not cumulative; qualifying applicants receive either the 25% or the 35% bidding credit, but not both.

61. The interests of the applicant, and of any individuals or entities with an attributable interest in the applicant, in other media of mass communications are considered when determining an applicant's eligibility for the new entrant bidding credit. Attributable interests are defined in 47 CFR 73.3555 and note 2 of that section. In Auction 111, the bidder's attributable interests, and thus, its maximum new entrant bidding credit eligibility, are determined as of the short-form application filing deadline. An applicant intending to divest a media interest or make any other ownership change, such as resignation of positional interests (officer or director) in order to avoid attribution for purposes of qualifying for the new entrant bidding credit, must have consummated such divestment transactions, or have completed such ownership changes, by no later than the FCC Form 175 filing deadline. However events occurring after the short-form application filing deadline, such as the acquisition of attributable interests in media of mass communications, may cause diminishment or loss of the bidding credit and, must be reported immediately.

62. Under broadcast attribution rules, those entities or individuals with an attributable interest in a bidder include: (1) All officers and directors of a corporate bidder; (2) any owner of 5% or more of the voting stock of a corporate bidder; (3) all general partners and limited partners of a partnership bidder, unless the limited partners are sufficiently insulated; and (4) all members of a limited liability company, unless sufficiently insulated.

63. In cases where an applicant's spouse or close family member holds other media interests, such interests are not automatically attributable to the bidder. The Commission decides attribution issues in this context based on certain factors traditionally considered relevant.

64. The eligibility standards for the new entrant bidding credit include attribution of the media interests held by very substantial investors in, or creditors of, an applicant claiming new entrant status. Specifically, the attributable mass media interests held by an individual or entity with an equity and/or debt interest in an applicant shall be attributed to that bidder for purposes of determining its eligibility for the new entrant bidding credit, if the equity and debt interests, in the aggregate, exceed 33% of the total asset value of the applicant, even if such an interest is non-voting.

65. The equity/debt plus (EDP) attribution standard was relaxed to allow for higher investment opportunities in entities meeting the definition of eligible entities, as defined in Note 2(i) of 47 CFR 73.3555. The Commission will allow the holder of an equity or debt interest in the applicant to exceed the above-noted 33% threshold without triggering attribution provided (1) the combined equity and debt in the ''eligible entity'' is less than 50%; or (2) the total debt in the ''eligible entity'' does not exceed 80% of the asset value, and the interest holder does not hold any equity interest, option, or promise to acquire an equity interest in the ''eligible entity'' or any related entity.

66. Generally, media interests will be attributable for purposes of the new entrant bidding credit to the same extent that such other media interests are considered attributable for purposes of the broadcast multiple ownership rules. Attributable interests held by a winning bidder in existing low power television, television translator or FM translator facilities, however, will not be counted among the applicant's other mass media interests in determining its eligibility for a new entrant bidding credit. A medium of mass communications is defined in 47 CFR 73.5008(b). Full service noncommercial educational stations, on both reserved and non-reserved channels, are included among ''media of mass communications'' as defined in 47 CFR 73.5008(b).

1. Application Requirements

67. In addition to the ownership information required pursuant to 47 CFR 1.2105 and 1.2112, applicants seeking a new entrant bidding credit are required to establish on their short-form applications that they satisfy the eligibility requirements to qualify for the bidding credit. In those cases, a certification under penalty of perjury must be provided in completing the short-form application. An applicant claiming that it qualifies for a 35% new entrant bidding credit must certify that neither it nor any of its attributable interest holders has any attributable interests in any other media of mass communications. An applicant claiming that it qualifies for a 25% new entrant bidding credit must certify that neither it nor any of its attributable interest holders has any attributable interests in more than three media of mass communications, and must identify and describe such media of mass communications.

2. Unjust Enrichment

68. Applicants should note that unjust enrichment provisions apply to a winning bidder that utilizes a bidding credit and subsequently seeks to assign or transfer control of its license or construction permit to an entity not qualifying for the same level of bidding credit.

J. Provisions Regarding Former and Current Defaulters

69. Pursuant to the rules governing competitive bidding, each applicant must make certifications regarding whether it is a current or former defaulter or delinquent. A current defaulter or delinquent is not eligible to participate in Auction 111, but a former defaulter or delinquent may participate so long as it is otherwise qualified and makes an upfront payment that is 50% more than would otherwise be necessary. Accordingly, each applicant must certify under penalty of perjury on its FCC Form 175 that it, its affiliates, its controlling interests, and the affiliates of its controlling interests are not in default on any payment for a Commission construction permit or license (including down payments) and that it is not delinquent on any non-tax debt owed to any Federal agency. Additionally, an applicant must certify under penalty of perjury whether it (along with its controlling interests) has ever been in default on any payment for a Commission construction permit or license (including down payments) or has ever been delinquent on any non-tax debt owed to any Federal agency, subject to the exclusions described below. For purposes of making these certifications, the term ''controlling interest'' is defined in 47 CFR 1.2105(a)(4)(i).

70. Under the Commission's rule regarding applications by former defaulters, an applicant is considered a ''former defaulter'' or a ''former delinquent'' when, as of the FCC Form 175 deadline, the applicant or any of its controlling interests has defaulted on any Commission construction permit or license or has been delinquent on any non-tax debt owed to any Federal agency, but has since remedied all such defaults and cured all of the outstanding non-tax delinquencies. For purposes of the certification under 47 CFR 1.2105(a)(2)(xii), the applicant may exclude from consideration any cured default on a Commission construction permit or license or cured delinquency on a non-tax debt owed to a Federal agency for which any of the following criteria are met: (1) The notice of the final payment deadline or delinquency was received more than seven years before the FCC Form 175 filing deadline, (2) the default or delinquency amounted to less than $100,000, (3) the default or delinquency was paid within two quarters (*i.e.,* six months) after receiving the notice of the final payment deadline or delinquency, or (4) the default or delinquency was the subject of a legal or arbitration proceeding and was cured upon resolution of the proceeding. With respect to the first exclusion, notice to a debtor may include notice of a final payment deadline or notice of delinquency and may be express or implied depending on the origin of any Federal non-tax debt giving rise to a default or delinquency. Additionally, for the third exclusion, the date of receipt of the notice of a final default deadline or delinquency by the intended party or debtor will be used for purposes of verifying receipt of notice.

71. In addition to the *Auction 111 Procedures Public Notice,* applicants should review previous guidance on default and delinquency disclosure requirements in the context of the auction short-form application process. Applicants may consult with Auctions Division staff if they have any questions about default and delinquency disclosure requirements.

72. The Commission considers outstanding debts owed to the United States Government, in any amount, to be a serious matter. The Commission adopted rules, including a provision referred to as the red light rule, that implement its obligations under the Debt Collection Improvement Act of 1996, which governs the collection of debts owed to the United States. Under the red light rule, applications and other requests for benefits filed by parties that have outstanding debts owed to the Commission will not be processed. When adopting that rule, the Commission explicitly declared, however, that its competitive bidding rules are not affected by the red-light rule. As a consequence, the Commission's adoption of the red light rule does not alter the applicability of any of its competitive bidding rules, including the provisions and certifications of 47 CFR 1.2105 and 1.2106, with regard to current and former defaults or delinquencies.

73. The Commission's Red Light Display System, which provides information regarding debts currently owed to the Commission, may not be determinative of an auction applicant's ability to comply with the default and delinquency disclosure requirements of 47 CFR 1.2105. Thus, while the red light rule ultimately may prevent the processing of amendments to long-form applications by auction winners, an auction applicant's lack of current red light status is not necessarily determinative of its eligibility to participate in an auction (or whether it may be subject to an increased upfront payment obligation). Moreover, any long-form applications amended after the close of bidding will be reviewed for compliance with the Commission's red light rule, and such review may result in the dismissal of a winning bidder's long-form application. Each applicant should carefully review all records and other available Federal agency databases and information sources to determine whether the applicant, or any of its affiliates, or any of its controlling interests, or any of the affiliates of its controlling interests, currently owes or was ever delinquent in the payment of non-tax debt owed to any Federal agency.

K. Optional Applicant Status Identification

74. An applicant owned by members of minority groups and/or women, as defined in 47 CFR 1.2110(c)(3), or that is a rural telephone company, as defined in 47 CFR 1.2110(c)(4), may identify itself as such in filling out its FCC Form 175. This applicant status information is collected for statistical purposes only and assists the Commission in monitoring the participation of various groups in its auctions.

L. Noncommercial Educational Status Election

75. 47 U.S.C. 309(j)(2)(C) exempts from competitive bidding applications for construction permits for noncommercial educational (NCE) broadcast. For purposes of Auction 111, this exemption applies to a construction permit application for a new or modified LPTV/translator station that will be owned and operated by a municipality and will transmit only noncommercial programs for educational purposes. Applications for such NCE stations are exempt from competitive bidding in Auction 111. Accordingly, in the FCC Form 175, applicants will have an opportunity to designate their status as an exempt NCE station application under the definition specified in 47 U.S.C. 397(6)(B).

76. Applications for exempt NCE stations on non-reserved spectrum, filed during an auction filing window, will be returned as unacceptable for filing if mutually exclusive with any application for a commercial station. If an FCC Form 175 identifies the application's proposed station as an exempt noncommercial educational and that

application remains mutually exclusive with any short-form application for a commercial station after the limited settlement period, the NCE application will be returned as unacceptable for filing and the applicant will not be provided with any further opportunity to become eligible to bid in this auction. For this reason, each prospective applicant in this auction should consider carefully whether it wishes to propose operation as an exempt noncommercial educational station under 47 U.S.C. 397(6)(B) for any LPTV/translator station acquired in this auction. This exempt NCE election cannot be reversed after the initial short-form application filing deadline. Short-form applications that do not identify the facilities proposed in the FCC Form 175 as NCE will be considered, as a matter of law, applications for commercial broadcast stations.

M. Modifications to FCC Form 175

1. Only Minor Modifications Allowed

77. After the initial short-form application filing deadline, an Auction 111 applicant will be permitted to make only minor changes to its FCC Form 175. Examples of minor changes include the deletion or addition of authorized bidders (to a maximum of three) and the revision of addresses and telephone numbers of the applicant, its responsible party, and its contact person. Major modification to an FCC Form 175 (*e.g.,* change of construction permit selection, certain changes in ownership that would constitute an assignment or transfer of control of the applicant, change in the required certifications, change in applicant's legal classification that results in a change in control, or change in claimed eligibility for a higher percentage of bidding credit) will not be permitted after the FCC Form 175 filing deadline. If an amendment reporting changes is a major amendment, as described in 47 CFR 1.2105(b)(2), the major amendment will not be accepted and may result in the dismissal of the application. Questions about FCC Form 175 amendments should be directed to the Auctions Division at (202) 418–0660.

2. Duty To Maintain Accuracy and Completeness of FCC Form 175

78. Pursuant to 47 CFR 1.65, each applicant has a continuing obligation to maintain the accuracy and completeness of information furnished in a pending application, including a pending application to participate in Auction 111 or a pending LPTV/TV translator station application. Consistent with the requirements for spectrum auctions, an applicant for Auction 111 must furnish additional or corrected information to the Commission within five business days after a significant occurrence, or amend its FCC Form 175, no more than five business days after the applicant becomes aware of the need for the amendment. In accordance with the Commission's rules, an applicant's obligation to make modifications to a pending auction application in order to provide additional or corrected information continues beyond the five-day period, even if the report is not made within the five-day period. An applicant is obligated to amend its pending application even if a reported change may result in the dismissal of the application because it is subsequently determined to be a major modification.

79. Additional information on the procedures for modifying an FCC Form 175 appear in the *Auction 111 Procedures Public Notice.* As with filing the FCC Form 175, any amendment(s) to the application and related statements of fact must be certified by an authorized representative of the applicant with authority to bind the applicant. Submission of any such amendment or related statement of fact constitutes a representation by the person certifying that he or she is an authorized representative with such authority and that the contents of the amendment or statement of fact are true and correct.

III. Preparing for Bidding in Auction 111

A. Due Diligence

80. Each potential bidder is solely responsible for investigating and evaluating all technical and marketplace factors that may have a bearing on the value of the construction permit(s) it is seeking in Auction 111. The Commission makes no representations or warranties about the use of this spectrum or these construction permits for particular services. Each applicant should be aware that a Commission auction represents an opportunity to become an FCC permittee in a broadcast service, subject to certain conditions and regulations. This includes the established authority of the Commission to alter the terms of existing licenses by rulemaking, which is equally applicable to licenses awarded by auction. A Commission auction does not constitute an endorsement by the Commission of any particular service, technology, or product, nor does a Commission construction permit or license constitute a guarantee of business success.

81. An applicant should perform its due diligence research and analysis before proceeding, as it would with any new business venture. In particular, each potential bidder should perform technical analyses and/or refresh its previous analyses to assure itself that, should it become a winning bidder for any Auction 111 construction permit, it will be able to build and operate facilities that will fully comply with all applicable technical and legal requirements. Stations in the LPTV/translator services are licensed and operate on a secondary interference basis. This means that they may not interfere with, and must accept interference from, primary services including full power television stations. As a result, the operating channel of an LPTV/translator station may be displaced by a full power television station and the LPTV/translator station will either have to relocate to a new channel that does not cause interference or else discontinue operations altogether. Each applicant should also inspect any prospective transmitter sites located in, or near, the service area for which it plans to bid, to confirm the availability of such sites, and to familiarize itself with the Commission's rules regarding any applicable federal, state, and local requirements, including the National Environmental Policy Act (NEPA), the National Historic Preservation Act (NHPA), and other environmental statutes.

82. Each applicant in Auction 111 should continue to conduct its own research throughout the auction in order to determine the existence of pending or future administrative or judicial proceedings that might affect its decision to continue participating in the auction. Each applicant is responsible for assessing the likelihood of the various possible outcomes and for considering the potential impact on construction permits available in this auction. The due diligence considerations mentioned in the *Auction 111 Procedures Public Notice* do not comprise an exhaustive list of steps that should be undertaken prior to participating in Auction 111. As always, the burden is on the potential bidder to determine how much research to undertake, depending upon specific facts and circumstances related to its interests.

83. Applicants are solely responsible for identifying associated risks and for investigating and evaluating the degree to which such matters may affect their ability to bid on, otherwise acquire, or make use of the construction permits available in Auction 111. Each potential bidder is responsible for undertaking

research to ensure that any permits won in this auction will be suitable for its business plans and needs. Each potential bidder must undertake its own assessment of the relevance and importance of information gathered as part of its due diligence efforts.

84. The Commission makes no representations or guarantees regarding the accuracy or completeness of information in its databases or any third-party databases, including, for example, court docketing systems. To the extent the Commission's databases may not include all information deemed necessary or desirable by an applicant, it must obtain or verify such information from independent sources or assume the risk of any incompleteness or inaccuracy in said databases. Furthermore, the Commission makes no representations or guarantees regarding the accuracy or completeness of information that has been provided by incumbent licensees and incorporated into its databases.

B. Bidder Education

85. Before the opening of the short-form application filing window for Auction 111, detailed educational information will be provided in various formats to would-be participants on the Auction 111 web page. Specifically, OEA will provide various materials on the pre-bidding processes in advance of the opening of the short-form application window, beginning with the release of step-by-step instructions for completing the FCC Form 175, which OEA will make available in the Education section of the Auction 111 website at *www.fcc.gov/auction/111.* In addition, OEA will provide an online tutorial for the auction, covering pre-auction procedures including completing a short-form application in the FCC Auction Application System, and bidding procedures including how to use the FCC auction bidding system. In advance of the start of the mock auction, OEA will release a user guide for the bidding system.

86. These materials will be accessible in the Education section of the Auction 111 website at *www.fcc.gov/auction/111.*

C. Short-Form Applications: Due Before 6:00 p.m. ET on November 9, 2021

87. In order to be eligible to bid in Auction 111, an applicant must first submit a short-form application (FCC Form 175) electronically via the Auction Application System following the instructions set forth in the FCC Form 175 Instructions, which are available on the Education tab of the Auction 111 website at *www.fcc.gov/auction/111.* The short-form application will become available with the opening of the initial filing window and must be submitted prior to 6:00 p.m. ET on November 9, 2021. Late applications will not be accepted. No filing fee is required to be paid at the time of filing a short-form application.

88. Applications may be filed at any time beginning at noon ET on November 1, 2021, until the filing window closes at 6:00 p.m. ET on November 9, 2021. Applicants are strongly encouraged to file early and are responsible for allowing adequate time for filing their applications. There are no limits or restrictions on the number of times an application can be updated or amended until the initial filing deadline on November 9, 2021.

89. An applicant must always click on the CERTIFY & SUBMIT button on the Certify & Submit screen to successfully submit its FCC Form 175 and any modifications; otherwise the application or changes to the application will not be received or reviewed by Commission staff. Additional information about accessing, completing, and viewing the FCC Form 175 is provided in the FCC Form 175 Instructions. Applicants requiring technical assistance should contact FCC Auctions Technical Support at (877) 480–3201, option nine; (202) 414–1250; or (202) 414–1255 (text telephony (TTY)). Hours of service are Monday through Friday, from 8:00 a.m. to 6:00 p.m. ET. In order to provide better service to the public, all calls to Technical Support are recorded.

D. Application Processing, Limited Settlement Opportunity, and Minor Modifications

1. Public Notice of MX Groups and Limited Settlement Opportunity

90. After the initial short-form application filing deadline, Commission staff will review all timely submitted applications for Auction 111 to identify the MX Groups listed in Attachment A to the *Auction 111 Procedures Public Notice* for which two or more short-form applications were submitted and which are therefore subject to competitive bidding procedures. Following this review, OEA and MB will release a public notice identifying the remaining MX Groups in Auction 111. That public notice will also specify a settlement period, of no more than 10 business days, for resolving mutual exclusivity by the filing of technical amendments, dismissal requests, and requests for approval of settlement agreements. Technical amendments submitted by applicants to resolve their mutual exclusivities must be minor, as defined by the applicable rules, and must not create any new mutual exclusivity or other application conflict. Unless the mutual exclusivity is resolved during this limited settlement opportunity, an applicant in one of these MX Groups cannot obtain the construction permit without placing a bid, even if no other auction applicant in that MX Group becomes qualified to bid or in fact places a bid.

91. No more than one construction permit will be awarded through Auction 111 for each MX group identified in Attachment A to the *Auction 111 Procedures Public Notice.* Likewise, any settlement reached during this limited settlement opportunity may not result in more than one surviving application for an LPTV/translator station construction permit. Accordingly, partial settlements (*i.e.,* settlements which reduce the number of proposals in a group, but which do not completely resolve the mutual exclusivity of that group) and engineering solutions that completely resolve the mutual exclusivity of the group but result in more than one surviving application will not be permitted. To facilitate resolution of mutual exclusivity, the prohibited communications rule will be suspended during the settlement period as specified by future public notice(s). Discussions between applicants of bids, bidding strategies, or settlements outside of any announced settlement period would violate the Commission's prohibition on certain communications by auction applicants.

92. Non-mutually exclusive applications will be listed in a subsequent public notice to be released by OEA and MB. Such applications will not proceed to auction, but will proceed in accordance with instructions set forth in that public notice.

2. Public Notice of Applicants' Initial Application Status and Opportunity for Minor Modifications

93. Commission staff will review all timely submitted applications for Auction 111 that remain mutually exclusive after the limited settlement period to determine whether each applicant has complied with the application requirements and whether it has provided all required information concerning its qualifications for bidding. After this review is completed, OEA and MB will issue a public notice announcing applicants' initial application status by identifying: (1) Those that are complete; (2) those that are rejected; and (2) those that are incomplete or deficient because of defects that may be corrected. That public notice also will establish an

application resubmission filing window, during which an applicant may make permissible minor modifications to its application to address identified deficiencies. The public notice will include the deadline for resubmitting corrected applications and a copy of the public notice will be sent by overnight delivery to the contact address listed in the FCC Form 175 for each applicant. OEA and MB ask all applicants to make sure that the contact address provided in its short-form application is accurate and is a location capable of accepting packages that require a signature. In addition, each applicant with an incomplete application will be sent information on the nature of the deficiencies in its application, along with the name and contact information of a Commission staff member who can answer questions specific to the application. To become a qualified bidder, an applicant must have a complete application (*i.e.,* have timely corrected any identified deficiencies) and make a timely and sufficient upfront payment. Qualified bidders will be identified by public notice at least 10 days prior to the mock auction.

94. After the initial application filing deadline on November 9, 2021, applicants can make only minor modifications to their applications. Major modifications will not be permitted. After the deadline for resubmitting corrected applications, an applicant will have no further opportunity to cure any deficiencies in its application or provide any additional information that may affect Commission staff's ultimate determination of whether and to what extent the applicant is qualified to participate in Auction 111.

95. Commission staff will communicate only with an applicant's contact person or certifying official, as designated on the applicant's FCC Form 175, unless the applicant's certifying official or contact person notifies Commission staff in writing that another representative is authorized to speak on the applicant's behalf. Authorizations may be sent by email to *auction111@fcc.gov.*

3. Public Notice of Applicants' Final Application Status After Upfront Payment Deadline

96. After Commission staff review resubmitted applications for Auction 111 and evaluate upfront payments, OEA and MB will release a public notice identifying applicants that have become qualified bidders. Qualified bidders are those applicants with submitted FCC Forms 175 that are deemed timely filed and complete and that have made a sufficient upfront payment.

E. Upfront Payments

97. In order to be eligible to bid in Auction 111, a sufficient upfront payment and a complete and accurate FCC Remittance Advice Form (FCC Form 159, Revised 2/03) must be submitted before 6:00 p.m. ET on January 25, 2022. After completing its short-form application, an applicant will have access to an electronic pre-filled version of the FCC Form 159. An accurate and complete FCC Form 159 must accompany each payment. Proper completion of this form is critical to ensuring correct crediting of upfront payments. Payers using the pre-filled FCC Form 159 are responsible for ensuring that all the information on the form, including payment amounts, is accurate. Instructions for completing FCC Form 159 for Auction 111 are provided in Attachment B to the *Auction 111 Procedures Public Notice.*

1. Making Upfront Payments by Wire Transfer for Auction 111

98. Upfront payments for Auction 111 must be wired to, and will be deposited in, the U.S. Treasury.

99. Wire transfer payments for Auction 111 must be received before 6:00 p.m. ET on January 25, 2022. No other payment method is acceptable. To avoid untimely payments, applicants should discuss arrangements (including bank closing schedules and other specific bank wire transfer requirements, such as an in-person written request before a specified time of day) with their bankers several days before they plan to make the wire transfer, and must allow sufficient time for the transfer to be initiated and completed before the deadline. Wire transfer information is specified in the Making Upfront Payments by Wire Transfer section of the *Auction 111 Procedures Public Notice.*

100. To meet the upfront payment deadline, an applicant's payment must be credited to the Commission's account for Auction 111 before the deadline.

101. Each applicant is responsible for ensuring timely submission of its upfront payment and for timely filing of an accurate and complete FCC Form 159. An applicant should coordinate with its financial institution well ahead of the due date regarding its wire transfer and allow sufficient time for the transfer to be initiated and completed prior to the deadline. The Commission repeatedly has cautioned auction participants about the importance of planning ahead to prepare for unforeseen last-minute difficulties in making payments by wire transfer. Each applicant also is responsible for obtaining confirmation from its financial institution that its wire transfer to the U.S. Treasury was successful and from Commission staff that its upfront payment was timely received and that it was deposited into the proper account. As a regulatory requirement, the U.S. Treasury screens all payments from all financial institutions before deposits are made available to specified accounts. If wires are suspended, the U.S. Treasury may direct questions regarding any transfer to the financial institution initiating the wire. Each applicant must take care to assure that any questions directed to its financial institution(s) are addressed promptly. To receive confirmation from Commission staff, contact Scott Radcliffe of the Office of Managing Director's Revenue & Receivables Operations Group/Auctions at (202) 418–7518 or Theresa Meeks at (202) 418–2945.

102. Please note the following information regarding upfront payments: (1) All payments must be made in U.S. dollars; (2) all payments must be made by wire transfer; and (3) upfront payments for Auction 111 go to an account number different from the accounts used in previous FCC auctions.

103. Failure to deliver a sufficient upfront payment as instructed in the *Auction 111 Procedures Public Notice* by the upfront payment deadline will result in dismissal of the short-form application and disqualification from participation in the auction.

2. Completing and Submitting FCC Form 159

104. An accurate and complete FCC Form 159 (February 2003 edition) must be sent to the FCC to accompany each upfront payment. At least one hour before placing the order for the wire transfer (but on the same business day), applicants must fax a completed Form 159 to the FCC at (202) 418–2843. Alternatively, the completed form can be scanned and sent as an attachment to an email to *RROGWireFaxes@fcc.gov.* On the fax cover sheet or in the email subject header, write Wire Transfer—Auction Payment for Auction 111.

3. Upfront Payments and Bidding Eligibility

105. The Commission has delegated authority to OEA and MB to determine appropriate upfront payments for each construction permit being auctioned, taking into account such factors as the efficiency of the auction process and the potential value of similar licenses. An upfront payment is a refundable deposit

made by each applicant seeking to participate in bidding to establish its eligibility to bid on construction permits. Upfront payments that are related to the specific construction permits being auctioned protect against frivolous or insincere bidding and provide the Commission with a source of funds from which to collect payments owed at the close of bidding. In the *Auction 111 Comment Public Notice,* OEA and MB proposed an upfront payment amount for each construction permit and sought comment on the upfront payment amounts. OEA and MB received no comments regarding the upfront payment amounts for Auction 111, and OEA and MB adopted the upfront payment amounts proposed in Attachment A of the *Auction 111 Comment Public Notice.*

106. An applicant must make an upfront payment sufficient to obtain bidding eligibility on the construction permits on which it will bid. The upfront payment amount submitted by an applicant will determine its initial bidding eligibility, the maximum number of bidding units on which a bidder may place bids in any single round. In order to bid on a particular construction permit, a qualified bidder must have a current eligibility level that meets or exceeds the number of bidding units assigned to that construction permit. At a minimum, therefore, an applicant's total upfront payment must be enough to establish eligibility to bid on at least one of the construction permits selected on its FCC Form 175 for Auction 111, or else the applicant will not become qualified to participate in the auction. An applicant does not have to make an upfront payment to cover all construction permits the applicant selected on its FCC Form 175, rather only enough to cover the maximum number of bidding units that are associated with construction permits on which the applicant wishes to place bids and hold provisionally winning bids in any given round. The total upfront payment does not affect the total dollar amount the bidder may bid on any given construction permit.

107. In calculating its upfront payment amount, an applicant must determine the maximum number of bidding units on which it may wish to bid in any single round and submit an upfront payment amount for the auction covering that number of bidding units. In order to make this calculation, an applicant should add together the bidding units for all construction permits on which it seeks to be active in any given round. Applicants should check their calculations carefully, as there is no provision for increasing a bidder's eligibility after the upfront payment deadline.

108. An applicant that is a former defaulter, as described above, must pay an upfront payment 50% greater than that required of an applicant that is not a former defaulter. For purposes of this rule, defaults and delinquencies of the applicant itself and its controlling interests are included. If an applicant is a former defaulter, it must calculate its upfront payment for all of its selected construction permits by multiplying the number of bidding units on which it wishes to be active (bid on or hold provisionally winning bids on) during a given round by 1.5. In order to calculate the number of bidding units to assign to former defaulters, the Commission will divide the upfront payment received by 1.5 and round the result up to the nearest bidding unit. If an applicant fails to submit a sufficient upfront payment to establish eligibility to bid on at least one of the construction permits selected on its FCC Form 175, the applicant will not be eligible to participate in bidding in the auction. This applicant will retain its status as an applicant in Auction 111 and will remain subject to 47 CFR 1.2105(c) and 73.5002(d).

F. Auction Registration

109. All qualified bidders for Auction 111 are automatically registered for the auction. Registration materials will be distributed prior to the auction by overnight delivery. The mailing will be sent only to the contact person at the contact address listed in the FCC Form 175 and will include the SecurID® tokens that will be required to place bids, the web address and instructions for accessing and logging in to the auction bidding system, FCC assigned username (User ID) for each authorized bidder, and the Auction Bidder Line phone number.

110. Qualified bidders that do not receive this registration mailing will not be able to submit bids. Therefore, if this mailing is not received by the contact person for a qualified bidder by noon on February 15, 2022, call the Auctions Hotline at (717) 338–2868. In no event, however, will the Commission send auction registration materials to anyone other than the contact person listed on the applicant's FCC Form 175 or respond to a request for replacement registration materials from anyone other than the authorized bidder, contact person, or certifying official listed on the applicant's FCC Form 175. Receipt of this registration mailing is critical to participating in the auction, and each qualified bidder is responsible for ensuring it has received all registration materials.

111. In the event that a SecurID® token is lost or damaged, only a person who has been designated as an authorized bidder, the contact person, or the certifying official on the applicant's short-form application may request a replacement. To request a replacement, call the Auction Bidder Line at the telephone number provided in the registration materials or the Auction Hotline at (717) 338–2868.

G. Remote Electronic Bidding via the FCC Auction Bidding System

112. Bidders will be able to participate in Auction 111 over the internet using the FCC Auction Bidding System (bidding system) or by telephonic bidding. Each applicant should indicate its bidding preference—electronic or telephonic—on its FCC Form 175. Please note that telephonic bid assistants are required to use a script when entering bids placed by telephone. Telephonic bidders are therefore reminded to allow sufficient time to bid by placing their calls well in advance of the close of a round. The length of a call to place a telephonic bid may vary; please allow a minimum of 10 minutes. The toll-free telephone number for the auction bidder line will be provided to qualified bidders prior to the start of bidding in the auction.

113. Only qualified bidders are permitted to bid. Each qualified bidder will be issued three SecurID® tokens, which the Commission will provide at no charge. Each authorized bidder for a qualified bidder must have an individually assigned SecurID® token in order to access the bidding system, either by telephone or over the internet. In order to access the bidding function of the bidding system, bidders must be logged in during the bidding round using the passcode generated by the SecurID® token and a personal identification number (PIN) created by the bidder. Bidders are strongly encouraged to print a bid summary for each round after they have completed all their activity for that round. For security purposes, the SecurID® tokens, bidding system web address, FCC assigned username, and the telephonic bidding telephone number are only mailed to the contact person at the contact address listed on the FCC Form 175. Each SecurID® token is tailored to a specific auction. SecurID® tokens issued for other auctions or obtained from a source other than the FCC will not work for Auction 111. Please note that the SecurID® tokens can be recycled, and the Commission requests that bidders return the tokens to the

FCC. Pre-addressed envelopes will be provided to return the tokens once the auction has ended.

114. The Commission makes no warranties whatsoever, and shall not be deemed to have made any warranties, with respect to the FCC Auction Application System and the auction bidding system, including any implied warranties of merchantability or fitness for a particular purpose. In no event shall the Commission, or any of its officers, employees, or agents, be liable for any damages whatsoever (including, but not limited to, loss of business profits, business interruption, loss of use, loss of revenue, loss of business information, or any other direct, indirect, or consequential damages) arising out of or relating to the existence, furnishing, functioning, or use of the FCC Auction Application System or the FCC auction bidding system. Moreover, no obligation or liability will arise out of the Commission's technical, programming, or other advice or service provided in connection with the FCC auction systems.

115. To the extent an issue arises with the bidding system itself, the Commission will take all appropriate measures to resolve such issues quickly and equitably. Should an issue arise that is outside the bidding system or attributable to a bidder, including, but not limited to, a bidder's hardware, software, or internet access problem that prevents the bidder from submitting a bid prior to the end of a round, the Commission shall have no obligation to resolve or remedy such an issue on behalf of the bidder. Similarly, if an issue arises due to bidder error using the bidding system, the Commission shall have no obligation to resolve or remedy such an issue on behalf of the bidder. Accordingly, after the close of a bidding round, the results of bid processing will not be altered absent evidence of any failure in the bidding system.

H. Mock Auction

116. All qualified bidders will be eligible to participate in a mock auction on February 17, 2022. The mock auction will enable qualified bidders to become familiar with the FCC auction bidding system and to practice submitting bids prior to the auction. OEA and MB recommend that all qualified bidders, including all their authorized bidders, participate to ensure that they can log in to the bidding system and gain experience with the bidding procedures. Participating in the mock auction may reduce the likelihood of a bidder making a mistake during the auction. Details regarding the mock auction will be announced in the public notice announcing the qualified bidders for Auction 111.

117. By public notice or by announcement through the FCC auction bidding system, OEA and MB may delay, suspend, or cancel bidding in the auction in the event of natural disaster, technical obstacle, network interruption, administrative or weather necessity, evidence of an auction security breach or unlawful bidding activity, or for any other reason that affects the fair and efficient conduct of competitive bidding. In such cases, OEA and MB, in their sole discretion, may elect to resume the auction starting from the beginning of the current round or from some previous round, or cancel the auction in its entirety. OEA and MB emphasize that they will exercise this authority solely at their discretion, and not as a substitute for situations in which bidders may wish to apply their activity rule waivers.

I. Environmental Review Requirements

118. Permittees or licensees must comply with the Commission's rules for environmental review under the National Environmental Policy Act, the National Historic Preservation Act, and other federal environmental statutes. The construction of a broadcast facility is a federal action, and the permittee or licensee must comply with the Commission's environmental rules for each such facility. These environmental rules require, among other things, that the permittee or licensee consult with expert agencies having environmental responsibilities, including the U.S. Fish and Wildlife Service, the State Historic Preservation Office, the U.S. Army Corps of Engineers, and the Federal Emergency Management Agency (through the local authority with jurisdiction over floodplains). In assessing the effect of facility construction on historic properties, the permittee or licensee must follow the provisions of the FCC's Nationwide Programmatic Agreement Regarding the Section 106 National Historic Preservation Act Review Process. The permittee or licensee must prepare environmental assessments for any facility that may have a significant impact in or on wilderness areas, wildlife preserves, threatened or endangered species, or designated critical habitats, historical or archaeological sites, Indian religious sites, floodplains, and surface features. In addition, the permittee or licensee must prepare environmental assessments for facilities that include high intensity white lights in residential neighborhoods or excessive radio frequency emission.

IV. Bidding

119. The first round of bidding for Auction 111 will begin on February 23, 2022. The initial bidding schedule will be announced in a public notice listing the qualified bidders, which is released at least one week before the start of bidding in the auction.

A. Auction Structure

1. Simultaneous Multiple Round Auction

120. All construction permits listed in Attachment A to the *Auction 111 Procedures Public Notice* will be auctioned in a single auction using a simultaneous multiple-round auction format. This type of auction offers every construction permit for bid at the same time and consists of successive bidding rounds in which qualified bidders may place bids on individual construction permits. Unless otherwise announced, bids will be accepted on all construction permits in each round of the auction until bidding stops on every construction permit.

2. FCC Auction Bidding System

121. All bidding will take place remotely either through the FCC auction bidding system or by telephonic bidding. Please note that telephonic bid assistants are required to use a script when entering bids placed by telephone. Telephonic bidders are therefore reminded to allow sufficient time to bid by placing their calls well in advance of the close of a round. The length of a call to place a telephonic bid may vary; please allow a minimum of ten minutes.

122. An Auction 111 bidder's ability to bid on specific construction permits is determined by two factors: (1) The construction permits selected by that applicant in its FCC Form 175 and (2) the bidder's bidding eligibility measured in bidding units. The FCC auction bidding system will allow bidders to submit bids on only those construction permits the bidder selected on its FCC Form 175.

123. In order to access the bidding function of the FCC auction bidding system, bidders must be logged in during a bidding round using the passcode generated by the SecurID® token and a PIN created by the bidder. Bidders are strongly encouraged to print a round summary for each round after they have completed all of their activity for that round.

3. Round Structure

124. The initial schedule of bidding rounds will be announced in the public

notice listing the qualified bidders in the auction. Each bidding round is followed by the release of round results. Multiple bidding rounds may be conducted each day.

125. OEA and MB retain the discretion to adjust the bidding schedule in order to foster an auction pace that reasonably balances speed with the bidders' need to study round results and adjust their bidding strategies. OEA and MB may change the amount of time for bidding rounds, the amount of time between rounds, or the number of rounds per day, depending upon bidding activity and other factors.

4. Eligibility and Activity Rules

126. The amount of the upfront payment submitted by a bidder will determine its initial bidding eligibility in terms of bidding units. A bidder's bidding eligibility is the maximum number of bidding units on which a bidder may be active (bid or hold provisionally winning bids) in a given round. In Auction 111, each construction permit is assigned a specific number of bidding units as listed in Attachment A to the *Auction 111 Procedures Public Notice.* Bidding units assigned to each construction permit do not change as prices rise during the auction. Upfront payments are not attributed to specific construction permits. Rather, a bidder may place bids on any of the construction permits selected on its FCC Form 175 as long as the total number of bidding units associated with those construction permits does not exceed the bidder's current eligibility.

127. Eligibility cannot be increased during the auction; it can only remain the same or decrease. Thus, in calculating its upfront payment amount, an applicant must determine the maximum number of bidding units on which it may wish to bid or hold provisionally winning bids in any single round, and submit an upfront payment amount covering that total number of bidding units. At a minimum, an applicant's upfront payment must cover the bidding units for at least one of the construction permits it selected on its short-form application. The total upfront payment does not affect the total dollar amount a bidder may bid on any given construction permit.

128. To ensure that an auction closes within a reasonable period of time, an activity rule requires bidders to bid actively throughout the auction, rather than wait until late in the auction before participating. A bidder in Auction 111 will be required to be active on 100% of its current bidding eligibility during each round of the auction. A bidder's activity level in a round is the sum of the bidding units associated with construction permits covered by the bidder's new bids in the current round and provisionally winning bids from the previous round. That is, a bidder must either place a bid or be a provisionally winning bidder during each round of the auction. Failure to maintain the requisite activity level will result in the use of an activity rule waiver, if any remain, or a reduction in the bidder's eligibility, possibly curtailing or eliminating the bidder's ability to place bids in subsequent rounds of the auction.

5. Activity Rule Waivers

129. Each bidder in the auction will have three activity rule waivers, which are principally a mechanism for a bidder to avoid the loss of bidding eligibility in the event that exigent circumstances prevent it from bidding in a particular round. Use of an activity rule waiver preserves the bidder's eligibility despite its activity in the current round being below the required minimum activity level. An activity rule waiver applies to an entire round of bidding and not to a particular construction permit. A bidder may use an activity rule waiver in any round of the auction as long as the bidder has not used all of its waivers.

130. The FCC auction bidding system will assume that a bidder that does not meet the activity requirement would prefer to use an activity rule waiver (if available) rather than lose bidding eligibility. Therefore, the system will automatically apply a waiver at the end of any bidding round in which a bidder's activity level is below the minimum required unless (1) the bidder has no activity rule waiver remaining, or (2) the bidder overrides the automatic application of a waiver by reducing eligibility, therefore meeting the activity requirement. If the bidder has no waivers remaining and does not satisfy the required activity level, the bidder's current eligibility will be permanently reduced, possibly curtailing or eliminating the ability to place additional bids in the auction.

131. A bidder with insufficient activity may wish to reduce its bidding eligibility rather than use an activity rule waiver. If so, the bidder must affirmatively override the automatic waiver mechanism during the bidding round by using the reduce eligibility function in the FCC auction bidding system. In this case, the bidder's eligibility will be permanently reduced to bring it into compliance with the activity rule described above. Reducing eligibility is an irreversible action once the round has closed, and a bidder cannot regain its lost bidding eligibility.

132. Finally, a bidder may apply an activity rule waiver proactively as a means to keep the auction open without placing a bid. If a bidder proactively applies an activity rule waiver (using the proactive waiver function in the FCC auction bidding system) during a bidding round in which no bids are placed, the auction will remain open and the bidder's eligibility will be preserved. An automatic waiver applied by the FCC auction bidding system in a round in which there is no new bid or a proactive waiver will not keep the auction open.

6. Stopping Rule

133. For Auction 111, OEA and MB will employ a simultaneous stopping rule approach, which means all construction permits remain available for bidding until bidding stops on every construction permit. Specifically, bidding will close on all construction permits after the first round in which no bidder submits a new bid or applies a proactive waiver.

134. In certain circumstances, OEA and MB may employ the alternative versions of the simultaneous stopping rule listed below for Auction 111, for example, where the auction is proceeding unusually slowly or quickly, there is minimal overall bidding activity, or it appears likely that the auction will not close within a reasonable period of time or will close prematurely. Before exercising these options, OEA and MB are likely to attempt to change the pace of the auction. For example, OEA and MB may adjust the pace of bidding by changing the number of bidding rounds per day and/or the minimum acceptable bids. OEA and MB retain the discretion to exercise any of these options with or without prior announcement during the auction:

Option 1. The auction would close for all construction permits after the first round in which no bidder applies a proactive waiver or places a new bid on any construction permit on which it is not the provisionally winning bidder. Thus, absent any other bidding activity, a bidder placing a new bid on a construction permit for which it is the provisionally winning bidder would not keep the auction open under this modified stopping rule.

Option 2. The auction would close for all construction permits after the first round in which no bidder applies a waiver or places any new bid on any construction permit that already has a provisionally winning bid. Thus, absent any other bidding activity, a bidder

placing a new bid on an FCC-held construction permit (a construction permit that does not have a provisionally winning bid) would not keep the auction open under this modified stopping rule.

Option 3. The auction would close using a modified version of the simultaneous stopping rule that combines Option 1 and Option 2 above.

Option 4. The auction would close after a specified number of additional rounds (special stopping rule) to be announced in advance in the FCC auction bidding system. If OEA and MB invokes this special stopping rule, it will accept bids in the specified final round(s), after which the auction will close.

Option 5. The auction would remain open even if no bidder places a new bid or applies a waiver. In this event, the effect will be the same as if a bidder had applied a waiver. Thus, the activity rule will apply as usual, and a bidder with insufficient activity will either lose bidding eligibility or use a waiver.

B. Bidding Procedures

1. Minimum Opening Bids and Acceptable Bid Amounts

135. Section 309(j) of the Communications Act of 1934 calls upon the Commission to prescribe methods by which a reasonable reserve price will be required or a minimum opening bid established when applications for FCC licenses or construction permits are subject to auction (*i.e.,* because they are mutually exclusive), unless the Commission determines that a reserve price or minimum opening bid is not in the public interest. Consistent with this mandate, the Commission directed the Bureaus to seek comment on the use of a minimum opening bid and/or reserve price prior to the start of each auction. Among other factors, OEA and MB must consider the amount of spectrum being auctioned, levels of incumbency, the availability of technology to provide service, the size of the geographic service areas, the extent of interference with other spectrum bands, and any other relevant factors that could have an impact on the spectrum being auctioned.

136. For Auction 111, there will be no reserve prices for specific construction permits listed in Attachment A to the *Auction 111 Procedures Public Notice* that are different from minimum opening bid amounts. This is consistent with previous broadcast spectrum auctions.

137. In the *Auction 111 Comment Public Notice,* OEA and MB sought comment on specifically proposed minimum opening amounts for each construction permit listed in Attachment A to the *Auction 111 Procedures Public Notice,* reasoning that a minimum opening bid, which has been used in other broadcast auctions, is an effective tool for accelerating the competitive bidding process. Specifically, a minimum opening bid was proposed for each construction permit by taking into account various factors relating to the efficiency of the auction and the potential value of the spectrum, including the type of service and class of facility offered, market size, population covered by the proposed broadcast facility, industry cash flow data, and recent broadcast transactions.

138. OEA and MB received no comments on the proposed minimum opening bids, and therefore they adopted the minimum opening bid amounts proposed in the *Auction 111 Comment Public Notice.* The specific minimum opening bid amounts for each of the construction permits are specified in Attachment A to the *Auction 111 Procedures Public Notice.*

139. In each round, a qualified bidder will be able to place a bid on a given construction permit in any of up to nine different amounts. The FCC auction bidding system interface will list the nine acceptable bid amounts for each construction permit.

140. To calculate the first of the acceptable bid amounts, OEA and MB will use a minimum acceptable bid increment percentage of 10%. This means that the minimum acceptable bid amount for a construction permit will be approximately 10% greater than the provisionally winning bid amount for the construction permit. To calculate the eight additional acceptable bid amounts, OEA and MB will use an additional bid increment percentage of 5%.

141. In Auction 111, the minimum acceptable bid amount for a construction permit will be equal to its minimum opening bid amount until there is a provisionally winning bid for the construction permit. After there is a provisionally winning bid for a construction permit, the minimum acceptable bid amount will be calculated by multiplying the provisionally winning bid amount by one plus the minimum acceptable bid percentage—*i.e.,* provisionally winning bid amount * 1.10, rounded. Under the Commission's standard rounding procedure for auctions, results above $10,000 are rounded to the nearest $1,000; results below $10,000 but above $1,000 are rounded to the nearest $100; and results below $1000 are rounded to the nearest $10.

142. In Auction 111, the FCC auction bidding system will calculate the eight additional bid amounts by multiplying the minimum acceptable bid amount by the additional bid increment percentage of 5%, and that result (rounded) is the additional increment amount. The first additional acceptable bid amount equals the minimum acceptable bid amount plus the additional increment amount. The second additional acceptable bid amount equals the minimum acceptable bid amount plus two times the additional increment amount; the third additional acceptable bid amount is the minimum acceptable bid amount plus three times the additional increment amount; etc. Because the additional bid increment percentage is 5%, the calculation of the additional increment amount is (minimum acceptable bid amount) * (0.05), rounded. The first additional acceptable bid amount equals (minimum acceptable bid amount) + (additional increment amount); the second additional acceptable bid amount equals (minimum acceptable bid amount) + (2*(additional increment amount)); the third additional acceptable bid amount equals (minimum acceptable bid amount) + (3*(additional increment amount)); etc.

143. OEA and MB retain the discretion to change the minimum acceptable bid amounts, the minimum acceptable bid increment percentage, the additional bid increment percentage, and the number of acceptable bid amounts if it determines that circumstances so dictate, consistent with past practice. OEA and MB also retain the discretion to do so on a construction permit-by-construction permit basis. OEA and MB also retain the discretion to limit (a) the amount by which a minimum acceptable bid for a construction permit may increase compared with the corresponding provisionally winning bid, and (b) the amount by which an additional bid amount may increase compared with the immediately preceding acceptable bid amount. For example, OEA and MB could set a $1,000 limit on increases in minimum acceptable bid amounts over provisionally winning bids. Thus, if calculating a minimum acceptable bid using the minimum acceptable bid increment percentage results in a minimum acceptable bid amount that is $1,200 higher than the provisionally winning bid on a construction permit, the minimum acceptable bid amount would instead be capped at $1,000 above the provisionally winning bid. OEA and MB typically exercise this discretion based on its monitoring of ongoing bidding. If OEA and MB

exercise this discretion, they will alert bidders by announcement in the FCC auction bidding system during the auction.

2. Provisionally Winning Bids

144. Consistent with practice in past auctions, the FCC auction bidding system at the end of each bidding round will determine a provisionally winning bid for each construction permit based on the highest bid amount received for that permit. A provisionally winning bid will remain the provisionally winning bid until there is a higher bid on the same construction permit at the close of a subsequent round. Provisionally winning bids at the end of the auction become the winning bids.

145. OEA and MB will use a pseudo-random number generator to select a single provisionally winning bid if identical high bid amounts are submitted on a construction permit in a given round (*i.e.,* tied bids). The FCC auction bidding system will assign a pseudo-random number to each bid upon submission. The tied bid with the highest pseudo-random number wins the tiebreaker and becomes the provisionally winning bid. The remaining bidders, as well as the provisionally winning bidder, can submit higher bids in subsequent rounds. However, if the auction were to close with no other bids being placed, the winning bidder would be the one that placed the provisionally winning bid. If the construction permit receives any bids in a subsequent round, the provisionally winning bid again will be determined by the highest bid amount received for the construction permit.

146. As a reminder, provisionally winning bids count toward activity for purposes of the activity rule.

3. Bid Removal and Bid Withdrawal

147. Each qualified bidder has the option of removing any bids placed in a round provided that such bids are removed before the close of that bidding round. By removing a bid within a round, a bidder effectively ''unsubmits'' the bid. A bidder removing a bid placed in the same round is not subject to withdrawal payments. Removing a bid will affect a bidder's activity because a removed bid no longer counts toward bidding activity for the round. Once a round closes, a bidder may no longer remove a bid.

148. In recognition of the site-specific nature and wide geographic dispersion of the permits available in this auction, as well as its experience with past auctions of broadcast construction permits, qualified bidders are prohibited from withdrawing any bid after close of the round in which that bid was placed. Bidders are cautioned to select bid amounts carefully because no bid withdrawals will be allowed, even if a bid was mistakenly or erroneously made.

4. Bidding Results

149. Bids placed during a round will not be made public until the conclusion of that round. After a round closes, OEA and MB will compile reports of all bids placed, current provisionally winning bids, new minimum acceptable bid amounts for the following round, whether the construction permit is FCC-held, and bidder eligibility status (bidding eligibility and activity rule waiver), and post the reports for public access.

5. Auction Announcements

150. Commission staff will use auction announcements to report necessary information, such as schedule changes, to bidders. All auction announcements will be available by clicking a link in the FCC auction bidding system.

V. Post-Auction Procedures

151. The public notice announcing the close of the bidding and auction results will be released shortly after bidding has ended in Auction 111. That public notice will also establish the deadlines for submitting down payments, final payments, and amendments to long-form applications.

A. Down Payments

152. The Commission's rules provide that, unless otherwise specified by public notice, within ten business days after the release of the auction closing public notice for Auction 111, each winning bidder must submit sufficient funds (in addition to its upfront payment) to bring its total amount of money on deposit with the Commission to 20% of the net amount of its winning bids (less any bidding credits, if applicable).

B. Final Payments

153. Each winning bidder will be required to submit the balance of the net amount for each of its winning bids within 10 business days after the deadline for submitting down payments.

C. Winning Bidder Amendments to Long-Form Applications

154. Because each party eligible to apply for Auction 111 has already filed an application for a new or modified LPTV/translator station (FCC Form 2100, Schedule C (Schedule for a Construction Permit for a LPTV or TV Translator Broadcast Station) of FCC Form 2100 (Application for Media Bureau Video Service Authorization)), a winning bidder will not be required to submit a separate long-form application following close of bidding in Auction 111, but instead will be required to submit a minor amendment to its previously filed LPTV/Translator station application by a deadline to be determined after the close of the auction. Amendments must be filed electronically in the Media Bureau's Licensing and Management System (LMS) available at *https://enterprise efiling.fcc.gov/dataentry/login.html*. Winning bidders' applications, as amended, will be placed on public notice, triggering the appropriate period for the filing of petitions to deny. A winning bidder claiming new entrant status must include an exhibit demonstrating its eligibility for the bidding credit. Further instructions will be provided to winning bidders in the auction closing public notice.

D. Default and Disqualification

155. Any winning bidder that defaults or is disqualified after the close of an auction (*i.e.,* fails to remit the required down payment by the specified deadline, fails to submit a timely long-form application, fails to make a full and timely final payment, or is otherwise disqualified) is liable for default payments as described in 47 CFR 1.2104(g)(2). A default payment consists of a deficiency payment, equal to the difference between the amount of the bidder's winning bid and the amount of the winning bid the next time a construction permit covering the same spectrum is won in an auction, plus an additional payment equal to a percentage of the defaulter's bid or of the subsequent winning bid, whichever is less.

156. The percentage of the applicable bid to be assessed as an additional payment for defaults in a particular auction is established in advance of the auction. The additional default payment for Auction 111 is 20% of the applicable bid.

157. Finally, in the event of a default, the Commission has the discretion to re-auction the construction permit or offer it to the next highest bidder (in descending order) at its final bid amount. In addition, if a default or disqualification involves gross misconduct, misrepresentation, or bad faith by an applicant, then the Commission may declare the applicant and its principals ineligible to bid in future auctions and may take any other action that it deems necessary, including institution of proceedings to

revoke any existing authorizations held by the applicant.

E. Refund of Remaining Upfront Payment Balance

158. All refunds of upfront payment balances will be returned to the payer of record as identified on the FCC Form 159 unless the payer submits written authorization instructing otherwise.

159. This written authorization must comply with the refund instructions provided in the *Auction 111 Procedures Public Notice*.

160. The refund request must be submitted by fax to the Revenue & Receivables Operations Group/Auctions at (202) 418–2843, or by email to *RROGWireFaxes@fcc.gov*.

VI. Procedural Matters

A. Paperwork Reduction Act

161. The Office of Management and Budget (OMB) has approved the information collections in the Application to Participate in an FCC Auction, FCC Form 175. The *Auction 111 Procedures Public Notice* does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. Therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198.

B. Congressional Review Act

162. The Commission has determined, and Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, concurs, that these rules are ''non-major'' under the Congressional Review Act, 5 U.S.C. 804(2). The Commission will send a copy of the *Auction 111 Procedures Public Notice* in a report to Congress and the Government Accountability Office pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A).

C. Supplemental Final Regulatory Flexibility Analysis

163. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission prepared Initial Regulatory Flexibility Analyses (IRFAs) in connection with the *Broadcast Competitive Bidding Notice of Proposed Rulemaking* (NPRM), 62 FR 65392, December 12, 1997, and other Commission NPRMs (collectively, *Competitive Bidding NPRMs*) pursuant to which Auction 111 will be conducted. Final Regulatory Flexibility Analyses (FRFAs) likewise were prepared in the *Broadcast Competitive Bidding Order,* 63 FR 48615, September 11, 1998, and other Commission rulemaking orders (collectively, *Competitive Bidding Orders*) pursuant to which Auction 111 will be conducted. In this proceeding, a Supplemental Initial Regulatory Flexibility Analysis (Supplemental IRFA) was incorporated in the *Auction 111 Comment Public Notice.* The Commission sought written public comment on the proposals in the *Auction 111 Comment Public Notice,* including comments on the Supplemental IRFA. The Supplemental Final Regulatory Flexibility Analysis (Supplemental FRFA) supplements the FRFAs in the *Competitive Bidding Orders* to reflect the actions taken in the *Auction 111 Procedures Public Notice* and conforms to the RFA.

164. *Need for, and Objectives of, the Public Notice.* The procedures for the conduct of Auction 111 as described in the *Auction 111 Procedures Public Notice* implement the Commission's competitive bidding rules, which have been adopted by the Commission in multiple notice-and-comment rulemaking proceedings. More specifically, the *Auction 111 Procedures Public Notice* provides an overview of the procedures, terms, and conditions governing Auction 111, and the post-auction application and payment processes, as well as setting the minimum opening bid amount for each of the LPTV/translator station construction permits that are subject to being assigned by competitive bidding.

165. To promote the efficient and fair administration of the competitive bidding process for all Auction 111 participants, including small businesses, in the *Auction 111 Procedures Public Notice,* OEA and MB announce the following procedures: (1) Use of a simultaneous multiple-round auction format, consisting of sequential bidding rounds with a simultaneous stopping procedure (with discretion to exercise alternative stopping rules under certain circumstances); (2) a specific upfront payment amount for each construction permit; (3) a specific minimum opening bid amount for each construction permit; (4) a specific number of bidding units for each construction permit; (5) a bidder's initial bidding eligibility will be based on the amount of that bidder's upfront payment; (6) use of an activity requirement in which a bidder is required to be active on 100% of its bidding eligibility in each round of the auction so that bidders must bid actively during the auction rather than waiting until late in the auction before participating; (7) provision of three activity waivers for each qualified bidder to allow it to preserve bidding eligibility during the course of the auction; (8) use of minimum acceptable bid amounts and additional acceptable increments, along with the methodology for calculating such amounts; (9) a procedure for breaking ties if identical high bid amounts are submitted on one permit in a given round; (10) a prohibition on bid withdrawals while allowing for bid removals (before the close of a bidding round); (11) establishment of an additional default payment percentage of 20% of the applicable bid in the event that a winning bidder defaults or is disqualified after the auction; (12) retention by OEA and MB to exercise discretion to delay, suspend, or cancel bidding in Auction 111 for any reason that affects the ability of the competitive bidding process to be conducted fairly and efficiently; and (13) retention of discretion by OEA to adjust the bidding schedule in order to manage the pace of Auction 111.

166. *Summary of Significant Issues Raised by Public Comments in Response to the IRFA.* There were no comments filed that specifically addressed the procedures and policies proposed in the Supplemental IRFA.

167. *Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration.* Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comment filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed procedures as a result of those comments. The Chief Counsel did not file any comments in response to the procedures that were proposed in the *Auction 111 Comment Public Notice*.

168. *Description and Estimate of the Number of Small Entities to Which the Procedures Will Apply.* The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the rules adopted herein. The RFA generally defines the term small entity as having the same meaning as the terms small business, small organization, and small governmental jurisdiction. In addition, the term small business has the same meaning as the term small business concern under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation;

and (3) satisfies any additional criteria established by the SBA.

169. The specific competitive bidding procedures and minimum opening bid amounts described in the *Auction 111 Procedures Public Notice* will affect all applicants participating in Auction 111, in which applicant eligibility is closed. Therefore, the specific competitive bidding procedures and minimum opening bid amounts described in the *Auction 111 Comment Public Notice* will affect only the 24 parties listed in Attachment A to the *Auction 111 Procedures Public Notice* and that are the only parties eligible to complete the remaining steps to become qualified to bid in Auction 111. These specific 24 Auction 111 parties include firms of all sizes.

170. *Television Broadcasting.* This Economic Census category comprises establishments primarily engaged in broadcasting images together with sound. These establishments operate television broadcast studios and facilities for the programming and transmission of programs to the public. These establishments also produce or transmit visual programming to affiliated broadcast television stations, which in turn broadcast the programs to the public on a predetermined schedule. Programming may originate in their own studio, from an affiliated network, or from external sources. The SBA has created the following small business size standard for such businesses: those having $41.5 million or less in annual receipts. The 2012 Economic Census reports that 751 firms in this category operated that entire year. Of that number, 656 had annual receipts of $25,000,000 or less, and 25 had annual receipts between $25,000,000 and $49,999,999. Based on this data OEA and MB therefore estimate that the majority of commercial television broadcasters are small entities under the applicable SBA size standard.

171. Additionally, the Commission has estimated the number of licensed commercial television stations to be 1,374. Of this total, 1,269 stations (or about 92.5%) had revenues of $41.5 million or less, according to Commission staff review of the BIA Kelsey Inc. Media Access Pro Television Database (BIA) on April 20, 2021, and therefore these stations qualify as small entities under the SBA definition.

172. In addition, the Commission has estimated the number of licensed noncommercial educational (NCE) television stations to be 384. These stations are non-profit, and therefore considered to be small entities.

173. There are also 2,371 LPTV stations, including Class A stations, and 3,306 TV translators. Given the nature of these services, OEA and MB presume that all of these entities qualify as small entities under the SBA small business size standard.

174. OEA and MB note, however, that the SBA size standard data does not enable them to make a meaningful estimate of the number of small entities that may participate in Auction 111.

175. In assessing whether a business entity qualifies as small under the SBA definition, business control affiliations must be included. The estimate therefore likely overstates the number of small entities that might be affected by this auction because the revenue figures on which this estimate is based does not include or aggregate revenues from affiliated companies. Moreover, the definition of small business also requires that an entity not be dominant in its field of operation and that the entity be independently owned and operated. The estimate of small businesses to which Auction 111 competitive bidding rules may apply does not exclude any television station from the definition of a small business on these bases and is therefore over-inclusive to that extent. Furthermore, OEA and MB are unable at this time to define or quantify the criteria that would establish whether a specific LPTV station or TV translator is dominant in its field of operation.

176. OEA and MB also note that they are unable to accurately develop an estimate of how many of the 24 parties in this auction are small businesses based on the number of small entities that applied to participate in prior broadcast auctions, because that information is not collected from applicants for broadcast auctions in which bidding credits are not based on an applicant's size (as is the case in auctions of licenses for wireless services). OEA and MB conclude, however, that the majority of Auction 111 eligible bidders would likely meet the SBA's definition of a small business concern.

177. *Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities.* For Auction 111, no new reporting, recordkeeping, or other compliance requirements for small entities or other auction applicants were proposed. The Commission designed the auction application process itself to minimize reporting and compliance requirements for applicants, including small business applicants. For all spectrum auctions, in the first part of the Commission's two-phased auction application process, parties desiring to participate in an auction file streamlined, short-form applications in which they certify under penalty of perjury as to their qualifications. Eligibility to participate in bidding is based on an applicant's short-form application and certifications, as well as its upfront payment. In the second phase of the auction application process, there are additional compliance requirements for winning bidders. Thus, a small business that fails to become a winning bidder does not need to provide the additional showings and more detailed demonstrations required of a winning bidder.

178. Auction 111 applicants, including small entities, will become qualified to bid in Auction 111 only if they comply with the following: (1) Submission of a short-form application that is timely and is found to be substantially complete, and (2) timely submission of a sufficient upfront payment for at least one of the construction permits that the applicant selected on its FCC Form 175. In accordance with the terms of 47 CFR 1.2105(b)(2), an applicant whose application is found to contain deficiencies will have a limited opportunity to bring its application into compliance with the Commission's competitive bidding rules during a resubmission window. In addition, each Auction 111 applicant must maintain the accuracy of its previously filed short-form application electronically using the FCC Auction Application System.

179. In the second phase of the process, there are additional compliance requirements only applicable to winning bidders. As with other winning bidders, any small entity that is a winning bidder will be required to comply with the terms of the following rules, among others: (1) 47 CFR 1.2107(b), by submitting as a down payment within 10 business days after release of the auction closing public notice sufficient funds (in addition to its upfront payment) to bring its total amount of money on deposit with the Commission for Auction 111 to 20% of the amount of its winning bid or bids; (2) 47 CFR 1.2109(a), by submitting within 10 business days after the down payment deadline the balance of the amount for each of its winning bids; and (3) 47 CFR 73.5005(a), by electronically filing an amended long-form application and required exhibits for each construction permit won through Auction 111.

180. Further, as required by 47 CFR 1.2105(c), reports concerning prohibited communications must be filed with the Chief of the Auctions Division, as

detailed in the *Auction 111 Procedures Public Notice.*

181. *Steps Taken to Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered.* The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.

182. OEA and MB intend that the procedures adopted in the *Auction 111 Procedures Public Notice* to facilitate participation in Auction 111 will result in both operational and administrative cost savings for small entities and other auction participants. In light of the numerous resources that will be available from the Commission to small entities and other auction participants at no cost, the processes and procedures announced in the *Auction 111 Procedures Public Notice* should minimize any economic impact of the auction processes and procedures on small entities and should result in both operational and administrative cost savings for small entities and other auction participants. For example, prior to the beginning of bidding in this auction, the Commission will hold a mock auction to allow qualified bidders the opportunity to familiarize themselves with both the processes and systems that will be used in Auction 111. During the auction, participants will be able to access and participate in bidding via the internet using a web-based system, or telephonically, providing two cost-effective methods of participation and avoiding the cost of travel for in-person participation. Further, small entities as well as other auction participants will be able to avail themselves of a telephone hotline for assistance with auction processes and procedures as well as a technical support telephone hotline to assist with issues such as access to or navigation within the electronic FCC Form 175 and use of the FCC's auction bidding system. In addition, all auction participants, including small business entities, will have access to various other sources of information and databases through the Commission that will aid in both their understanding and participation in the process. These mechanisms are made available to facilitate participation by all qualified bidders and may result in significant cost savings for small business entities that utilize these mechanisms. These resources, coupled with the description and communication of the bidding procedures before bidding begins in Auction 111, should ensure that the auction will be administered predictably, efficiently and fairly, thus providing certainty for small entities as well as other auction participants.

183. *Notice to SBA.* The Commission will send a copy of the *Auctions 111 Procedures Public Notice,* including the Supplemental FRFA, to the Chief Counsel for Advocacy of the SBA.

Federal Communications Commission.

William Huber,

Associate Chief, Auctions Division, Office of Economics and Analytics.

[FR Doc. 2021–21559 Filed 10–4–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket Nos. 03–123 and 10–51; DA 20–219; FR ID 50873]

Structure and Practices of the Video Relay Services Program; Correction

AGENCY: Federal Communications Commission.

ACTION: Correcting amendments.

SUMMARY: An amendment to the rules of the Federal Communications Commission (Commission) published in the **Federal Register** on July 7, 2021. The document inadvertently removed the incorporation by reference for the Request for Comments (RFC) 6351, xCard; vCard XML Representation and inadvertently retained the incorpation by reference for the Interoperabilty Profile for Relay User Equipment. This document corrects the regulation.

DATES: Effective on October 5, 2021

FOR FURTHER INFORMATION CONTACT: Michael Scott, Consumer and Governmental Affairs Bureau, at (202) 418–1264, or email *Michael.Scott@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document corrects 49 CFR 64.621. The final rules document published at 86 FR 35632, July 7, 2021.

List of Subjects in 47 CFR Part 64

Incorporation by reference, Individuals with disabilities, Telecommunications, Telecommunications relay services.

Federal Communications Commission.

Gregory Haledjian,

Legal Advisor, Consumer and Governmental Affairs Bureau.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission corrects 47 CFR part 64 by making the following correcting amendment:

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 47 U.S.C. 151, 152, 154, 201, 202, 217, 218, 220, 222, 225, 226, 227, 227b, 228, 251(a), 251(e), 254(k), 262, 276, 403(b)(2)(B), (c), 616, 620, 1401–1473, unless otherwise noted; Pub. L. 115–141, Div. P, sec. 503, 132 Stat. 348, 1091.

■ 2. Amend § 64.621 by:

■ a. Removing and reserving paragraph (c)(2)(i); and

■ b. Adding paragraph (c)(2)(ii).

The revision reads as follows:

§ 64.621 Interoperability and portability.

* * * * *

(c) * * *

(2) * * *

(ii) Request for Comments (RFC) 6351, xCard: vCard XML Representation (August 2011) *https://tools.ietf.org/html/rfc6351.*

[FR Doc. 2021–21572 Filed 10–4–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 160426363–7275–02; RTID 0648–XB395]

Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region; 2021–2022 Commercial Quota Reduction for King Mackerel in the Run-Around Gillnet Fishery of the Gulf of Mexico

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; commercial quota reduction.

SUMMARY: NMFS implements an accountability measure (AM) through this temporary rule for commercial

harvest of king mackerel in the southern zone of the Gulf of Mexico (Gulf) exclusive economic zone (EEZ) using run-around gillnet gear. NMFS has determined that landings of king mackerel harvested by run-around gillnet gear in the southern zone of the Gulf EEZ exceeded the commercial annual catch limit (ACL), equivalent to the commercial quota, in the 2020–2021 fishing year. Therefore, NMFS reduces the southern zone commercial ACL for king mackerel fishing using run-around gillnet gear in the Gulf EEZ during the 2021–2022 fishing year. This commercial ACL reduction is necessary to protect the Gulf king mackerel resource.

DATES: The temporary rule is effective from 6 a.m. local time on January 18, 2022, through June 30, 2022.

FOR FURTHER INFORMATION CONTACT: Kelli O'Donnell, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *kelli.odonnell@noaa.gov.*

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish in the Gulf includes king mackerel, Spanish mackerel, and cobia, and is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils, and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All weights for the Gulf migratory group of king mackerel (Gulf king mackerel) described in this temporary rule apply as either round or gutted weight.

The commercial ACL (equivalent to the commercial quota) for Gulf king mackerel is divided into separate ACLs for hook-and-line and run-around gillnet gear. The use of run-around gillnets for king mackerel is restricted to the Gulf southern zone. The Gulf southern zone includes the EEZ off Collier and Monroe Counties in south Florida. The Gulf southern zone encompasses an area of the EEZ south of a line extending due west from the boundary of Lee and Collier Counties on the Florida west coast, and south of a line extending due east from the boundary of Monroe and Miami-Dade Counties on the Florida east coast (50 CFR 622.369(a)(1)(iii)).

For the 2020–2021 fishing season, the commercial gillnet quota for Gulf king mackerel was 575,400 lb (260,997 kg). Regulations at 50 CFR 622.8(b) and 622.388(a)(1) require NMFS to close any component of the king mackerel commercial sector when its respective quota has been reached, or is projected to be reached, by filing a notification with the Office of the Federal Register. On January 28, 2021, NMFS determined that the 2020–2021 commercial gillnet quota had been reached, and closed the commercial gillnet component for the remainder of the 2020–2021 fishing year (86 FR 7815, February 2, 2021).

NMFS' most recent landings data for the 2020–2021 fishing year indicate that the commercial gillnet component exceeded the 575,400-lb (260,997-kg) quota by 11,920 lb (5,407 kg). The AM specified in 50 CFR 622.388(a)(1)(iii) states if commercial landings of king mackerel caught by run-around gillnet gear exceed the commercial gillnet ACL, then NMFS will reduce the commercial gillnet ACL in the following fishing year by the amount of the ACL overage.

Prior to the application of the ACL reduction, the 2021–2022 commercial gillnet ACL for Gulf king mackerel in the southern zone is 575,400 lb (260,997 kg) (50 CFR 622.384(b)(1)(iii)(B)). The fishing season for run-around gillnet gear is currently closed from July 1, 2021, through January 17, 2022, and will open at 6 a.m. on January 18, 2022. The 2021–2022 fishing year runs through June 30, 2022.

Consistent with the AM, NMFS reduces the 2021–2022 commercial gillnet quota by the amount of the 2020–2021 commercial gillnet ACL overage resulting in a run-around gillnet ACL of 563,480 lb (255,590 kg). If king mackerel commercial gillnet landings do not exceed the adjusted ACL in the 2021–2022 fishing year, then in the 2022–2023 fishing year, the component's commercial quota will again be 575,400 lb (260,997 kg) as specified in 50 CFR 622.384(b)(1)(iii)(B).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.8(b) and 622.388(a)(1)(iii), which were issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, because prior notice and opportunity for public comment on this temporary rule is unnecessary. Such procedure is unnecessary because the rule that implemented the commercial ACL and the associated AM for the commercial ACL reduction has already been subject to public notice and comment, and all that remains is to notify the public of the commercial ACL reduction.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 30, 2021.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21719 Filed 9–30–21; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 140818679–5356–02; RTID 0648–XB465]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Reopening of the Red Snapper Recreational For-Hire Fishing Season in the Gulf of Mexico

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reopening.

SUMMARY: NMFS is temporarily reopening the recreational fishing season for the Federal charter vessel/headboat (for-hire) component for red snapper in the exclusive economic zone (EEZ) of the Gulf of Mexico (Gulf) through this temporary rule. The most recent landings data for the red snapper for-hire component in the Gulf indicates the component annual catch target (ACT) for the 2021 fishing year has not yet been reached. The red snapper recreational for-hire component in the Gulf EEZ will reopen for 22 days to allow harvest of the remaining for-hire component ACT. NMFS intends this action to increase benefits to for-hire fisherman while protecting the Gulf red snapper resource by continuing to constrain harvest to the component quota.

DATES: This temporary rule is effective from 12:01 a.m., local time, on October 15, 2021, through 12:01 a.m., local time, on November 6, 2021.

FOR FURTHER INFORMATION CONTACT: Daniel Luers, NMFS Southeast Regional Office, telephone: 727–551–5719, email: *daniel.luers@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Gulf reef fish fishery, which includes red snapper, is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The FMP was prepared by the Gulf of

Mexico Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The final rule implementing Amendment 40 to the FMP established two components within the recreational sector fishing for Gulf red snapper: The private angling component, and the Federal for-hire component (80 FR 22422, April 22, 2015). Amendment 40 also allocated the red snapper recreational ACL (recreational quota) between the components and established separate seasonal closures for the two components. The Federal for-hire component's red snapper annual catch target (ACT) is 9 percent below the for-hire component quota (85 FR 9684, February 20, 2020; 50 CFR 622.41(q)(2)(iii)(B)). The measures in Amendment 40 were subsequently extended indefinitely through Amendment 45 to the FMP (81 FR 86971; December 2, 2016).

The red snapper for-hire component seasonal closure is projected from the component ACT. Projecting the for-hire component's seasonal closure using the ACT reduces the likelihood of the harvest exceeding the component quota and the total recreational quota.

All weights described in this temporary rule are in round weight.

The Federal for-hire component 2021 ACT for red snapper in the Gulf EEZ is 2.848 million lb (1.292 million kg) (50 CFR 622.41(q)(2)(iii)(B)).

The 2021 Federal Gulf red snapper for-hire fishing season was previously determined to be 63 days based on NMFS' projection of the date landings were expected to reach the component ACT. For details about the calculation of the projection for 2021, see *https://www.fisheries.noaa.gov/southeast/sustainable-fisheries/gulf-mexico-recreational-red-snapper-management.* NMFS previously announced in the **Federal Register** that the 2021 recreational season for the Federal for-hire component would begin at 12:01 a.m., local time, on June 1, 2021, and close at 12:01 a.m., local time, on August 3, 2021 (86 FR 15430; March 23, 2021).

However, the most recent landings data for the Gulf red snapper for-hire component plus projected landings for data that is not yet available indicate that approximately 670,113 lb (303,958 kg) of the for-hire component ACT remains. NMFS projects that this amount of the remaining ACT will be harvested in 22 days.

Therefore, in accordance with 50 CFR 622.8(c), NMFS reopens the Gulf red snapper Federal for-hire component for 22 days to allow the component ACT to be harvested. The recreational season for the Federal for-hire component will reopen at 12:01 a.m., local time, on October 15, 2021, and close at 12:01 a.m., local time, on November 6, 2021. When the for-hire component closes again on November 6, 2021, the bag and possession limits for red snapper for Federal for-hire vessels are zero. When the Federal for-hire component is closed, these bag and possession limits apply in the Gulf on board a vessel for which a valid Federal for-hire permit for Gulf reef fish has been issued, without regard to where such species were harvested, *i.e.,* in state or Federal waters. In addition, a person aboard a vessel that has been issued a charter vessel/headboat permit for Gulf reef fish any time during the fishing year may not harvest or possess red snapper in or from the Gulf EEZ when the Federal charter vessel/headboat component is closed.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is taken under 50 CFR 622.8(c), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866, and other applicable laws.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment is unnecessary and contrary to the public interest.

Such procedures are unnecessary because the regulation at 50 CFR 622.8(c) has already has already been subject to notice and public comment, and all that remains is to notify the public that additional harvest is available under the established Federal for-hire component ACT, and therefore, the Federal for-hire component for Gulf red snapper will reopen. Such procedures are contrary to the public interest because many for-hire operations book trips for clients in advance and require as much notice as NMFS is able to provide to adjust their business plans to account for the reopening of the fishing season. Additionally, a reopening of the component in October instead of later in the fishing year is preferable because it may reduce the likelihood of encountering inclement weather that generally occurs with greater frequency later in the fishing year.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 30, 2021.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21674 Filed 9–30–21; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RTID 0648–XB483

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS is transferring 140 metric tons (mt) of Atlantic bluefin tuna (BFT) quota from the Reserve category to the General category. This action is intended to provide further opportunities for General category fishermen to participate in the October through November General category fishery, based on consideration of the regulatory determination criteria regarding inseason adjustments. This action would affect Atlantic Tunas General category (commercial) permitted vessels and Highly Migratory Species (HMS) Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT.

DATES: Effective October 4, 2021, through November 30, 2021.

FOR FURTHER INFORMATION CONTACT: Larry Redd, Jr., 301–427–8503, Nicholas Velseboer, 978–281–9260, or Lauren Latchford, 301–427–8503.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries, including BFT fisheries, are managed under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan (FMP) and its amendments are implemented by regulations at 50 CFR part 635. Section 635.27 divides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic

fishing categories, per the allocations established in the 2006 Consolidated HMS FMP and its amendments. NMFS is required under the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

The baseline General and Reserve category quotas are 555.7 mt and 29.5 mt, respectively. The General category baseline subquota for the October through November time-period is 72.2 mt. Under the regulations, any unused General category quota rolls forward from one time-period to the next and is available for use in subsequent time-periods. To date for 2021, NMFS has published several actions that adjusted the Reserve category quota (86 FR 8717, February 9, 2021; 86 FR 43420, August 9, 2021; 86 FR 51016, September 14, 2021). NMFS recently also recently adjusted the Reserve category quota using the allowable underharvest from 2020 to 2021. The current adjusted Reserve category quota is 151.5 mt.

Transfer of 140 mt From the Reserve Category to the General Category

Under § 635.27(a)(9), NMFS has the authority to transfer quota among fishing categories or subcategories after considering determination criteria provided under § 635.27(a)(8). NMFS has considered all of the relevant determination criteria and their applicability to this inseason quota transfer. These considerations include, but are not limited to, the following:

Regarding the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(8)(i)), biological samples collected from BFT landed by General category fishermen and provided by tuna dealers provide NMFS with valuable parts and data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. Additional opportunity to land BFT in the General category would support the continued collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS also considered the catches of the General category quota to date (including during the summer/fall and winter fisheries in the last several years) and the likelihood of closure of that segment of the fishery if no adjustment is made (§ 635.27(a)(8)(ii) and (ix)). The General category October through November time-period subquota has not yet been exceeded, but without a quota transfer at this time, NMFS would likely need to close the General category fishery shortly, and participants would have to stop BFT fishing activities while commercial-sized BFT remain available in the areas where General category permitted vessels operate at this time of year. Transferring 140 mt of quota from the Reserve category for the October through November 2021 subquota time-period would provide limited additional opportunities to harvest the U.S. BFT quota while avoiding exceeding it. NMFS also took into consideration a recently published final rule that would set restricted-fishing days for the General category during the months of September through November 2021 (86 FR 43421, August 9, 2021). That rule would further increase the likelihood that the fishery would remain open throughout the subperiod and year.

Regarding the projected ability of the vessels fishing under the General category quota to harvest the additional amount of BFT quota transferred before the end of the fishing year (§ 635.27(a)(8)(iii)), NMFS considered General category landings over the last several years and landings to date this year. Landings are highly variable and depend on access to commercial-sized BFT and fishing conditions, among other factors, such as the restrictions that some dealers placed on their purchases of BFT from General category participants this year. In the unlikely event that any of this quota is unused by November 30, such quota will roll forward to the next subquota time period within the calendar year (*i.e.,* to the December period), and NMFS anticipates that it would be used before the end of the fishing year. Thus, this quota transfer would allow fishermen to take advantage of the availability of fish on the fishing grounds and provide a reasonable opportunity to harvest available U.S. BFT quota.

NMFS also considered the estimated amounts by which quotas for other gear categories of the BFT fishery might be exceeded (§ 635.27(a)(8)(iv)) and the ability to account for all 2021 landings and dead discards. In the last several years, total U.S. BFT landings have been below the available U.S. quota such that the United States has carried forward the maximum amount of underharvest allowed by ICCAT from one year to the next. NMFS recently took such an action to carryover the allowable 127.3 mt of underharvest from 2020 to 2021. NMFS will need to account for 2021 landings and dead discards within the adjusted U.S. quota, consistent with ICCAT recommendations, and anticipates having sufficient quota to do that.

NMFS also considered the effects of the adjustment on the BFT stock and the effects of the transfer on accomplishing the objectives of the FMP (§ 635.27(a)(8)(v) and (vi)). This transfer would be consistent with established quotas and subquotas, which are implemented consistent with ICCAT recommendations (established in Recommendation 17–06 and maintained in Recommendation 20–06), ATCA, and the objectives of the 2006 Consolidated HMS FMP and amendments. In establishing these quotas and subquotas and associated management measures, ICCAT and NMFS considered the best scientific information available, objectives for stock management and status, and effects on the stock. This quota transfer is in line with the established management measures and stock status determinations. Another principal consideration is the objective of providing opportunities to harvest the available General category quota without exceeding the annual quota, based on the objectives of the 2006 Consolidated HMS FMP and its amendments, including to achieve optimum yield on a continuing basis and to allow all permit categories a reasonable opportunity to harvest available BFT quota allocations (related to § 635.27(a)(8)(x)). Specific to the General category, this includes providing opportunities equitably across all time-periods.

Given these considerations, NMFS is transferring 140 mt of the available 151.5 mt of Reserve category quota to the General category. Therefore, NMFS adjusts the General category October through November 2021 subquota to 212.2 mt and adjusts the Reserve category quota to 11.5 mt. The General category fishery will remain open until November 30, 2021, or until the adjusted General category quota is reached, whichever comes first.

Monitoring and Reporting

NMFS will continue to monitor the BFT fishery closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustments, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General category and HMS Charter/Headboat vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov* or by using the HMS Catch Reporting app or calling

(888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional adjustments (*e.g.,* quota adjustment, daily retention limit adjustment, or closure) are necessary to ensure available quota is not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281–9260, or access *hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act and regulations at 50 CFR part 635 and is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and its amendments provide for inseason retention limit adjustments to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Affording prior notice and opportunity for public comment to implement the quota transfer for the October through November 2021 time-period is contrary to the public interest as such a delay would likely fail to prevent the closure of the General category fishery when the baseline subquota for the October through November time-period is met and the need to re-open the fishery, with attendant costs to the fishery, including administrative costs and lost fishing opportunities. The delay would preclude the fishery from harvesting BFT that are available on the fishing grounds and that might otherwise become unavailable during a delay. This action does not raise conservation and management concerns. Transferring quota from the Reserve category to the General category does not affect the overall U.S. BFT quota, and the adjustment would have a minimal risk of exceeding the ICCAT-allocated quota. NMFS notes that the public had an opportunity to comment on the underlying rulemakings that established the U.S. BFT quota and the inseason adjustment criteria. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For these reasons, there also is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effective date.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: September 30, 2021.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21718 Filed 9–30–21; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 201209–0332; RTID 0648–XB484]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfers From VA to RI and NJ to MA

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification; quota transfers.

SUMMARY: NMFS announces that the Commonwealth of Virginia and the State of New Jersey are transferring a portion of their 2021 commercial bluefish quota to the State of Rhode Island and the Commonwealth of Massachusetts, respectively. These quota adjustments are necessary to comply with the Atlantic Bluefish Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial bluefish quotas for Virginia, Rhode Island, New Jersey, and Massachusetts.

DATES: Effective September 30, 2021, through December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Laura Hansen, Fishery Management Specialist, (978) 281–9225.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.162, and the final 2021 allocations were published on December 16, 2020 (85 FR 81421).

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan (FMP) published in the **Federal Register** on July 26, 2000 (65 FR 45844), and provided a mechanism for transferring bluefish quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval to transfer or combine bluefish commercial quota under § 648.162(e)(1)(i) through (iii). The Regional Administrator must approve any such transfer based on the criteria in § 648.162(e). In evaluating requests to transfer a quota or combine quotas, the Regional Administrator shall consider whether: The transfer or combinations would preclude the overall annual quota from being fully harvested; the transfer addresses an unforeseen variation or contingency in the fishery; and the transfer is consistent with the objectives of the FMP and the Magnuson-Stevens Act.

Virginia is transferring 20,000 lb (9,072 kg) to Rhode Island, and New Jersey is transferring 50,000 lb (22,680 kg) to Massachusetts through mutual agreement of the states. These transfers were requested to ensure that Rhode Island and Massachusetts would not exceed their 2021 state quota. The revised bluefish quotas for 2021 are: Virginia, 238,800 lb (108,318 kg); Rhode Island, 223,434 lb (101,348 kg); New Jersey, 320,082 lb (145,187 kg); and, Massachusetts, 235,904 lb (107,004 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 30, 2021.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21676 Filed 9–30–21; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 86, No. 190
Tuesday, October 5, 2021

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 203 and 206

[Docket No. FR–6151–A–01]

RIN 2502–AJ51

Adjustable Rate Mortgages: Transitioning From LIBOR to Alternate Indices

AGENCY: Office of Housing, HUD.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The majority of adjustable rate mortgages (ARMs) insured by the Federal Housing Administration (FHA) are based on the London Interbank Offered Rate (LIBOR), an interest rate index that is likely to become uncertain after December 31, 2021 and no longer be published after June 30, 2023. In reaction to this uncertainty, HUD has begun to transition away from LIBOR as an approved interest rate index. HUD has also approved the Secured Overnight Financing Rate (SOFR) index in some circumstances.

HUD recognizes there may be operational difficulties for mortgagees to implement the change to a new index. HUD is considering a rule that would address a Secretary-approved replacement index for existing loans and provide for a transition date consistent with the cessation of the LIBOR index. HUD is also considering replacing the LIBOR index with the SOFR interest rate index, with a compatible spread adjustment to minimize the impact of the replacement index for legacy ARMs.

DATES: Public comment due date: December 6, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this advanced notice of proposed rulemaking to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–402–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Information Relay Service, toll-free, at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joshua J. Miller, Senior Advisor to the Deputy Assistant Secretary for Single Family Housing, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410–8000; telephone number 202–402–5052 (this is not a toll-free number). Hearing- and speech-impaired persons may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Provisions

Section 251(a) of the National Housing Act (NHA) (12 U.S.C. 1715z–16(a)) authorizes HUD to insure ARMs, and provides that adjustments to the interest rate shall correspond to a specified interest rate index approved in regulations by the Secretary, which must be readily accessible to mortgagors from generally available published sources. For Home Equity Conversion Mortgages (HECM or reverse mortgages), Section 255(d) of the National Housing Act (12 U.S.C. 1715z–20(d)) authorizes FHA to insure variable rate HECMs and impose additional eligibility requirements on HECMs, which could include requirements for HECM ARMs.

B. Forward Mortgages

HUD initially provided for mortgage insurance of ARMs for single family forward mortgages under part 203 and for part 234 condominium mortgages in 1984 (49 FR 23580, June 6, 1984). As provided in the statute at this time, such mortgages had to be adjusted annually, and there was a 1 percent cap on annual adjustments and an overall cap of 5 percent above the initial interest rate over the term of the mortgage. The index initially used was the Constant Maturity Treasury (CMT) rate. Subsequent to the statutory change allowing HUD to insure ARMs for mortgages that have fixed interest rates for 3 years or more and are not subject to interest rate caps if the interest rate remains fixed for more than 3 years, HUD, in 2004, issued a rule providing mortgage insurance for forward ARMs with rates first adjustable 1 year, 3 years, 5 years, 7 years, and 10 years from the date of the mortgagor's first debt service payment (69 FR 11500, March 10, 2004, codified at 24 CFR 203.49(d)).

Under the 2004 rule, for 1-year, and 3-year, and 5-year ARMs, each adjustment provided for a cap in either direction of one percentage point from

the interest rate in effect for the period immediately preceding the adjustment. For the life of the mortgage the overall 5 percent cap remained from the initial contract rate. For 7-year and 10-year ARMs, HUD raised the per-adjustment cap to 2 percent of the rate in effect for the immediately preceding period, and the life-of-mortgage cap to 6 percent from the initial contract rate. In all cases, changes of more than these amounts could not be carried over for inclusion in an adjustment for the subsequent year. In 2005, HUD revised the regulation to allow for annual adjustments of 2 percent for, and a life-of-mortgage cap of 6 percent for 5-year ARMs in 2005 (70 FR 16080, March 29, 2005), conforming 5-year ARMs to HUD's 7-year and 10-year ARM products.

In 2007, HUD added the LIBOR, along with the CMT, as acceptable indices for ARM adjustments for its ARM products. For forward mortgages, the applicability of these indices is codified at 24 CFR 203.49. The cap on 1-year and 3-year ARMs (no more than 1 percent in either direction per single adjustment, with a 5 percent from initial contract rate cap over the life of the loan) is codified at § 203.49(f)(1). The caps for 5-year, 7-year and 10-year ARMs (2 percent in either direction per adjustment, with a six percent from initial contract rate cap for the life of the mortgage) are located at § 203.49(f)(2). HUD also created model note documents for forward mortgages, which may have varied over the years. The 2015 model note contains provisions for the substitution of an index by the note holder based on ''comparable information,'' should the index specified in the note become unavailable.

C. Reverse Mortgages or HECMs

In 1989, the Home Equity Conversion Mortgage program rule provided for capped and uncapped ARMs (54 FR 24822, June 9, 1989). For capped HECM ARMs, the rule retained the 5 percentage point life-of-mortgage limit on interest rate increases and decreases in § 203.49, but increased the annual limit on rate increases and decreases from 1 percentage point to 2 percentage points (54 FR 24825). The rule also provided for an ARM that set a maximum interest rate that could be charged without a cap on monthly or annual increases or decreases. *Id.* In 2007, in the same rule in which LIBOR was added for forward mortgages, HUD added the LIBOR as an acceptable index for HECM ARM adjustments (72 FR 40048, July 20, 2007); these changes are codified in current §§ 206.3 (definitions) and 206.21 (interest rate). HUD's model HECM notes may have varied over the years, but the 2015 version contains provisions for the substitution of a Secretary-prescribed index, should the index specified in the note become unavailable.

For the capped option at § 206.21(b)(1), the interest rate cap structure is the same as provided in forward mortgages under § 203.49(a), (b), (d), and (f), except that under § 203.49(d), the reference to first debt service payment means the date of closing in the HECM context, and under § 203.49(f)(1), the cap on adjustments for 1-year and 3-year mortgages is 2 percentage points in the HECM context. Section 206.21(b)(1)(ii) applies the LIBOR and CMT index options in the same manner as forward mortgages at § 203.49(b) for both the capped and uncapped options. In addition, the uncapped option at § 206.21(b)(2) includes options to adjust based on the one-month CMT or one-month LIBOR index. Section 206.21(b)(1)(iii) also includes ARM interest rate adjustment options for HECMs in the same manner as forward mortgages at § 203.49(d).

On March 11, 2021, in Mortgagee Letter 2021–08, HUD removed LIBOR as an approved index for new HECM ARM originations and approved the SOFR index for new annually adjusted HECM ARM originations. (As explained in that Mortgagee Letter, the changes made by the Mortgagee Letter revised the existing HECM regulations pursuant to the authority granted in the Reverse Mortgage Stabilization Act of 2013 (Pub. L. 113–29; Section 255(h)(3) of the National Housing Act (12 U.S.C. 1715z–20(h)(3)). A mortgagee may set rates using CMT or SOFR for annually adjusted HECM ARMs and CMT only for monthly adjusted HECM ARMs. Also, among other changes to the ARM requirements in the Mortgagee Letter, HUD published revised model mortgage documents with ''fallback'' language intended to address future interest rate index transition events. This language was modeled after the Alternative Reference Rates Committee's (ARRC [1]) published fallback language for residential adjustable rate mortgages.[2]

D. Phase-Out of LIBOR

The financial industry is seeking to transition from LIBOR given its increasing unreliability. The publication of US Dollar (USD) LIBOR tenors of one-month and one-year was recently extended to June 30, 2023. [3] However, the announcements included supervisory guidance encouraging banks to stop new USD LIBOR issuances by the end of 2021.[4]

As noted by the Financial Stability Oversight Council, the scarcity of underlying transactions makes LIBOR potentially unsustainable, as many banks have grown uncomfortable in providing submissions based on expert judgment and may eventually choose to stop submitting altogether. Two banks stopped submitting to USD LIBOR in 2016.[5] The relatively small number of transactions underpinning LIBOR has been driven by changing market structure, regulatory capital, and liquidity requirements as well as changes in bank risk appetite for short-term funding, creating uncertainty as to the integrity of the rate. In July of 2017, the U.K. Financial Conduct Authority (FCA), the financial regulator of LIBOR, announced that it will no longer persuade or compel contributing banks to submit rates used to calculate LIBOR after December 31, 2021, which will further heighten the uncertainty of LIBOR.[6] On November 30, 2020, the Federal Reserve Board announced that regulators had proposed clear end dates for the USD LIBOR immediately following the December 31, 2021 publication for the one week and two month USD LIBOR settings, and the June 30, 2023 publication for other USD LIBOR tenors to ease transition away from LIBOR.[7]

[1] The Alternative Reference Rates Committee (ARRC) is a group of private-market participants convened by the Federal Reserve Board and the New York Fed to help ensure a successful transition from U.S. dollar (USD) LIBOR to a more robust reference rate, its recommended alternative, the Secured Overnight Financing Rate (SOFR). The ARRC is comprised of a diverse set of private-sector entities that have an important presence in markets affected by USD LIBOR and a wide array of official-sector entities, including banking and financial sector regulators, as ex-officio members. *https://www.newyorkfed.org/arrc.*

[2] *ARRC Recommendations Regarding More Robust LIBOR Fallback Contract Language for New Closed-End, Residential Adjustable Rate Mortgages,* newyorkfed.org (Nov. 15, 2019), *https://www.newyorkfed.org/medialibrary/Microsites/arrc/files/2019/ARM_Fallback_Language.pdf.*

[3] Statement on LIBOR Transition—November 30, 2020—*https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20201130a1.pdf.*

[4] *ARRC Applauds Major Milestone in Transition from U.S. Dollar LIBOR,* Alternative Reference Rates Comm. (Nov. 23, 2020), *https://www.newyorkfed.org/medialibrary/Microsites/arrc/files/2020/ARRC_Press_Release_Applauds_Milestone_Transition_US_Dollar_LIBOR.pdf.*

[5] *See Frequently Asked Questions,* Alternative Reference Rates Comm. (Jan. 31, 2019), *https://www.sec.gov/spotlight/fixed-income-advisory-committee/arrc-faqs-041519.pdf.*

[6] Andrew Bailey, *The Future of LIBOR,* Fin. Conduct Authority (July 27, 2017), *https://www.fca.org.uk/news/speeches/the-future-of-libor.*

[7] See *Federal Reserve Board Welcomes and Supports Release of Proposal and Supervisory Statements that Would Enable Clear End Date for U.S. Dollar (USD) LIBOR and Would Promote the Safety and Soundness of the Financial System,* Board of Governors of the Federal Reserve System

Continued

In December 2020, the ICE Benchmark Administration Limited (IBA) announced a consultation on its intention to cease publication of certain LIBOR tenors. On March 5, 2021, the IBA published the feedback to its consultation, announcing it will cease publication of the one month and one year USD LIBOR immediately following the LIBOR publication on June 30, 2023.[8]

With the uncertainty of LIBOR and upcoming phase-out, mortgagees must prepare to select a new replacement interest rate index for existing ARM contracts. The ARRC, a group of private market participants convened by the Federal Reserve Board and the Federal Reserve Bank of New York to ensure the transition from USD LIBOR to a reliable reference rate, has recommended selection of the SOFR for use in new USD contracts.[9] SOFR is published by the Federal Reserve Bank of New York in cooperation with the Office of Financial Research, an independent bureau with the U.S. Department of the Treasury, and ''. . . is a broad measure of the cost of borrowing cash overnight collateralized by U.S. Treasury securities in the repurchase agreement (repo) market.'' [10] It is anticipated that a spread-adjusted SOFR will be published to minimize the impact of the transition on legacy ARMs and other LIBOR-based contracts.

According to the ARRC, ''SOFR is suitable to be used across a broad range of financial products, including but not limited to, derivatives (listed, cleared, and bilateral-OTC), and many variable rate cash products that have historically referenced LIBOR.'' [11]

II. This Advanced Notice of Proposed Rulemaking

HUD intends to issue a proposed rulemaking to remove LIBOR as an available interest rate index and provide a new available index for periodic adjustments for newly-insured forward and HECM ARMs, to recommend a replacement comparable index for existing forward mortgages, and to implement a Secretary-prescribed replacement index for existing HECMs. Upon the cessation of LIBOR, a mortgagee would be able to replace LIBOR with the spread adjusted index approved by HUD. HUD intends to propose two separate transitions: A transition to replace LIBOR for existing mortgages and a transition to remove LIBOR and approve a new index for new forward originations.

HUD recognizes that existing mortgages and new originations present different challenges. For existing mortgages, the contract (*i.e.,* loan documents) for each loan governs the terms of the loan. As long as the LIBOR index is available, mortgagees may not have flexibility under their loan contracts to substitute a new index without a modification or a new contract, depending on which FHA model note form was used. Under some existing ARM contracts, a lender may only use a substitute index when the initial index ''is no longer available.'' Once the publication of the one-month and 12-month LIBOR cease to be published, mortgagees will be able to use a replacement index and provide notice to the borrower of the replacement, in accordance with the terms of the loan documents. HUD's goal is to avoid disrupting existing loans or causing unnecessary confusion during the transition. HUD also seeks to transition to an index which will best serve the goals of HUD's forward and reverse mortgage programs. HUD intends that changes made to the existing forward mortgage program and reverse mortgage program occur simultaneously. While HUD has already made certain regulatory amendments to the HECM ARM origination requirements in Mortgagee Letter 2021–08 pursuant to the authority granted in the Reverse Mortgage Stabilization Act of 2013 (Pub. L. 113–29; NHA section 255(h)(3)(12 U.S.C. 1715z–20(h)(3)), HUD will codify those requirements in the rulemaking. Also, HUD did not address the LIBOR transition for legacy HECM contracts in Mortgagee Letter 2021–08.

HUD seeks public comment on the best method of making such a transition for legacy loans and new originations. For each of the questions asked below, and regarding any other issue, HUD is interested specifically in public comment on whether and how HUD should take a different course of action for HECM and forward mortgages. While the following lists are not exhaustive, HUD is particularly interested in comments on the following questions:

Questions Regarding Replacing LIBOR for Existing Loans

Question for Comment 1: What alternative index would be preferred and/or what alternative index would be considered ''comparable'' to LIBOR?

Question for Comment 2: Will servicing mortgagees seek to replace the interest rate index from LIBOR prior to the last one-month and twelve-month USD LIBOR publication on June 30, 2023?

Question for Comment 3: What documentation would servicing mortgagees need to modify in moving to an alternative index? Would this documentation need to be modified before or after the Transition date, or both?

Question for Comment 4: How long would servicing mortgagees need to transition technology to an alternative index?

Question for Comment 5: How long would servicing mortgagees need to transition operations to an alternative index?

Question for Comment 6: What communication plan is being considered from servicing mortgagees to borrowers and how should borrower protections be addressed for this population?

Question for Comment 7: Do servicing mortgagees have any alternate proposals to negotiating new agreements?

Question for Comment 8: If servicing mortgagees intend to replace the index for existing ARMs prior to LIBOR ceasing to be published, how long would servicing mortgagees need to negotiate new agreements with borrowers to incorporate a new interest rate including providing a revised annual total cost of the loan?

Question for Comment 9: Do industry partners anticipate any concerns over a single interest rate change date for all existing mortgages?

Question for Comment 10: What methods of communication would servicing mortgagees expect to be most beneficial in communicating with borrowers on this index change?

Question for Comment 11: What issues do servicing mortgagees anticipate regarding HECM principal limit growth resulting from an index change?

Questions Regarding Removal of LIBOR and Establishing a New Index for New Originations

Question for Comment 12: What alternative index would be preferred?

Question for Comment 13: What tenure rate(s) would be preferred for the alternative index?

(Nov. 30, 2020), *https://www.federalreserve.gov/newsevents/pressreleases/bcreg20201130b.htm.*

[8] *ICE LIBOR® Feedback Statement on Consultation on Potential Cessation,* ICE Benchmark Admin. (March 5, 2021), *https://www.theice.com/publicdocs/ICE_LIBOR_feedback_statement_on_consultation_on_potential_cessation.pdf.*

[9] *About,* Alternative Reference Rates Comm., *https://www.newyorkfed.org/arrc/about* (last visited June 10, 2021).

[10] *Transition from LIBOR,* Alternative Reference Rates Comm., *https://www.newyorkfed.org/arrc/sofr-transition* (last visited June 10, 2021).

[11] *Frequently Asked Questions,* Alternative Reference Rates Comm (April 21, 2021), *https://www.newyorkfed.org/medialibrary/Microsites/arrc/files/ARRC-faq.pdf.*

Question for Comment 14: How many tenure rate(s) would be needed for the alternative index?

III. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to, ''identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public.''

The current rules providing for the use of LIBOR as an index for interest rate adjustments for ARMs in HUD's forward and reverse mortgage insurance programs are becoming obsolete as LIBOR is in the process of being phased out. HUD is required by statute to approve by regulation interest rate indexes for its forward ARM products. HUD must also amend by regulation its permitted interest rate indices for HECM ARM products and permit lenders to transition from LIBOR to a replacement index for existing HECM ARMs. Therefore, this rule is necessary to avoid HUD's rules on ARMs from becoming obsolete as well as to avoid the risk of financial harm for ARM lenders, borrowers, and the larger ARM market.

This advanced notice of proposed rulemaking has been reviewed by OMB. As a result of this review, OMB determined that this advanced notice of proposed rulemaking is not significant under Executive Order 12866 and Executive Order 13563.

Environmental Review

This advanced notice of proposed rulemaking consists of ''[s]tatutorily required and/or discretionary establishment and review of interest rates, loan limits, building cost limits, prototype costs, fair market rent schedules, HUD-determined prevailing wage rates, income limits and exclusions with regard to eligibility for or calculation of HUD housing assistance or rental assistance, and similar rate and cost determinations and related external administrative or fiscal requirements or procedures which do not constitute a development decision that affects the physical condition of specific project areas or building sites.'' Accordingly, under 24 CFR 50.19(c)(6), this advanced notice of proposed rulemaking is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Lopa P. Kolluri,

Principal Deputy Assistant Secretary, Office of Housing—Federal Housing Administration.

[FR Doc. 2021–21512 Filed 10–4–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2021–0582]

RIN 1625–AA08

Notice of Proposed Rule Making; Atlantic Ocean, Key West, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary special local regulation for the RWO Offshore World Championship on November 10, 12 and 14, 2021. This action is necessary to ensure safety of life on navigable waters on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance in Key West, FL. This proposed rulemaking would prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within the regulated area without permission from the Captain of the Port Key West or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before October 20, 2021.

ADDRESSES: You may submit comments identified by docket number USCG–2021–0582 using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Ensign Vera Max, Sector Key West Waterways Management Division, Coast Guard; telephone (305) 292–8768, email *SKWWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On May 7, 2021, Race World Offshore notified the Coast Guard that it will be conducting a high speed boat race from 9:30 a.m. to 4:30 p.m. on November 10, 12, and 14, 2021. Approximately 50 participants and 200 spectator craft will attend the event, which will take place in the Atlantic Ocean, off the tip of Key West, Florida, on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance in Key West, FL. The Captain of the Port Key West has determined the potential hazards associated with the high speed boat race would be a safety concern for the participants, participant vessels, and the general public.

The purpose of this rulemaking is to protect event participants, spectators, and vessels on the navigable waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70041.

The Coast Guard is issuing this notice of proposed rulemaking (NPRM) with a 15-day prior notice and opportunity to comment pursuant to section (b)(3) of the Administrative Procedure Act (APA) (5 U.S.C. 553). This provision authorizes an agency to publish a rule in less than 30 days before its effective date for ''good cause found and published with the rule.'' Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for publishing this NPRM with a 15-day comment period because it is impracticable to provide a 30-day comment period because we must establish this safety zone by November 10, 2021. A 15-day comment period would allow the Coast Guard to provide for public notice and comment, but also update the proposed regulation soon enough that the length of the notice and comment period does not compromise safety.

III. Discussion of Proposed Rule

The COTP Key West proposes to establish a temporary special local regulation from 9:30 a.m. until 4:30 p.m. each day on November 10, 12, and 14, 2021. The proposed special local regulation would consist of two regulated areas: (1) A race and safety buffer area and (2) a spectator area. These areas would prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within the race area or buffer zone and prohibits vessels from transiting at speeds that cause wake within the spectator area, unless authorized by the Captain of the Port Key West or a designated representative. The special local regulation would cover all navigable waters in the Atlantic Ocean, off the tip of Key West, Florida, on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the location, duration, and time-of-day of the regulated area. Although persons and vessels may not enter, transit through, anchor in, or remain within the area without authorization from the COTP or a designated representative, they will be able to safely transit around the area. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the area, and the rule would allow vessels to seek permission to enter the area between race heats.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a temporary special local regulation for a 7 hour duration on 3 days that would prohibit entry into the race area or buffer zone, and prohibit vessels from transiting at speeds that cause wake within the spectator area. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the

person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *https://www.regulations.gov/privacyNotice.*

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add a temporary § 100.T799–0582 to read as follows:

§ 100.T799–0582 Special Local Regulation; RWO World Championship, Key West, FL.

(a) *Locations.* The following regulated areas are established as special local regulations. All coordinates are North American Datum 1983.

(1) *Race and Safety Buffer Area.* Waters of the Atlantic Ocean of Key West, FL that are encompassed within the following points: Starting at Point 1 in position 24°32.506′ N, 81°49.984′ W; thence southwest to Point 2 in position 24°32.455′ N, 81°49.040′ W; thence northwest to Point 3 in position 24°32.559′ N, 81°49.584′ W; thence northwest to Point 4 in position 24°32.608′ N, 81°49.628′ W; thence northwest to Point 5 in position 24°33.095′ N, 81°49.265′ W; thence northeast to Point 6 in position 24°33.518′ N, 81°48.902′ W; thence northeast to Point 7 in position 24°33.908′ N, 81°48.448′ W; thence east to Point 8 in position 24°33.898′ N, 81°48.364′ W; thence southeast back to origin.

(2) *Spectator Area.* All waters of the Atlantic Ocean in Key West, FL that are encompassed within the following points: Starting at Point 1 in position 24°33.123′ N, 81°49.290′ W; thence northeast to Point 2 in position 24°33.545′ N, 81°48.923′ W; thence east to Point 3 in position 24°33.518′ N, 81°48.902′ W thence southwest to point 4 in position 24°33.095′ N, 81°49.265′ W thence west back to origin.

(b) *Definition.* As used in this section, the term ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Key West in the enforcement of the safety zone.

(c) *Regulations.*

(1) All non-participant persons and vessels, except those persons and vessels participating in the high-speed boat races, are prohibited from entering, transiting through, anchoring in, or remaining within the regulated areas described in paragraph (a) of this section unless authorized by the Captain of the Port Key West or their designated representative.

(2) All persons are prohibited from entering the water or swimming in the spectator area described in paragraph (a)(2) of this section.

(3) All vessels are prohibited from transiting at speeds that cause wake within the spectator area described in paragraph (a)(2) of this section.

(4) To seek permission to enter, contact the Captain of the Port Key West or a designated representative by telephone at (305) 433–0954, or via VHF radio on channel 16. If authorization is granted by the Captain of the Port Key West or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Key West or a designated representative

(5) The Coast Guard will provide notice of the regulated area by Broadcast Notice to Mariners and on-scene designated representatives.

(d) *Enforcement Period.* This section will be enforced from 9:30 a.m. until 4:30 p.m. each day on November 10, 12, and 14, 2021.

Dated: September 29, 2021.

A. Chamie,

Captain, U.S. Coast Guard, Captain of the Port Key West.

[FR Doc. 2021–21575 Filed 10–4–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[ED–2021–OESE–0115]

Request for Information Regarding the Implementation of Maintenance of Equity Provisions in the American Rescue Plan Act of 2021

AGENCY: Office of Elementary and Secondary Education, U.S. Department of Education.

ACTION: Request for information.

SUMMARY: The U.S. Department of Education (Department) is requesting information in the form of written comments regarding implementation of the statutory requirements for the American Rescue Plan Elementary and Secondary School Emergency Relief (ARP ESSER) Fund, under the American Rescue Plan (ARP) Act of 2021, that each State educational agency (SEA) and each local educational agency (LEA) that receives ARP ESSER funds maintain equity. Information received through this request may be used to assist the Department in preparing further guidance, providing technical assistance, engaging in potential rulemaking, and developing other resources.

DATES: We must receive your comments on or before November 4, 2021.

ADDRESSES: Submit your response to this request for information (RFI) through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive

duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

Federal eRulemaking Portal: Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ.''

Postal Mail, Commercial Delivery, or Hand Delivery: If you mail or deliver your comments in response to the request for information, address them to U.S. Department of Education, 400 Maryland Avenue SW, Room 3W113, Washington, DC 20202. Mailed comments must be postmarked by November 4, 2021, to be accepted.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov*. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

This is a request for information only. This RFI is not a request for proposals (RFP) or a promise to issue an RFP or a notice inviting applications. This RFI does not commit the Department to contract for any supply or service whatsoever. Further, we are not seeking proposals and will not accept unsolicited proposals. The Department will not pay for any information or administrative costs that you may incur in responding to this RFI. The documents and information submitted in response to this RFI become the property of the U.S. Government and will not be returned.

FOR FURTHER INFORMATION CONTACT: Britt Jung, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. Telephone: (202) 453–5563. Email: *ESSERF@ed.gov*.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Background: The ARP Act provides a total of nearly $122 billion via the ARP ESSER Fund to SEAs and LEAs to help schools return safely to in-person instruction; sustain the safe operation of schools; and address the social, emotional, mental health, and academic impacts of the COVID–19 pandemic on the Nation's students.

Section 2004 of the ARP Act includes maintenance of equity (MOEquity) provisions that are a condition for an SEA and LEA to receive funds under the ARP ESSER Fund. Under section 2004(b) of the ARP Act, the MOEquity provisions ensure that an SEA does not disproportionately reduce State funding in fiscal years (FYs) 2022 and 2023 for LEAs serving a large share of students from low-income families and, for the highest-poverty LEAs, does not decrease State funding below their FY 2019 level. Similarly, under section 2004(c) of the ARP Act, the MOEquity provisions ensure that each LEA safeguards its high-poverty schools from disproportionate reductions to funding and staffing.

On June 9, 2021, the Department published Frequently Asked Questions on the MOEquity requirements (which the Department updated on August 6, 2021),[1] providing detailed guidance on how each SEA and LEA can comply with the MOEquity provisions.

Since issuing the guidance, the Department has continued to engage with a wide array of stakeholders to understand the opportunities and challenges related to MOEquity implementation within the context of the coronavirus disease 2019 (COVID–19) pandemic. The Department is eager to learn from the experiences and perspectives of SEAs, LEAs, and other stakeholders. We are, therefore, issuing this RFI to invite public comment on a range of MOEquity implementation questions. At the same time, the Department is publishing elsewhere in this issue of the **Federal Register** a Notice of Proposed Requirements (NPR) that would require each SEA to make publicly available information on how each LEA in the State is maintaining fiscal and staffing equity to ensure public transparency and accountability for the implementation of the MOEquity provisions.

Invitation to Comment: The Department is committed to supporting SEAs and LEAs in implementing the ARP Act MOEquity provisions with fidelity to the law. The Department recognizes that each State's education finance system is unique and that additional guidance may be needed regarding how to apply the MOEquity requirements with fidelity in the context of specific and varied State circumstances.

To help inform its support for SEAs and LEAs in implementing the MOEquity provisions, the Department is seeking input from the public. The Department is interested in responses to the specific questions below, as well as additional information and perspectives on MOEquity implementation. Because this RFI is intended to inform further guidance and any potential rulemaking, the Department does not anticipate responding to each comment received. When responding to this RFI, please address one or more of the following questions:

1. The Department is aware that each State's K–12 education funding system is unique and that State-specific considerations may impact how an SEA implements MOEquity requirements in a manner that is both meaningful and meets the technical requirements of the ARP Act. What types of State-specific considerations (*e.g.,* funding mechanisms, definitions of revenue sources, etc.) are relevant to the implementation of the State and local MOEquity provisions? What types of barriers exist to implementing the MOEquity provisions due to the State-specific approach to education funding? How might guidance or potential rulemaking account for unique State education finance systems so that State MOEquity implementation will be consistent with the goal of maintaining equity?

2. The Department recognizes that LEAs with small enrollments may exhibit greater annual variation in per-pupil funding and other calculations based primarily on their size. How might this issue be addressed to ensure the small size of an LEA does not render year-over-year comparisons unreliable, so that State MOEquity implementation will be consistent with the goal of maintaining equity?

3. MOEquity requires comparisons of ''per-pupil funding.'' Please identify any considerations that are relevant to implementation related to enrollment data and funding sources used in determining per-pupil funding. Are there safeguards that should be considered to ensure that State-specific enrollment methodologies do not distort per-pupil funding levels (*e.g.,* the use of hold harmless provisions or rolling averages)? Since MOEquity calculations are important to inform budget allocation decisions, what data are SEAs and LEAs most likely to have available and rely on for conducting initial MOEquity calculations?

4. LEAs may be exempted from MOEquity requirements per the ARP Act based on ''exceptional or uncontrollable circumstance[s].'' What factors should the Department be aware of related to the types of exceptional or

[1] See *https://oese.ed.gov/files/2021/08/Maintenance-of-Equity-updated-FAQs_final_08.06.2021.pdf*. (Maintenance of Equity Frequently Asked Questions).

uncontrollable circumstances, both specific to FY 2022 implementation and, more generally, to ensure that such exceptions do not contradict the intent of the law and are consistent with the goal of maintaining equity?

5. The purpose of the MOEquity provisions is to ensure that schools and LEAs serving large proportions of underserved groups of students—including students from low-income families, students of color, English learners, students with disabilities, and students experiencing homelessness—receive an equitable share of State and local funds as the Nation continues to respond to the COVID–19 pandemic's impact. In light of this purpose, what other information or related issues should the Department consider to ensure that the purpose of the MOEquity provisions are achieved?

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov*. At this site you can view this document, as well as all other documents of the Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2021–21766 Filed 10–4–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED–2021–OESE–0116]

Proposed Requirement—American Rescue Plan Act Elementary and Secondary School Emergency Relief Fund

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Proposed requirement.

SUMMARY: The Department of Education (Department) proposes a requirement for the American Rescue Plan Elementary and Secondary School Emergency Relief (ARP ESSER) Fund, under the American Rescue Plan Act of 2021 (ARP Act). This requirement is intended to promote accountability and transparency and ensure that each State educational agency (SEA) and each local educational agency (LEA) meets the statutory requirement to maintain equity.

DATES: We must receive your comments on or before November 4, 2021.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ.''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about the proposed requirement, address them to U.S. Department of Education, 400 Maryland Avenue SW, Room 3W113, Washington, DC 20202.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov*. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Britt Jung, U.S. Department of Education, 400 Maryland Avenue SW, Room 3W113, Washington, DC 20202. Telephone: (202) 453–5563. Email: *ESSERF@ed.gov*.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding the proposed requirement. To ensure that your comments have maximum effect in developing the requirement, we urge you to clearly identify the specific section of the proposed requirement that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from the proposed requirement. In addition to your general comments and recommended clarifications, we seek input on (i) what demographic information (*e.g.,* poverty status, race/ethnicity, students with disabilities, and English learners) LEAs should publicly post on the schools the LEA identifies as high-poverty schools as noted in proposed requirement (a)(2) and (ii) on any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of our programs.

During and after the comment period, you may inspect all public comments about the proposed requirement by accessing *Regulations.gov*. Due to the novel coronavirus 2019 (COVID–19) pandemic, the Department buildings are currently not open to the public. However, upon reopening you may also inspect the comments in person in room 3C124, 400 Maryland Avenue SW, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

At the same time the Department is publishing this Notice of Proposed Requirement, it is publishing a Request For Information (RFI) to help inform its support for SEAs and LEAs in implementing the MOEquity provisions. Through the RFI, the Department is seeking input from the public with respect to specific questions as well as additional information and perspectives on MOEquity implementation.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other

documents in the public rulemaking record for the proposed requirement. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The ARP ESSER Fund provides a total of nearly $122 billion to SEAs and LEAs to help them safely reopen and sustain the safe operation of schools and address the impacts of the COVID–19 pandemic on the Nation's students by addressing students' academic, social, emotional, and mental health needs. As a condition of receiving the funds, each SEA and LEA must comply with multiple requirements, including the maintenance of equity (MOEquity) requirements in section 2004 of the ARP Act.

Program Authority: ARP Act of 2021, Public Law 117–2, March 11, 2021.

Proposed Requirement: This document contains one proposed requirement.

Background

The ARP Act provides a total of nearly $122 billion via the ARP ESSER Fund to SEAs and LEAs to help schools return safely to in-person instruction; sustain the safe operation of schools; and address the academic, social, emotional, and mental health impacts of the COVID–19 pandemic on the Nation's students. Section 2004 of the ARP Act includes new MOEquity provisions that are a condition for an SEA and LEA to receive funds under the ARP ESSER Fund. Under section 2004(b) of the ARP Act, the MOEquity provisions ensure that LEAs and schools serving a large share of students from low-income backgrounds do not experience a disproportionate share of reduced funding in fiscal years (FYs) 2022 and 2023, and that, for the highest-poverty LEAs, State funding is not decreased below their FY 2019 level. In addition, the MOEquity provisions ensure that each LEA safeguards its high-poverty schools from disproportionate cuts to funding and staffing. On August 6, 2021, the Department issued a Dear Colleague Letter (DCL) to Chief State School Officers and District School Superintendents emphasizing the importance of maintaining equity and addressing specific implementation challenges for fiscal year 2022. On August 6, the Department also issued updated Frequently Asked Questions on the Maintenance of Equity Requirements (MOEquity FAQs) [1] providing detailed guidance on how each SEA and LEA can maintain equity and comply with the MOEquity provisions. In that guidance, the Department indicated that SEAs and LEAs should consider making MOEquity data publicly available.

In Appendix A to the MOEquity frequently asked questions issued in June 2021 and updated on August 6, 2021, the Department asked each SEA to report to it baseline and initial data on the State's high-need and highest-poverty LEAs, the statewide per-pupil amount of State funds provided to all LEAs in FYs 2021 and 2022 as well as the per-pupil amount provided to each high-need LEA in those years, the per-pupil amount of State funds provided to each highest-poverty LEA in FYs 2019 and 2022, and a list of the highest-poverty LEAs for which the State must maintain equity. The Department is posting these data on its website at *https://oese.ed.gov/offices/american-rescue-plan/american-rescue-plan-elementary-and-secondary-school-emergency-relief/maintenance-of-equity/* and will update the data as new data become available. These data are available to interested stakeholders and the public. The Department also intends to collect SEA-level MOEquity data through each State's annual performance report and will make those data publicly available.

Although data on State-level MOEquity will be available on the Department's website, there are not publicly available data for LEA-level MOEquity. Accordingly, in the proposed requirement, the Department addresses this need to emphasize the importance of transparency and accountability in ways that are consistent with the Department's policy goals of ensuring that schools and LEAs serving large proportions of historically underserved groups of students—including students from low-income families, students of color, English learners, students with disabilities, migratory students, and students experiencing homelessness—receive an equitable share of State and local funds as the Nation continues to recover from the impact of the COVID–19 pandemic on our education system. To support these goals, and to ensure public accountability for the implementation of the MOEquity provisions of the ARP Act, the Department proposes to require that each SEA make publicly available information on how each LEA in the State is maintaining fiscal and staffing equity. Requiring that MOEquity data be publicly available will allow parents, families, and local communities to access information on how the LEA is maintaining equity for schools with high concentrations of students from low-income families. Additionally, public posting of data and information on how each LEA in the State is maintaining equity is an important accountability tool for SEAs and the Department.

Several questions in the MOEquity FAQs on LEA-level maintenance of equity (see generally Questions 22–32) address the data an SEA would report under this proposed requirement. For example, Question 32 discusses LEAs that may be excepted under paragraph (a)(1) below from meeting the MOEquity requirements, including those LEAs that qualify as having exceptional or uncontrollable circumstances in FY 2022 due to the pandemic. (See also the August 6, 2021, DCL.) Similarly, Questions 23–25 clarify how to identify high-poverty schools under paragraph (a)(2)(i). Question 26 provides information applicable to paragraphs (a)(2)(ii) and (iii) on how the amount of per-pupil funding aligns with reporting on per-pupil expenditures under section 1111(h)(1)(C)(x) of the Elementary and Secondary Education Act of 1965. Questions 28 and 29 clarify how to determine full-time-equivalent (FTE) staff applicable to paragraphs (a)(2)(iv) and (v). Finally, Questions 27 and 30 address how to determine if an LEA has maintained equity in its high-poverty schools for paragraph (a)(2)(vi).

Proposed Requirement

(a) By December 31 of each applicable school year, an SEA must publish the following MOEquity data on its website, in a way that is machine-readable and accessible, for each LEA in the State, listed by the applicable National Center for Education Statistics LEA and school ID, in a location accessible for parents and families:

(1) Whether the LEA is exempt from MOEquity requirements under section 2004(c)(2) of the ARP Act, including but not limited to an LEA that demonstrates an exceptional or uncontrollable circumstance.

(2) If an LEA is not exempt from MOEquity requirements as detailed in paragraph (a)(1)—

(i) Which schools in the LEA are identified as high-poverty schools as defined in section 2004(d)(4) of the ARP Act and demographic information for each such school compared to the entire LEA.

[1] See *https://oese.ed.gov/files/2021/08/Maintenance-of-Equity-updated-FAQs_final_08.06.2021.pdf.*

(ii) The per-pupil amount of funding for each high-poverty school in the LEA in FYs 2021, 2022, and 2023, as applicable for the year in which the data are published.

(iii) The per-pupil amount of funding in the aggregate for all schools in the LEA in FYs 2021, 2022, and 2023, as applicable for the year in which the data are published.

(iv) The per-pupil number of FTE staff for each high-poverty school in the LEA in FYs 2021, 2022, and 2023, as applicable for the year in which the data are published, which may also be indicated as the number of students per FTE staff.

(v) The per-pupil number of FTE staff in the aggregate for all schools in the LEA in FYs 2021, 2022, and 2023, as applicable for the year in which the data are published, which may also be indicated as the number of students per FTEs.

(vi) Whether the LEA did not maintain equity for any high-poverty school in FY 2022 or 2023, as applicable for the year in which the data are published.

(b) If an LEA maintains equity by grade span, the SEA must post the LEA's data described in paragraphs (a)(2)(i)–(vi) by grade span.

(c) When reporting on each data element in paragraph (a), the SEA must ensure that the data reported are accurate and consistent with the requirements in section 2004(c) of the ARP.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive Order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive Order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing the proposed requirement only on a reasoned determination that its benefits would justify its costs. In choosing among alternative regulatory approaches, we selected the approach that would maximize net benefits. Based on an analysis of anticipated costs and benefits, we believe that the proposed requirement is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with the Executive Orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

Potential Costs and Benefits

The Department has analyzed the costs and benefits of complying with the proposed requirement. Due to the varying capacity and administrative structures of affected entities, we cannot estimate, with absolute precision, the likely effects of the proposed requirement. However, as discussed below, we estimate that the proposed requirement would have a net cost of $60,000 over two years.

For the purposes of these estimates, the Department assumes that, as part of their routine compliance efforts and effective administration of the affected Federal grants, States already collect and retain the relevant MOEquity data on each LEA's implementation of the MOEquity requirements and that such data are stored in a single repository (*e.g.,* a single data file including information for all of the State's LEAs). We further assume that States regularly collect and retain demographic data on schools within the State. To the extent that these assumptions are incorrect, actual costs borne by States could be higher than those outlined below.

We assume that a representative from each of the 50 States, the District of Columbia, and Puerto Rico (hereafter referred to as States) would review the final requirement. We assume that such review would take, on average, one hour per State for a one-time cost of approximately $2,800.[2]

We assume that, for each State, a management analyst would need to spend approximately eight hours, on average, compiling the relevant data and preparing it for posting. Within this estimate, we assume a management analyst would compile and incorporate

[2] The Department assumes a loaded wage rate of $53.79 per hour based on the average hourly wage rate for management analysts employed in State governments, excluding schools and hospitals (*https://www.bls.gov/oes/current/naics4_999200.htm*), which is multiplied by 1.61 to account for the employer cost for employee compensation (*https://www.bls.gov/news.release/pdf/ecec.pdf*).

demographic data into the same file as the MOEquity data, employ any necessary data suppression rules, and make any necessary formatting changes for posting of the data. We assume that posting the data online would take a network administrator ($59.09 [3] per hour) approximately 30 minutes. In total, we assume posting data would cost approximately $32,300 per year.

Finally, we assume that approximately 20 States would need to update their data after initial posting. We assume the updates would take a management analyst approximately 4 hours to complete and would require 30 minutes for a network administrator to post. In total, we assume posting corrections would cost approximately $6,500 per year.

As noted above, approximately 20 States would need to post their data twice. As such, we estimate that the proposed requirement would cost a total of approximately $60,000 over two years.

In general, we believe that the costs outlined above could be offset with funds the States have reserved under the ARP ESSER grant program. The benefit of publicly posting this local MOEQuity data is to facilitate public accountability so that parents and families will be able to access publicly available information on how each LEA in the State is maintaining fiscal and staffing equity. As such, we believe the benefit to the general public would far outweigh any burden on States.

Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum ''Plain Language in Government Writing'' require each agency to write regulations that are easy to understand.

The Secretary invites comments on how to make the proposed requirement easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulations clearly stated?
- Do the proposed regulations contain technical terms or other wording that interferes with their clarity?
- Would the proposed regulations be difficult to understand for or to explain to someone with literacy challenges or limited English proficiency?
- Does the format of the proposed regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?
- Would the proposed regulations be easier to understand if we divided them into more (but shorter) sections?
- Could the description of the proposed regulations in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the proposed regulations easier to understand? If so, how?
- What else could we do to make the proposed regulations easier to understand?

To send any comments that concern how the Department could make the proposed requirement easier to understand, see the instructions in the **ADDRESSES** section.

Intergovernmental Review: These programs are subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for these programs.

Regulatory Flexibility Act Certification

The Secretary certifies that this proposed regulatory action would not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration Size Standards define proprietary institutions as small businesses if they are independently owned and operated, are not dominant in their field of operation, and have total annual revenue below $7,000,000. Nonprofit institutions are defined as small entities if they are independently owned and operated and not dominant in their field of operation. Public institutions are defined as small organizations if they are operated by a government overseeing a population below 50,000.

The proposed regulatory action would affect only States, none of which is a small entity for the purpose of this analysis.

Paperwork Reduction Act

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This helps ensure that the public understands the Department's collection instructions, respondents provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

The proposed requirement that an SEA must publish on its website MOEquity data for each LEA in the State contains an information collection requirement. Under the PRA, the Department has submitted this requirement to OMB for its review.

A Federal agency may not conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of the law, no person is required to comply with, or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently valid OMB control number.

As discussed in the *Potential Costs and Benefits* section of the *Regulatory Impact Analysis,* this proposed requirement would create cost and burden hours for SEAs. In the following paragraphs, we estimate the cost and burden hours associated with complying with this proposed requirement. Differences between the estimates in the *Regulatory Impact Analysis* and this section are due to differences in calculating the net impact and annual impact of this requirement.

We assume that, for each SEA, including the District of Columbia and the Commonwealth of Puerto Rico, a management analyst, at an hourly rate of $53.79, will spend approximately 8 hours compiling the relevant data and preparing it for publication on the SEA website. At an hourly rate of $59.09, we estimate that posting the data online would take a network administrator approximately 30 minutes. We estimate that posting the MOEquity data would cost each SEA $460 and result in 8.5 burden hours annually for a total annual cost of $23,900, and 442 burden hours.

We estimate that approximately 20 States will need to update their data after initial posting. We assume the updates would take a management analyst approximately 4 hours to complete and would require 30 minutes for a network administrator to post. We estimate posting corrections will cost each SEA $240 and result in 4.5 burden hours for a total cost of $4,900, and 90 burden hours.

Collectively, we estimate that this proposed requirement would result in a

[3] The Department assumes a loaded wage rate of $59.09 per hour based on the average hourly wage rate for network and computer systems administrators employed in State governments, excluding schools and hospitals (*https://www.bls.gov/oes/current/naics4_999200.htm*), which is multiplied by two to account for overhead and benefits.

total estimated cost of $23,800 and a total estimated burden of 532 hours to the public annually.

The Department is requesting paperwork clearance on the OMB 1810–0759 data collection associated with this proposed requirement. That request will account for all burden hours and costs discussed within this section. Consistent with 5 CFR 1320.8(d), the Department is soliciting comments on the information collection through this document. We must receive your comments on the collection activities contained in this proposed requirement on or before December 6, 2021. Comments related to the information collection activities must be submitted electronically through the Federal eRulemaking Portal at *www.regulations.gov* by selecting the Docket ID number ED–2021–OESE–0116 or via postal mail, commercial delivery, or hand delivery by referencing the Docket ID number and the title of the information collection request at the top of your comment. Comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, Room 6W208D, Washington, DC 20202–8240.

Note: The Office of Information and Regulatory Affairs and the Department review all comments related to the information collection activities posted at *www.regulations.gov*.

COLLECTION OF INFORMATION

Information collection activity	Estimated number responses	Hours per response	Total estimated burden hours	Estimated total cost
MOEquity Data Posting	52	8.5	442	$32,300
MOEquity Data Updates	20	4.5	90	6,500
Annualized Total	72	.....	532	38,800

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov*. At this site you can view this document, as well as all other documents of the Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs Delegated the authority to perform the functions and duties of the Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2021–21764 Filed 10–4–21; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0408; FRL–8902–01–R9]

Clean Air Plans; Base Year Emissions Inventories for the 2015 Ozone Standards; California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the California State Implementation Plan (SIP) concerning the base year emissions inventories for 18 areas designated as nonattainment areas (NAAs) for the 2015 ozone National Ambient Air Quality Standards (2015 ozone NAAQS) submitted on July 24, 2020. The areas include: Amador County, Butte County, Calaveras County, Imperial County, Kern County (Eastern Kern), Los Angeles—San Bernardino Counties (West Mojave Desert), Los Angeles—South Coast Air Basin, Mariposa County, Nevada County (Western part), Riverside County (Coachella Valley), Sacramento Metro, San Francisco Bay Area, San Joaquin Valley, San Luis Obispo (Eastern part), Sutter Buttes, Tuolumne County, Tuscan Buttes, and Ventura County. We are proposing to approve these revisions under the Clean Air Act (CAA or ''the Act''), which establishes emissions inventory requirements for all ozone nonattainment areas.

DATES: Written comments must arrive on or before November 4, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2021–0408 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Khoi Nguyen, Air Planning Office (AIR–2), EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 947–4120, or by email at *nguyen.khoi@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. Background

On October 26, 2015, the EPA promulgated a revised 8-hour ozone NAAQS of 0.070 parts per million (ppm).[1] In accordance with section 107(d) of the CAA, the EPA must designate an area ''nonattainment'' if it is violating the NAAQS or if it is contributing to a violation of the NAAQS in a nearby area.

The EPA designated 21 areas in California as nonattainment for the 2015 ozone NAAQS on June 4, 2018, effective August 3, 2018.[2] Amador County, Calaveras County, Butte County, Imperial County, Mariposa County, San Francisco Bay Area, San Luis Obispo (Eastern part), Sutter Buttes, Tuolumne County, and Tuscan Buttes NAAs were classified as Marginal nonattainment. Kern County (Eastern Kern), Nevada County (Western part), Sacramento Metro, and San Diego County NAAs were classified as Moderate nonattainment. The EPA classified the Ventura County NAA as Serious nonattainment. The EPA classified the Los Angeles-San Bernardino Counties (West Mojave Desert) and Riverside County (Coachella Valley) NAAs as Severe-15 nonattainment. The EPA classified the Los Angeles-South Coast Air Basin and San Joaquin Valley NAAs as Extreme nonattainment. The EPA designated the lands of the Pechanga Band of Luiseño Mission Indians of the Pechanga Reservation and the Morongo Band of Mission Indians as separate NAAs and classified them as Marginal and Serious nonattainment, respectively. The State of California does not have regulatory authority on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction.

The EPA finalized the 2015 ozone NAAQS SIP Requirements Rule (SRR) on December 6, 2018.[3] The SRR established implementation requirements for the 2015 ozone NAAQS, including requirements for ''base year'' emissions inventories under CAA section 182(a)(1). The 2015 Ozone SRR is codified at 40 CFR part 51, subpart CC, and the emissions inventory requirements are codified at 40 CFR 51.1315.

Within two years of designations, Section 182(a)(1) of the CAA and 40 CFR 51.1315 require states and local governments to prepare base year emissions inventories for all areas exceeding the ozone standards. On July 27, 2020, the California Air Resources Board (CARB) submitted the ''70 ppb Ozone SIP Submittal'' (''2020 CARB SIP Submittal'') to the EPA.[4] The 2020 CARB SIP Submittal contains a staff report with a release date of May 22, 2020, and attachments of emissions inventories that address base year inventory requirements for 18 of the 21 NAAs in California.[5] In this action, we are evaluating and proposing action on the 2020 CARB SIP Submittal.[6]

[1] 80 FR 65292 (October 26, 2015).

[2] 83 FR 25776 (June 4, 2018).

[3] ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements,'' Final Rule, 83 FR 62998 (December 6, 2018).

[4] Letter dated July 24, 2020, from Richard W. Corey, Executive Officer, CARB, to John Busterud, Regional Administrator, EPA Region IX (submitted electronically July 27, 2020).

[5] CARB's submittal does not include the San Diego NAA, which was submitted separately via the State Planning Electronic Collaboration System (SPeCS) for SIPs on January 12, 2021. The EPA will take action on the emissions inventory for the San Diego NAA in a separate rulemaking. Because the State of California does not have regulatory authority over the Pechanga and Morongo NAAs, CARB's submittal does not include emissions inventories for these areas.

[6] The 2020 CARB SIP Submittal, Section III addresses Vehicle Miles Travel (VMT) offsets for the South Coast Air Basin, San Joaquin Valley, and Coachella Valley. The EPA will take action on VMT offsets in a separate rulemaking.

II. Summary and Analysis of the State's Submittal

A. Statutory and Regulatory Requirements

1. Procedural Requirements for Adoption and Submittal of SIP Revisions

CAA sections 110(a)(1) and 110(l) and 40 CFR 51.102 require states to provide reasonable notice and an opportunity for a public hearing prior to adoption of SIP revisions. Section 110(k)(1)(B) requires the EPA to determine whether a SIP submittal is complete within 60 days of receipt. Any plan that the EPA does not affirmatively determine to be complete or incomplete will become complete six months after the day of submittal by operation of law. A finding of completeness does not approve the submittal as part of the SIP, nor does it indicate that the submittal is approvable. It does start a 12-month clock for the EPA to act on the SIP submittal (see CAA section 110(k)(2)).

2. Requirements for Base Year Inventories

CAA section 182(a)(1) and 40 CFR 51.1315 require states to develop and submit, as a SIP revision, emissions inventories for all areas designated as nonattainment for any NAAQS. An emissions inventory for ozone is an estimation of actual emissions of air pollutants that contribute to the formation of ozone in an area. Ozone is a gas that is formed by the reaction of volatile organic compounds (VOC) and oxides of nitrogen (NO_X) in the atmosphere in the presence of sunlight (VOC and NO_X are referred to as ozone precursors). Therefore, an emissions inventory for ozone focuses on the emissions of VOC and NO_X. VOC is emitted by many types of sources, including power plants, industrial sources, on-road and off-road mobile sources, smaller stationary sources collectively referred to as area sources, and biogenic sources. NO_X is primarily emitted by combustion sources, both stationary and mobile.

Emissions inventories provide emissions data for a variety of air quality planning tasks, including establishing baseline emissions levels (*i.e.,* the level of anthropogenic emissions associated with violations of the ozone standard), calculating emissions reduction targets needed to attain the NAAQS and to achieve reasonable further progress (RFP) toward attainment of the ozone standard, determining emissions inputs for ozone air quality modeling analyses, and tracking emissions over time to

determine progress toward achieving air quality and emissions reduction goals. For the 2015 ozone NAAQS, states should submit ozone season day [7] emissions estimates for an inventory calendar year to be consistent with the baseline year for the RFP plan as required by 40 CFR 51.1310(b). For the RFP baseline year for the 2015 ozone NAAQS states may use a calendar year for the most recently available complete triennial (3-year cycle) emissions inventory (40 CFR 51, subpart A) preceding the year of the area's effective date of designation as a nonattainment area.[8] States are required to submit estimates of VOC and NO_X emissions for four general classes of anthropogenic sources: Stationary point sources; area sources; on-road mobile sources; and off-road mobile sources.

B. Summary of the State's Submittal

The 2020 CARB SIP Submittal documents the public review process followed prior to its submittal to the EPA as a revision to the SIP. The submittal includes a copy of a CARB notice of public meeting on June 25, 2020 to consider the approval of the submittal,[9] a transcript from the June 25, 2020 meeting,[10] a signed resolution stating that CARB made the emissions inventories available for public review at least 30 days prior to the board hearing and that the emissions inventories were adopted after notice and public hearing,[11] and a compilation of comments received by CARB prior to and during the June 25, 2020 public meeting.[12]

CARB selected 2017 as the base year because it was the most recent calendar year for which a complete triennial inventory was required to be submitted to the EPA, and because the year is consistent with the baseline year for the reasonable further progress (RFP) plan.[13] The submitted base year emissions inventories are expressed as 2017 average ozone season day emissions in tons per day (tpd) [14] and categorized as stationary point sources, area-wide sources, on-road mobile sources, and off-road mobile sources. The 2020 CARB SIP Submittal describes methods used to estimate emissions for each category and subcategory.[15] The 2020 CARB SIP Submittal also describes how emissions were calculated for ''split regions'' not defined by CARB's county, air basin, and district boundaries,[16] and CARB's quality assurance and quality control process.[17]

Table 1 summarizes the 2017 emissions inventories in tons of emissions per ozone season day for the Amador County, Butte County, Calaveras County, Imperial County, Kern County (Eastern Kern), Los Angeles—San Bernardino Counties (West Mojave Desert), Los Angeles—South Coast Air Basin, Mariposa County, Nevada County (Western part), Riverside County (Coachella Valley), Sacramento Metro, San Francisco Bay Area, San Joaquin Valley, San Luis Obispo (Eastern part), Tuolumne County, and Ventura County NAAs for NO_X and VOC [18] emissions.[19] The 2020 CARB SIP Submittal indicated that the Sutter Buttes and Tuscan Buttes NAAs are both small, high elevation areas and contained no anthropogenic sources; therefore there are no associated emissions inventories with these two NAAs.[20]

TABLE 1—2017 AVERAGE OZONE SEASON DAY EMISSIONS INVENTORIES

[tpd]

Category	NO_X	% of total	VOC	% of total
Amador County				
Stationary Sources	2.21	59	0.88	23
Area-wide Sources	0.05	1	1.55	41
On-road Mobile	1.05	28	0.64	17
Off-Road Mobile	0.44	12	0.72	19
Total	3.76	100	3.79	100
Butte County				
Stationary Sources	1.11	9	2.07	17
Area-wide Sources	0.68	5	5.09	42
On-road Mobile	4.94	39	2.52	21
Off-Road Mobile	5.92	47	2.52	21
Total	12.65	100	12.19	100

[7] See 40 CFR 51.1300(q). Also see ''Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards (NAAQS) and Regional Haze Regulations,'' EPA–454/B–17–002, EPA, May 2017. The selected ozone season should be representative of the conditions leading to nonattainment.

[8] 83 FR 63034–63035 (December 6, 2018). The RFP requirements specified in CAA section 182(b)(1) apply to all areas designated nonattainment for ozone classified Moderate or higher.

[9] Notice of Public Meeting to Consider 70 Parts Per Billion Ozone State Implementation Plan Submittal, California Air Resources Board, May 22, 2020.

[10] Videoconference Meeting, State of California, Air Resources Board, CAL/EPA Headquarters, Byron Sher Auditorium, Second Floor, 1001 I Street, Sacramento, California 95814, Thursday, June 25, 2020, 9:03 a.m., James F. Peters, CSR, Certified Shorthand Reporter, License Number 10063.

[11] CARB, ''70 Parts Per Billion Ozone State Implementation Plan Submittal,'' Resolution 20–17, June 25, 2020, Agenda Item No.: 20–6–1, signed by Ryan Sakazaki, Board Clerk.

[12] Compilation of comments received for 70 Parts Per Billion Ozone State Implementation Plan Submittal. CARB indicated in its July 24, 2020 transmittal letter to the EPA that CARB has considered all comments and has determined all are non-substantive and do not pertain to the action.

[13] 2020 CARB SIP Submittal, page 9.

[14] 2020 CARB SIP Submittal, pages 5 and 9. The submittal indicates that statewide attainment challenges for the 8-hour ozone standard occur in the summer months, defined as May–October, and that seasonal inventories account for temporal activity variations throughout the year, as determined by category-specific temporal profiles.

[15] 2020 CARB SIP Submittal, pages 10–33.

[16] 2020 CARB SIP Submittal, page 9.

[17] 2020 CARB SIP Submittal, pages 9–10.

[18] The State of California refers to reactive organic gases (ROG) rather than VOC in some of its ozone-related SIP submissions. As a practical matter, ROG and VOC refer to the same set of chemical constituents, and for simplicity, we refer to this set of gases as VOC in this proposed rule.

[19] 2020 CARB SIP Submittal, pages 7–35.

[20] 2020 CARB SIP Submittal, page 6.

TABLE 1—2017 AVERAGE OZONE SEASON DAY EMISSIONS INVENTORIES—Continued

[tpd]

Category	NO_X	% of total	VOC	% of total
Calaveras County				
Stationary Sources	0.04	2	0.19	4
Area-wide Sources	0.1	5	2.05	43
On-road Mobile	1.4	63	0.84	18
Off-Road Mobile	0.67	30	1.66	35
Total	2.21	100	4.74	100
Imperial County				
Stationary Sources	1.38	9	1.33	10
Area-wide Sources	0.21	1	6.88	49
On-road Mobile	6.05	41	2.6	19
Off-Road Mobile	7.14	48	3.18	23
Total	14.78	100	13.98	100
Kern County (Eastern Kern)				
Stationary Sources	18.13	67	1.4	20
Area-wide Sources	0.12	0	1.17	16
On-road Mobile	3.94	15	1.27	18
Off-Road Mobile	4.82	18	3.33	46
Total	27.01	100	7.18	100
Los Angeles—San Bernardino Counties (West Mojave Desert)				
Stationary Sources	23.95	32	13.88	36
Area-wide Sources	0.93	1	10.85	28
On-road Mobile	23.06	31	9.03	23
Off-Road Mobile	27.02	36	4.89	13
Total	74.95	100	38.64	100
Los Angeles—South Coast Air Basin				
Stationary Sources	43.28	12	94.27	23
Area-wide Sources	10.35	3	125.28	30
On-road Mobile	180.29	51	91.96	22
Off-Road Mobile	118.41	34	99.25	24
Total	352.32	100	410.75	100
Mariposa County				
Stationary Sources	0.02	2	0.07	3
Area-wide Sources	0.01	1	1.33	51
On-road Mobile	0.48	59	0.34	13
Off-Road Mobile	0.3	37	0.89	34
Total	0.8	100	2.63	100
Nevada County (Western part)				
Stationary Sources	0.1	3	0.76	16
Area-wide Sources	0.15	4	1.65	35
On-road Mobile	2.8	72	1.21	26
Off-Road Mobile	0.82	21	1.07	23
Total	3.86	100	4.68	100
Riverside County (Coachella Valley)				
Stationary Sources	1.31	7	3.58	24
Area-wide Sources	0.29	1	3.82	26
On-road Mobile	12.19	62	4.22	29
Off-Road Mobile	5.91	30	3.09	21
Total	19.7	100	14.71	100

TABLE 1—2017 AVERAGE OZONE SEASON DAY EMISSIONS INVENTORIES—Continued

[tpd]

Category	NO_X	% of total	VOC	% of total
Sacramento Metro				
Stationary Sources	6.21	9	23.31	25
Area-wide Sources	2.34	3	31.69	34
On-road Mobile	36.37	53	19.68	21
Off-Road Mobile	24.25	35	19.79	21
Total	69.16	100	94.46	100
San Francisco Bay Area				
Stationary Sources	32.96	17	68.49	29
Area-wide Sources	6.79	4	76.8	33
On-road Mobile	78.28	41	41.21	18
Off-Road Mobile	72.87	38	46.6	20
Total	190.9	100	233.1	100
San Joaquin Valley				
Stationary Sources	28.04	13	83.75	27
Area-wide Sources	4.21	2	154.67	50
On-road Mobile	100.38	46	34.06	11
Off-Road Mobile	87.57	40	35.37	11
Total	220.2	100	307.85	100
San Luis Obispo (Eastern part)				
Stationary Sources	0.45	58	0.09	20
Area-wide Sources	0.01	1	0.22	49
On-road Mobile	0.2	26	0.1	22
Off-Road Mobile	0.12	15	0.04	9
Total	0.77	100	0.44	100
Tuolumne County				
Stationary Sources	1.05	28	0.5	7
Area-wide Sources	0.07	2	2.15	30
On-road Mobile	1.59	42	1.15	16
Off-Road Mobile	1.08	28	3.38	47
Total	3.78	100	7.18	100
Ventura County				
Stationary Sources	2.02	11	8.08	27
Area-wide Sources	0.63	3	10.45	35
On-road Mobile	8.41	44	5.08	17
Off-Road Mobile	8.09	42	6.63	22
Total	19.14	100	30.23	100

Source: Attachment A of 2020 CARB SIP Submittal. The sum of the emissions values may not equal the totals shown due to rounding. The table excludes biogenic emissions. Additionally, there are no anthropogenic emissions from the Sutter Buttes and Tuscan Buttes NAAs.

1. Stationary Point Source Emissions

CARB estimates stationary point source emissions based on annual reports submitted by the local air districts. The inventory reflects actual emissions from industrial point sources reported to local air districts by facility operators through calendar year 2017.[21] The local air districts are responsible for working with facility operators to compile estimates, using source testing, direct measurement, or engineering calculations. CARB estimates emissions from smaller point sources, such as gasoline dispensing facilities and residential water heaters, as a group and reports them in a single source category. CARB groups stationary point source emissions into the following categories: Fuel combustion, waste disposal, cleaning and surface coatings, petroleum production and marketing, and industrial processes.[22]

[21] 2020 CARB SIP Submittal, page 14.

[22] 2020 CARB SIP Submittal, Attachment A. Fuel combustion subcategories: Electric utilities, cogeneration, oil and gas production (combustion), manufacturing and industrial, food and agricultural processing, service and commercial, other (fuel combustion). Waste disposal subcategories: Sewage treatment, incinerators, other (waste disposal). Cleaning and surface coatings subcategories: Laundering, degreasing, coatings and related process solvents, printing, adhesives, and sealants. Petroleum productions and marketing

Continued

CARB describes the methodologies it uses for smaller point sources in Section II.B of the ''Emission Inventory Components'' summary of the 2020 CARB SIP Submittal.[23] The categories for these smaller point sources include: Stationary non-agricultural diesel engines, agricultural diesel irrigation pumps, wine fermentation and aging, laundering, degreasing, coatings and thinners, adhesives and sealants, gasoline dispensing facilities, gasoline cargo tank, marine petroleum loading, marine petroleum unloading, and oil and gas production. In addition to describing each category, CARB provides website links to additional information on each methodology. For example, while CARB reports most of the food and agricultural processing emissions sources as individual point sources, CARB estimates the exhaust emissions from agricultural irrigation pumps from a model developed by CARB staff. This category includes emissions from the operation of diesel-fueled stationary and mobile agricultural irrigation pumps.[24]

2. Area-Wide Source Emissions

CARB's area-wide source inventories include categories where emissions take place over a wide geographic area, such as consumer products, cooking, and agricultural burning. CARB groups area-wide source emissions as either solvent evaporation or miscellaneous processes.[25]

CARB describes the methodologies for each area-wide source emissions category in Section II.C of the ''Emission Inventory Components'' summary of the 2020 CARB SIP Submittal.[26] Area-wide source emissions estimates are developed by CARB staff as well as some air districts. The methodologies are reviewed by CARB and air district staff before inclusion in the emissions inventory. CARB uses various models and methodologies for estimating emissions from area-wide source categories. CARB also provides information describing the methodologies used for the following area-wide sources: Consumer products and aerosol coatings, architectural coatings, pesticides, residential wood combustion, residential natural gas combustion, residential distillate oil and liquified petroleum gas, farming operations, fires, managed burning and disposal, and commercial cooking.[27] In addition to describing each category, CARB provides website links to additional information on each methodology. A few examples are provided below.

For the consumer products emissions estimates, CARB utilized sales and formulation data from CARB's mandatory survey of all consumer products sold in California for calendar years 2013 through 2015.[28] Based on the survey data, CARB staff determined the total product sales and total VOC emissions for the various product categories. Growth for personal care products is based on real disposable personal income projections per Regional Economic Models, Inc. (REMI) version 2.3. No growth is assumed for aerosol coatings. Growth for all other personal care products is based on California Department of Finance.

The California Department of Pesticide Regulation (DPR) develops month-specific emissions estimates for agricultural and structural pesticides for CARB.[29] The DPR applies Emission Potential values from the DPR database to the amount of grower-reported pesticide application in DPR's Pesticide Use Report database.[30]

CARB uses survey data and emissions factors to estimate emissions from residential wood combustion, a subcategory of residential fuel combustion.[31] In 2011, CARB updated its methodology for residential wood combustion to include more recent survey data on residential wood burning devices and consumption rates, updates to the EPA National Emissions Inventory emissions factors and improved calculation approaches.[32] The update reflects wood combustion surveys conducted by several districts including the Bay Area Air Quality Management District (AQMD) in 2007, South Coast AQMD in 2003 and 2006, Placer County Air Pollution Control District (APCD) in 2007, San Joaquin Valley APCD in 2014, and Sacramento Metropolitan AQMD in 2007. CARB also assumes no growth for this category based on the relatively stagnant residential wood fuel use over the past decade according to the American Community Survey and United States Energy Information Administration.

3. Off-Road Mobile Source Emissions

CARB has developed category-specific models for numerous off-road (also known as ''nonroad'') sources, including locomotives, ships, industrial and construction equipment, and recreational vehicles.[33] CARB estimated emissions from off-road sources using a suite of category-specific models or, where a new model was not available, the OFFROAD2007 model. The submittal indicated that many of the newer models were developed to support recent regulations, including in-use off-road equipment, ocean-going vessels, and others. CARB provided information describing the updates made to following off-road sources: Ocean going vessels,[34] commercial harbor craft, pleasure crafts and recreational vehicles, locomotives, fuel storage and handling equipment, fuel storage and handling, diesel agricultural equipment, in-use off-road equipment (*i.e.,* construction, industrial, mining, oil drilling, and ground support equipment), cargo handling equipment, and transportation refrigeration units.[35] In addition to describing each category, CARB provides website links to additional information on each methodology. These descriptions include the type of source represented,

subcategories: Oil and gas production, petroleum marketing, other (petroleum production and marketing). Industrial processes subcategories: Food agriculture, mineral processes, metal processes, wood and paper, other (industrial processes).

[23] 2020 CARB SIP Submittal, pages 14–19.

[24] Section II.B.b of 2020 CARB SIP Submittal, page 15. Additional information on agricultural diesel irrigation pumps is available at *https://ww3.arb.ca.gov/ei/areasrc/fullpdf/full1-1.pdf.*

[25] 2020 CARB SIP Submittal, Attachment A. Solvent evaporation subcategories: Consumer products, architectural coatings and related process solvents, pesticides/fertilizers, asphalt paving/roofing. Miscellaneous processes subcategories: Residential fuel combustion, farming operations, construction and demolition, paved road dust, unpaved road dust, fugitive windblown dust, fires, managed burning and disposal, cooking, and other (miscellaneous processes).

[26] 2020 CARB SIP Submittal, pages 19–22.

[27] 2020 CARB SIP Submittal, pages 19–22.

[28] 2020 CARB SIP Submittal, page 19. Additional information on CARB's consumer products surveys is available at: *https://ww2.arb.ca.gov/our-work/programs/consumer-products-program/consumer-commercial-product-surveys.*

[29] 2020 CARB SIP Submittal, page 20. Additional information about CARB's pesticides program is available at: *https://ww2.arb.ca.gov/solvent-evaporation-methodologies.*

[30] The EP value is the fraction of the product that is assumed to potentially contribute to atmospheric VOC. California's pesticide use reporting program requires that all agricultural pesticide use must be reported monthly by growers to county agricultural commissions, who in turn, report the data to DPR. See *https://ww2.arb.ca.gov/solvent-evaporation-methodologies.*

[31] 2020 CARB SIP Submittal, page 20. Additional information on this methodology is available at: *https://ww2.arb.ca.gov/miscellaneous-process-methodologies.*

[32] CARB, Section 7.1 Residential Wood Combustion (Revised October 2015), available at: *http://www.arb.ca.gov/ei/areasrc/fullpdf/full7-1_2011.pdf.*

[33] 2020 CARB SIP Submittal, pages 11–14.

[34] CARB clarified via email that the link for ocean going vessels was updated to: *https://ww3.arb.ca.gov/msei/offroad/pubs/2019_ogv_inventory_writeup_ver_oct_18_2019.pdf.* See email dated February 9, 2021, from Stephanie Huber, CARB to Khoi Nguyen, EPA Region IX.

[35] Aircrafts are also considered off-road mobile sources. In CARB's February 9, 2021 email, CARB clarified that aircraft emissions are estimated by the districts.

the types and source of data used, and the models used.

For example, CARB groups commercial harbor craft into nine vessel types, including ferry and excursion vessels, tow boats, tugboats, pilot vessels, work boats, crew and supply vessels, commercial fishing vessels, charter fishing vessels, and other.[36] Vessel and engine data were reported to CARB by vessel operators in compliance with CARB's 2007 Commercial Harbor Craft Regulation. Staff updated the crew and supply vessel emissions inventory using 2009 reporting data and developed barge and dredge vessel emissions inventory using information from a 2009 CARB survey. Vessel population data were collected from various sources, including the U.S. Coast Guard, the California Department of Fish and Wildlife registration data, the CARB Harbor Craft Survey, and information from recent emissions inventory estimates generated for Los Angeles. Vessel and engine profiles, including vessel and engine type, age, size, annual hours of operation, and annual fuel use were developed based on the CARB survey.

4. On-Road Mobile Source Emissions

CARB estimated on-road mobile emissions from cars, light and heavy-duty trucks, motorcycles, buses, and motor homes using its Emission Factors (EMFAC) model version 2017,[37] which was the latest EPA-approved version available at the time the emissions inventories were prepared.[38] The on-road emissions were calculated by applying EMFAC2017 emissions factors to the transportation activity data provided by the local metropolitan planning organizations. CARB states that EMFAC2017 includes data on California's car and truck fleets and travel activity. Light-duty motor vehicle fleet age, vehicle type, and vehicle population were based on data from the Department of Motor Vehicles (DMV), updated in 2016. The model also reflects the emissions benefits of CARB's rulemakings such as the Pavley Standards and Advanced Clean Cars Program and includes the emissions benefits from CARB's Truck and Bus Rule and previously adopted rules for other on-road diesel fleets. CARB also indicates that EMFAC2017 utilizes a socio-econometric regression modeling approach to forecast new vehicle sales and to estimate future fleet mix. Light-duty passenger vehicle population includes 2016 DMV registration data along with updates to mileage accrual using data from the Bureau of Automotive Repair Smog Check Program. Updates to heavy-duty trucks include model year specific emissions factors based on new test data, and population estimates using DMV data for in-state trucks and International Registration Plan data for out-of-state trucks.

C. The EPA's Evaluation of the State's Submittal

1. Evaluation of Procedural Requirements

Based on the documentation included in CARB's submittal, the EPA finds that the submittal satisfies the procedural requirements of sections 110(a)(1) and 110(l) of the Act requiring states to provide reasonable notice and an opportunity for public hearing prior to adoption of SIP revisions. CARB's submittal became complete by operation of law on January 24, 2021 pursuant to section 110(k)(1)(B).

2. Evaluation of Base Year Inventory Requirements

The EPA has reviewed the 2020 CARB SIP Submittal for consistency with sections 172(c)(3) and 182(a)(1) of the CAA, and the EPA's emissions inventory requirements. In particular, the EPA has reviewed the techniques used by CARB to derive and quality assure the emissions estimates.

CARB documented the procedures used to estimate the emissions for each of the major source types. The documentation of the emissions estimation procedures is adequate for the EPA to determine that CARB followed acceptable procedures to estimate emissions.

CARB has established a quality assurance and quality control (QA/QC) process to ensure the integrity and accuracy of the emissions inventories used in the development of air quality plans. These QA/QC procedures were summarized in the documentation describing how the emissions totals were developed.[39] The EPA has determined that the QA/QC procedures are complete, adequate, and acceptable.

The EPA has also reviewed the 2017 average ozone season day base year emissions inventories in the 2020 CARB SIP Submittal. Our review included the emissions estimates for stationary sources, area-wide sources, and mobile sources. We find that CARB's selection of 2017 as the base year was appropriate for these areas because 2017 was the most recent calendar year for which a consistent and comprehensive statewide inventory was available. We also find that the emissions inventories appropriately address ozone season day emissions consistent with the definition of ozone season day emissions under 40 CFR 51.1300(q). The submittal provides sufficient information and explanation to allow the EPA to make a determination on the acceptability of the emissions inventories.

The EPA proposes to find that CARB has developed approvable inventories of NO_X and VOC emissions for the following ozone nonattainment areas as required under the CAA and SRR (40 CFR 51.1315, see also CAA section 172(c)(3)): Amador County, Butte County, Calaveras County, Imperial County, Kern County (Eastern Kern), Los Angeles—San Bernardino Counties (West Mojave Desert), Los Angeles—South Coast Air Basin, Mariposa County, Nevada County (Western part), Riverside County (Coachella Valley), Sacramento Metro, San Francisco Bay Area, San Joaquin Valley, San Luis Obispo (Eastern part), Sutter Buttes, Tuolumne County, Tuscan Buttes, and Ventura County.

III. Proposed Action

We are proposing to approve the 2020 CARB SIP Submittal to address the ozone-related emissions inventory requirements for 18 ozone nonattainment areas for the 2015 ozone NAAQS. These areas are: Amador County, Butte County, Calaveras County, Imperial County, Kern County (Eastern Kern), Los Angeles—San Bernardino Counties (West Mojave Desert), Los Angeles—South Coast Air Basin, Mariposa County, Nevada County (Western part), Riverside County (Coachella Valley), Sacramento Metro, San Francisco Bay Area, San Joaquin Valley, San Luis Obispo (Eastern part), Sutter Buttes, Tuolumne County, Tuscan Buttes, and Ventura County. The emissions inventories we are approving into the SIP are specified in Table 1. We are proposing to approve the emissions inventories because they contain comprehensive, accurate, and current inventories of actual emissions for all relevant sources in accordance with CAA sections 172(c)(3) and 182(a), and because CARB adopted the emissions inventories after providing for

[36] 2020 CARB SIP Submittal, page 11. Additional information on CARB's CHC methodology is available at: *https://www.arb.ca.gov/regact/2010/chc10/appc.pdf*.

[37] EMFAC is short for EMission FACtor. In August 2019, the EPA approved EMFAC2017 for SIP development and transportation purposes in California. 84 FR 41717 (August 15, 2019). CARB provides additional information and documentation on the EMFAC2017 model, available at: *https://ww2.arb.ca.gov/our-work/programs/mobile-source-emissions-inventory/msei-road-documentation*.

[38] 2020 CARB SIP Submittal, page 10.

[39] 2020 CARB SIP Submittal, page 9.

reasonable public notice and opportunity for a public hearing.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: September 29, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2021–21738 Filed 10–4–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R10–RCRA–2021–0439; FRL–8853–01–R10]

Oregon: Proposed Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Oregon has applied to the Environmental Protection Agency (EPA) for final authorization of changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA), as amended. EPA has reviewed Oregon's application, and has determined that these changes satisfy all requirements needed to qualify for authorization. Therefore, we are proposing to authorize the State's changes. EPA seeks public comment prior to taking final action.

DATES: Comments on this proposed rule must be received on or before November 4, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–RCRA–2021–0439 through the *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include all points the commenter wishes to make. EPA will generally not consider comments or comment contents located outside of the primary submissions (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.* The EPA encourages electronic submittals, but if you are unable to submit electronically or need other assistance, please contact Margaret Olson, the contact listed below. Please also contact Margaret Olson if you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you.

FOR FURTHER INFORMATION CONTACT: Margaret Olson, U.S. Environmental Protection Agency, Region 10, Oregon Operations Office, 805 SW Broadway, Suite 500, Portland, Oregon 97205, phone number: (503) 326–5874, email: *olson.margaret@epa.gov*.

SUPPLEMENTARY INFORMATION:

A. Why are revisions to state programs necessary?

States that have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, states must change their programs and ask EPA to authorize the changes. Changes to state programs may be necessary when Federal or state statutory or regulatory authority is modified or when certain other changes occur. Most commonly, states must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 268, 270, 273, and 279.

New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates pursuant to the Hazardous and Solid Waste Amendments of 1984 (HSWA) take effect in authorized states at the same time that they take effect in unauthorized states. Thus, EPA will implement those requirements and prohibitions in Oregon, including the issuance of new permits implementing

those requirements, until the State is granted authorization to do so.

B. What decisions has EPA made in this rule?

On October 16, 2020, Oregon submitted a complete program revision application seeking authorization of changes to its hazardous waste program that correspond to certain Federal rules promulgated between October 22, 1998 and April 17, 2015. EPA is proposing to determine that Oregon's application to revise its authorized program meets all the statutory and regulatory requirements established by RCRA, as set forth in RCRA section 3006(b), 42 U.S.C. 6926(b), and 40 CFR part 271. Therefore, EPA proposes to grant Oregon final authorization to operate its hazardous waste program with the changes described in the authorization application, and as outlined below in Section G of this document. Oregon has responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDFs) within its borders (except in Indian country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of HSWA, as discussed above.

C. What is the effect of this proposed authorization decision?

If Oregon is authorized for the changes described in Oregon's authorization application, these changes will become part of the authorized State hazardous waste program and will therefore be federally enforceable. Oregon will continue to have primary enforcement authority and responsibility for its State hazardous waste program. EPA would maintain its authorities under RCRA sections 3007, 3008, 3013, and 7003, including its authority to:

- Conduct inspections, and require monitoring, tests, analyses and reports;
- Enforce RCRA requirements, including authorized State program requirements;
- Suspend or revoke permits; and
- Take enforcement actions regardless of whether the State has taken its own actions.

This action will not impose additional requirements on the regulated community because the regulations which EPA is proposing to authorize in Oregon are already effective under state law and are not changed by today's proposed action.

D. What happens if EPA receives comments that oppose this action?

If EPA receives comments on this proposed action, we will address all such comments in a later final rule. You may not have another opportunity to comment. If you want to comment on this authorization, you should do so at this time.

E. What has Oregon previously been authorized for?

Oregon initially received final authorization on January 30, 1986, effective January 31, 1986 (51 FR 3779), to implement the RCRA hazardous waste management program. EPA granted authorization for changes to Oregon's program on March 30, 1990, effective on May 29, 1990 (55 FR 11909); August 5, 1994, effective October 4, 1994 (59 FR 39967); June 16, 1995, effective August 15, 1995 (60 FR 31642); October 10, 1995, effective December 7, 1995 (60 FR 52629); September 10, 2002, effective September 10, 2002 (67 FR 57337); June 26, 2006 effective June 26, 2006 (71 FR 36216); and January 7, 2010, effective January 7, 2010 (75 FR 918).

F. What changes are we proposing with today's action?

On October 16, 2020, Oregon submitted a final complete program revision application, seeking authorization of changes to its hazardous waste management program in accordance with 40 CFR 271.21. EPA proposes to determine, subject to receipt of written comments that oppose this action, that Oregon's hazardous waste program revisions are equivalent to, consistent with, and no less stringent than the federal program, and therefore satisfy all the requirements necessary to qualify for final authorization. Therefore, EPA is proposing to authorize Oregon for the following program changes as identified in the list below.

Description of Federal requirement and Checklist [1] No.	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous state authority
NA—Hazardous Waste Manifest Printing Specifications Correction Rule.	76 FR 36363, 6/22/11	OAR 340–100–0002.
174—partial adoption—Standards Applicable to Owners and Operators of Closed and Closing Hazardous Waste Management Facilities: Post-Closure Permit Requirement; Closure Process.	63 FR 56710, 10/22/98	Oregon Revised Statutes 465.009, 465.505, and 466.020. OAR 340–100–0002.
203—Used Oil Management Standards	75 FR 76633, 9/8/05 ..	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002.
210—Standardized Permit for RCRA HW Management Facilities.	70 FR 53420, 9/8/05 ..	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002/OAR 340–100–0001(3)/OAR 340–100–0004/OAR 340–101–0001(2)/OAR 340–101–0030/OAR 340–102–0010(2)–(3)/OAR 340–104–0001(2)/OAR 340–105–0001(2)/OAR 340–106–0001(2)/OAR 340–109–0001(2)/OAR 340–111–0010(3)(d).
217—NESHAP: Standards for RCRA HW Management Facilities.	73 FR 18970, 4/8/08 ..	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002.
218—Amendment to Hazardous Waste Code F019	73 FR 31756, 6/4/08 ..	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002.
220 [2]—Academic Laboratories Generator Standards	73 FR 72911, 12/1/08	Oregon Revised Statutes Chapters 183, 192, and 459, and Sections 465.009, 465.505, 466.015, 466.020, 466.075, 466.090, 466.105, 466.165, 466.195, 468, and 646. OAR 340–100–0002/340–102–0200(1)–(4).
222—Export Shipments of Spent Lead-Acid Batteries	75 FR 1236, 1/9/10	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002.
223—Hazardous Waste Technical Corrections and Clarification Rule.	75 FR 12989, 3/18/10	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002.

Description of Federal requirement and Checklist [1] No.	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous state authority
224—Withdrawal of the Emissions Comparable Fuel Exclusion.	75 FR 33712, 6/5/10)	Oregon Revised Statutes 465.009, 465.505, 466.020. OAR 340–100–0002.
225NA—Removal of Saccharin and its Salt from the Lists of Hazardous Constituents.	75 FR 78918, 12/17/10	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002.
226—Academic Laboratories Generator Standards Technical Corrections.	75 FR 79304, 12/20/10	Oregon Revised Statutes Chapter 183, Chapter 192, Chapter 459, 465.009, 465.505, 466.015, 466.020, 466.075, 466.090, 466.105, 466.165, 466.195, Chapter 468, Chapter 646. OAR 340–100–0002.
227—Revision of the Treatment Standards for Carbamate Wastes.	76 FR 34147, 6/13/11	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002.
228—Hazardous Waste Technical Corrections and Clarifications Rule.	77 FR 22229, 7/31/13	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002.
229 [2]—Conditional Exclusions for Solvent-Contaminated Wipes.	78 FR 46447, 7/31/13	Oregon Revised Statute 192, 465.009, 465.505, 466.015, 466.020, 466.075, 466.090, 466.180, 468.020, and 646. OAR 340–100–002/OAR 340–101–0004(3)–(5).
231—Modifications of Hazardous Waste Manifest System: Electronic Manifest.	79 FR 7518, 2/7/14	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002/OAR 340–100–0002(2).
232—Revisions to the Export Provisions of the Cathode Ray Tube.	78 FR 36220, 6/26/14	Oregon Revised Statutes 465.009, 466.020, 465.505. OAR 340–100–0002.
234—Vacatur of the Comparable Fuels Rule and the Gasification Rule.	80 FR 18777, 4/8/15 ..	Oregon Revised Statute 465.009, 465.505, 466.020. OAR 340–100–0002.
235—Disposal of Coal Combustion Residues from Electric Utilities.	80 FR 21301, 4/17/15	Oregon Revised Statute 465.009, 465.505, 466.020. OAR 340–100–0002.

[1] The Checklist is a document that addresses the specific changes made to the Federal regulations by one or more related final rules published in the **Federal Register**. The EPA develops these checklists as tools to assist states in developing their authorization application and in documenting specific state regulations analogous to the Federal regulations. For more information, see the EPA's RCRA State Authorization website at *https://www.epa.gov/rcra/state-authorization-under-resource-conservation-and-recovery-act-rcra#about*.

[2] State rule contains more stringent and/or broader in scope provisions. For identification of these provisions refer to the authorization revision application's Attorney General Statement and Checklists found in the docket for this proposed rule. Some of these provisions are discussed in Section G of this rule.

G. Where are the revised State rules different from the Federal rules?

When revised state rules differ from the Federal rules in the RCRA state authorization process, EPA determines whether the state rules are equivalent to, more stringent than, or broader in scope than the federal program. Pursuant to RCRA Section 3009, 42 U.S.C. 6929, state programs may contain requirements that are more stringent than the federal regulations. Such more stringent requirements can be federally authorized and, once authorized, become federally enforceable.

The following Oregon provisions documented in this authorization action are more stringent than the Federal program:

- Oregon is more stringent than the Federal program at OAR 340–102–0041(2) by requiring annual reporting rather than biennial reporting.
- Oregon is more stringent than the Federal program at OAR 340–102–0200(4) which requires when opting-in to Subpart K, an eligible academic entity is required to submit their completed Laboratory Management Plan as defined in 40 CFR 262.214.
- Oregon is more stringent than the Federal program at OAR 340–102–0200(2) which requires container labels be affixed or attached to the container and eliminates the possibility of these labels being associated with the wrong container.
- Oregon is more stringent than the Federal program at OAR 340–101–0004(4) and (5) by requiring containers of solvent contaminated wipes be either laundered or disposed as hazardous waste. Oregon does not allow disposal of solvent contaminated wipes in a municipal landfill or non-hazardous waste incinerator.

Although the statute does not prevent states from adopting regulations that are broader in scope than the Federal program, states cannot receive authorization for such regulations, and they are not federally enforceable. Oregon is broader in scope than the Federal program documented in this authorization action by requiring academic laboratories that opt into Subpart K to obtain an EPA identification number.

Oregon has identified regulatory language at OAR 340–100–0004(3) as broader in scope. At 40 CFR 261.4(a)(26)(i) and 261.4(b)(18)(i), EPA regulations exclude solvent-contaminated wipes from the definitions of solid waste and hazardous waste, respectively, so long as the wipes are (among other things) stored in containers labeled ''Excluded Solvent-Contaminated Wipes.'' Oregon specifies at OAR 340–100–0004(3) that such wipes may also be ''labeled with equivalent wording describing the contents of the container and recognizing the exclusion[.]'' EPA has evaluated this regulatory language and determined that it is functionally equivalent to the Federal program, so we are including it in this proposed action.

H. Who handles permits after the final authorization takes effect?

When the final authorization takes effect, Oregon will issue permits for all the provisions for which it is authorized and will administer the permits it issues. Permits issued by EPA prior to authorizing Oregon for these revisions would continue in force until the effective date of the State's issuance or denial of a State hazardous waste management permit, at which time, the EPA would modify the existing EPA permit to expire at an earlier date, terminate the existing EPA permit, or allow the existing EPA permit to otherwise expire by its terms, except for those facilities located in Indian Country. The EPA will not issue new permits or new portions of permits for provisions for which Oregon is authorized after the effective date of this authorization. The EPA will continue to implement and issue permits for HSWA

requirements for which Oregon is not yet authorized.

I. How does today's action affect Indian country (18 U.S.C. 1151) in Oregon?

Oregon is not authorized to carry out its hazardous waste program in Indian country within the State, which includes:

- All lands within the exterior boundaries of Indian reservations within or abutting the State of Oregon.
- Any land held in trust by the U.S. for an Indian tribe; and
- Any other land, whether on or off an Indian reservation, that qualifies as Indian country.

Therefore, this action has no effect on Indian country. EPA retains jurisdiction over Indian country and will continue to implement and administer the RCRA program on these lands.

J. What is codification and will EPA codify Oregon's hazardous waste program as proposed in this rule?

Codification is the process of placing citations and references to the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. EPA does this by adding those citations and references to the authorized State rules in 40 CFR part 272. EPA is not proposing to codify the authorization of Oregon's changes at this time. However, EPA reserves the ability to amend 40 CFR part 272, subpart MM at a later date.

K. Statutory and Executive Order Reviews

The Office of Management and Budget (OMB) has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). This action proposes to authorize State requirements for the purpose of RCRA section 3006 and imposes no additional requirements beyond those imposed by State law. Therefore, this action is not subject to review by OMB. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action proposes to authorize pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538). For the same reason, this action also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely proposes to authorize State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant and it does not make decisions based on environmental health or safety risks. This action is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

Under RCRA section 3006(b), the EPA grants a state's application for authorization as long as the state meets the criteria required by RCRA. It would thus be inconsistent with applicable law for the EPA, when it reviews a state authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in proposing this rule, the EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. The EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of this action in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). ''Burden'' is defined at 5 CFR 1320.3(b). Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. Because this action proposes authorization of pre-existing State rules which are at least equivalent to, and no less stringent than existing Federal requirements, and imposes no additional requirements beyond those imposed by State law, and there are no anticipated significant adverse human health or environmental effects, this proposed rule is not subject to Executive Order 12898.

Authority: This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: September 28, 2021.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

[FR Doc. 2021–21565 Filed 10–4–21; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket No. 12–375, DA 21–1192, FRID 51251]

Third Mandatory Data Collection for Inmate Calling Services

AGENCY: Federal Communications Commission.

ACTION: Solicitation of comments.

SUMMARY: The Wireline Competition Bureau and the Office of Economics and Analytics (WCB/OEA) seek comment on the contours and specific requirements of the forthcoming Third Mandatory Data Collection for inmate calling services. WCB/OEA have drafted proposed instructions, a template, and a certification form for the Third Mandatory Data Collection. WCB/OEA seek comment on all aspects of these documents.

DATES: Comments are due November 4, 2021. Reply Comments are due November 19, 2021.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Katherine Morehead, Pricing Policy Division of the Wireline Competition Bureau, at (202) 418–0696 or via email at *katherine.morehead@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of a document that the Federal Communications Commission's Wireline Competition Bureau released on September 22, 2021. A full-text version of the document is available at the following internet address: *https://docs.fcc.gov/public/attachments/DA-21-1192A1.pdf.*

I. Introduction and Background

By this document, the Wireline Competition Bureau (WCB) and the Office of Economics and Analytics (OEA) (collectively, WCB/OEA) seek comment on the contours and specific requirements of the forthcoming Third Mandatory Data Collection for inmate calling services (ICS). In 2020, the Commission sought comment on whether and how the Commission should proceed with any new data collection. The record demonstrated the need to ''collect, in a more consistent and directed manner, the data and information necessary to respond to the various criticisms in the record about the imperfections and inconsistencies in the data from the Second Mandatory Data Collection.'' In the *2021 ICS Order,* the Commission directed WCB/OEA to develop a new data collection related to providers' operations, costs, demand, and revenues. The Commission has conducted two prior mandatory data collections relating to inmate calling services in the past eight years—the 2013 First Mandatory Data Collection and the 2015 Second Mandatory Data Collection. The Commission explained that it would use the collected data to set permanent interstate and international ICS provider-related rate caps that more closely reflect providers' costs of serving correctional facilities. The Commission also emphasized that the data would enable it to evaluate and, if warranted, revise the current ancillary service charge caps.

The Commission delegated authority to WCB/OEA to implement this Third Mandatory Data Collection, including ''determining and describing the types of information required related to providers' operations, costs, demand, and revenues,'' and directed WCB/OEA to develop a template and instructions for the collection. The draft instructions and template for the Third Mandatory Data Collection are posted on the Commission's website and are located at this link: Third Mandatory Data Collection Instructions. The template consists of a Word document and Excel spreadsheets. For simplicity, WCB/OEA refer to these respective portions of the template as the Word template and the Excel template. The Commission also directed WCB/OEA to consider record suggestions regarding, among other matters, data granularity, cost allocation, and specificity in definitions and instructions in designing the data collection, and ''to require each provider to fully explain and justify each step of its costing process'' including, where appropriate, ''to specify the methodology the provider shall use in any or all of those steps.'' The Commission also directed WCB/OEA to ''incorporate lessons learned from the two prior data collections to ensure that [the Commission] collect[s], to the extent possible, uniform cost, demand, and revenue data from each provider.''

II. Overall Structure of the Data Collection

Pursuant to WCB/OEA's delegated authority, WCB/OEA have drafted proposed instructions, a template, and a certification form for the Third Mandatory Data Collection. WCB/OEA seek comment on all aspects of these documents. Do they sufficiently implement the requirements the Commission articulated for the mandatory data collection in the *2021 ICS Order*? If not, what steps should WCB/OEA take to improve the proposed documents? The Commission's prior data collections have demonstrated that detailed and specific instructions and templates are essential to ensure that providers use similar procedures to determine and report their costs, revenues, and other data. WCB/OEA invite comment on whether the proposed instructions and template are sufficiently detailed to accomplish this objective. If not, what additional instructions, inquiries, or fields should WCB/OEA add? Conversely, are there any instructions, inquiries, or fields that should be removed because they are unnecessary to ensure that providers report uniform and accurate data and other information?

A. Instructions to the Third Mandatory Data Collection

WCB/OEA seek comment on whether the instructions provide sufficient guidance to ensure that providers use uniform methodologies and report the required information in a consistent manner. What improvements can WCB/OEA make to the instructions? Are there any changes that would clarify the instructions or increase uniformity across providers' responses, particularly regarding how to report and allocate their costs? If so, what specific changes should WCB/OEA make? Are there any definitions that are unclear? Are there any undefined terms WCB/OEA should define? Is there alternative or additional language that would minimize ambiguity in any instruction? The proposed instructions also include many requests that are not specifically described below. WCB/OEA seek comment on all aspects of the proposed instructions, including on those requests that WCB/OEA do not address individually in this document.

Reporting Period. The proposed instructions generally seek data for each calendar year from 2019 through 2021, but seek cost data only for calendar year 2021, in part to minimize the burden of responding to this data collection. Is this the correct period for general data requests, such as revenues, site commission payments, and calling minutes? Is cost data only for calendar year 2021 the most relevant to collect? Would cost data from 2019, on the other hand, provide the most representative data set, given that the data from 2020 and 2021 will reflect the impact of the COVID–19 pandemic upon operations? Should WCB/OEA adopt a longer or shorter period for any set of requests? If so, why? Are there any specific known and measurable changes to ICS-related investments, expenses, revenues, and demand over the next few years that are not reflected in the data the proposed instructions seek to collect?

Financial Information. The proposed instructions require providers to report financial data in accordance with generally accepted accounting principles and specify that the carrying value of all assets shall reflect the results of recent impairment testing that accurately removes any overstatement of carrying value otherwise recorded in a provider's book of accounts. Under generally accepted accounting principles, an asset or asset group is impaired when its carrying amount, that is, the value reflected on the balance sheet, net of depreciation or amortization, exceeds its fair market value. In that case, the value of the impaired asset or asset group is written down and the reduced value is reflected on the balance sheet and a loss is recorded on the income statement. Is this the correct approach? If not, why not? How often do providers test their assets for impairment and how often are they required to do so under generally accepted accounting principles? Are additional instructions needed to ensure that the carrying value of providers' assets is not overstated? If so, what other instructions should WCB/OEA adopt?

WCB/OEA seek comment on whether providers maintain sufficient records to enable them to respond fully to the data collection. If not, what additional steps should WCB/OEA take to ensure that the Commission has sufficient information to set reasonable permanent provider-related rate caps for interstate and international ICS and to revise the current ancillary service change caps? Should WCB/OEA adopt workarounds that would provide reasonable proxies for any financial data that providers are unable to report and, if so, what workarounds should WCB/OEA specify?

Cost Allocation. WCB/OEA propose several steps for providers to follow in allocating their costs among various services, as set forth in the proposed instructions. What refinements, if any, should WCB/OEA make to the proposed cost allocation methodology? Is there an alternative methodology that would better ensure that providers allocate their costs in a manner consistent with how they are incurred? If so, what is that methodology and why would it produce more accurate results than the proposed method? Are there additional allocation steps or instructions that would result in greater uniformity in providers' cost allocation procedures or greater accuracy in the cost allocation results? Do all or most providers routinely track certain data in the normal course of operating their businesses that should be used to develop allocators for particular costs or groups of costs? Are there additional steps WCB/OEA should take to ensure that each provider will directly assign its investments and expenses to the extent possible? Similarly, are there additional steps WCB/OEA can take to ensure that each provider will allocate shared and common investments and expenses in a cost-causative manner?

Response Granularity. WCB/OEA propose that all providers submit data both at the company-wide level and for each correctional facility in which the provider offered calling services during the reporting period. WCB/OEA seek comment on this approach. Assuming WCB/OEA should require providers to report data on a facility-level basis, how should WCB/OEA require providers that track costs only on a contract level to respond? Are the cost allocation procedures set forth in the instructions sufficient to enable these providers to allocate costs down to the facility and, if not, what additional procedures should WCB/OEA require? Are there any additional data WCB/OEA should seek that would help ensure that providers allocate costs to facilities in a manner that more accurately reflects how such costs are incurred? How and to what degree should a provider document or explain the way it derives facility-level costs?

The proposed instructions give providers the option of reporting their investment and expense data for ICS and related ancillary services without separating them into interstate and intrastate components or, if they prefer, to perform that separation prior to reporting their data. This approach reflects the fact that WCB/OEA are unaware of any material cost differences between providing interstate and intrastate calling services based on the record in this proceeding to date. Is that understanding correct? Are there any data for which a separation into interstate and intrastate components would be helpful in determining the costs providers incur solely in providing interstate and international calling services and related ancillary services?

B. Template

WCB/OEA propose to require providers to submit the requisite data using a reporting template, to be filed through the Commission's electronic comment filing system (ECFS). The proposed template consists of a Word document (Appendix A to the instructions) for responses requiring narrative information and Excel spreadsheets (Appendix B to the instructions) for responses that require specific numbers or information. WCB/OEA seek suggestions for improvements WCB/OEA can make to the template. Is there an alternative organization that would reduce any perceived burdens? Are there other organizational or substantive improvements WCB/OEA can make to the reporting requirements? Are there inquiries WCB/OEA should add to the templates? Are there inquiries WCB/OEA should eliminate? If so, why? Do any questions require clarification?

III. Specific Inquiries

General Categories of Information Requested. The proposed instructions require providers to submit certain types of information related to their operations, costs, demand, and revenues. Are the categories of data described in sufficient detail in the proposed instructions? Are there additional categories or subcategories of information WCB/OEA should require providers to submit, in order to gather accurate, consistent, and sufficiently disaggregated data? Is there additional information that would help quantify the relative financial importance of different products and services in each provider's business portfolio or ICS operations? Is there additional information WCB/OEA could seek to facilitate a thorough accounting of the providers' investments, particularly to distinguish investments in intangible assets that were created internally from investments in intangible assets and goodwill generated by acquisitions or asset purchases? If so, how should WCB/OEA draw this distinction and how should any distinctions be reflected in the development of permanent rate caps? Is there additional information WCB/OEA should seek to help thoroughly account for a provider's recurring capital expenses or recurring operating expenses? Should customer deposits be subtracted from the provider's net investment in assets, the base upon which an allowable rate of return is calculated? Do customer deposits represent non-investor-supplied capital? Does the provider pay interest on the outstanding customer deposit balance? Is the provider able to earn a return on the outstanding customer deposit balance? Are there additional subcategories of data WCB/OEA should seek that will enable the Commission to better estimate providers' costs of serving individual correctional facilities?

Demand for Interstate and International Calling Services. WCB/OEA propose to seek information on providers' demand for interstate and international calling services by requiring providers to report billed minutes, unbilled minutes, average daily population, number of telephones installed, and the number of kiosks installed. Are there other types of data that would provide a more accurate picture of demand such as the number of beds, or the rate of new account generation, at a particular facility? For example, would the rates of new account generation or account termination serve as accurate proxies for demand, or otherwise reflect cost drivers that could be used to better allocate provider costs? Could a measure of demand other than minutes be used as the unit of sale for the permanent rate caps? If providers do not know the average daily population of certain facilities they serve, what data could they report to provide a reasonable proxy for average daily population in those instances? What impact has the COVID–19 pandemic had on the cost of providing and the demand for intrastate, interstate, and international calling services? Do providers expect that impact to persist?

Data for Jails with Fewer than 1,000 ADP. The Commission explained in the *2021 ICS Order* that ''[a]lthough in some places WCB/OEA use the term 'smaller jails' to refer to facilities with average

daily populations less than 1,000, that usage is not meant to imply that such jails are small in any absolute sense.'' In the *2021 ICS Order,* the Commission observed that the record then before it did not ''allow [it] to reasonably set permanent or even new interim interstate rate caps for jails with less than 1,000 average daily population.'' What types of data would provide a more accurate picture of the costs providers incur in serving such jails? What are the specific factors that differentiate the costs associated with serving such jails from the costs of serving larger jails? What data should WCB/OEA collect to analyze those factors? What are the one-time costs that providers incur to initiate service for a newly incarcerated person in such jails as compared to larger jails? Should WCB/OEA require providers to separately report these one-time costs? If so, what are the appropriate one-time cost categories? The record suggests that higher turnover in jails with less than 1,000 ADP may affect providers' and facilities' costs. How should providers be required to report turnover data, and how can WCB/OEA analyze those data to identify the impact of turnover on provider and facility costs, or to distinguish between them? Are there additional data WCB/OEA can request that would help the Commission quantify and evaluate the effect of turnover?

Site Commissions. WCB/OEA propose to require that providers separately identify the amounts of (1) legally mandated, (2) contractually prescribed, (3) monetary, and (4) in-kind site commission payments. Are there other categories of information WCB/OEA should seek regarding site commissions? How should providers submit information concerning in-kind payments? For example, should WCB/OEA require providers to describe their in-kind payments in detail and assign them a dollar value? In the *2021 ICS Order,* the Commission observed that the record did not allow it to ''determine on a permanent basis whether and what portion of [site commission] payments are legitimately related to the cost'' of providing inmate calling service.'' What types of information should WCB/OEA seek to help make this determination? Should WCB/OEA, for example, require providers to explain whether they agree to pay site commission on ICS calls to get footholds in facilities where they can offer non-ICS products and services that will not be subject to site commission payments obligations? If so, how can WCB/OEA ensure that providers allocate their site commission payments between their ICS-related operation and those other operations in a cost-causative manner?

Security Services. As the Commission explained in 2021, to determine whether any costs associated with security services should be recovered through ICS rates, it first must be able to determine whether any of those costs are directly related to the provision of ICS and distinguish them from other security costs incurred by correctional institutions. To facilitate this determination, the proposed instructions would require providers to report security costs in connection with the providers' ICS-related and non-ICS-related operations. Are there other data WCB/OEA should seek concerning such costs? What categories of security costs are properly considered directly related to ICS? What categories are not? How should WCB/OEA require providers to separate and report security costs which are legitimately or directly related to ICS from general facility security costs? Should WCB/OEA require providers to specify whether any such cost is incurred by the ICS provider or the facility? In 2021, the Commission observed that there is record evidence suggesting that some of the security and surveillance functions described by the National Sheriffs' Association as being performed by correctional facility staff appear to duplicate some of the security functions that providers report as costs. Are there any other data WCB/OEA could collect that would assist the Commission in determining whether security costs are directly or legitimately related to the provision of ICS? Should WCB/OEA collect specific data about security costs that may not be directly or legitimately related to the provision of ICS, such as costs incurred to monitor and record every call made by an incarcerated person?

Ancillary Service Charges. WCB/OEA propose to require providers to report revenues and disaggregated costs incurred for ancillary services. WCB/OEA seek comment on this proposal, as reflected in the instructions. In the *2021 ICS Order,* the Commission observed that the existing record did not allow it to ''adjust [the] caps on ancillary service fees beyond the new cap on fees for single-call services and third-party financial transaction fees.'' The instructions for the Second Mandatory Data Collection required certain ancillary service revenues to be reported separately, but providers were not required to report their ancillary service costs separately from other inmate calling services costs. Further, providers were not required to separately report costs relating to any specific ancillary service. The Commission found that there was ''no reliable way to exclude ancillary service costs from [the] provider-related rate caps calculations at this time.'' By consequence, the Commission allowed such costs to ''remain as part of the industry costs'' used in the calculations for the interim rate caps. What other revenue or disaggregated cost data should WCB/OEA seek to enable the Commission to evaluate and, if warranted, revise the current ancillary service charge caps and/or isolate and exclude ancillary service costs from any future calculations related to per-minute rate caps?

In the *2021 ICS Order,* the Commission identified ''confusion among industry stakeholders regarding the relationship between the automated payment fee and third-party financial transaction fees as they relate to credit card processing fees.'' To determine how credit card processing works in relation to these two ancillary services, WCB/OEA propose to require providers to report the total amount of revenues derived from charging automated payment fees and third-party transaction fees, to report the amount of that total that is credit card processing separately, and specify whether the provider, an affiliate, or a third party performs the processing. Do commenters agree with this approach? If not, how should WCB/OEA require providers to report credit card processing revenues embedded in revenues derived from these two ancillary service charges?

The Commission also expressed concern about ''the adverse effect of revenue-sharing arrangements between calling service providers and third-party financial institutions'' in the context of ancillary services. To assist the Commission in understanding the prevalence and effect of such agreements, WCB/OEA propose to require providers to identify revenue-sharing agreements related to ancillary services and the revenues shared under those agreements. What other information should WCB/OEA seek on revenue-sharing agreements?

Additional Data. Beyond the foregoing, are there other types of data WCB/OEA should require providers to submit to ensure that WCB/OEA fully capture the costs of providing ICS? Are there additional data that may enable the Commission to better understand the costs ICS providers and correctional facilities incur in connection with ICS? How should any such data be compiled and used to ensure that direct and shared and common costs are assigned

or allocated in the most cost-causative manner? What data should WCB/OEA collect concerning international calling costs to isolate those costs and to eliminate the risk of double counting?

Are there other issues WCB/OEA should consider regarding the data WCB/OEA propose to collect? Should WCB/OEA seek data on the marketing and sale of inmate calling services, such as contracts by which correctional facilities purchase calling services on behalf of incarcerated persons at fixed monthly rates? If so, what data should WCB/OEA ask for? For example, should WCB/OEA direct providers to identify in narrative responses the terms of any bulk-purchasing arrangements they have with correctional facilities? ''Bulk purchasing'' in this context refers to the purchase by a correctional facility of ICS at fixed monthly rates or other similar arrangements such as unlimited calling plans at fixed rates. What data should WCB/OEA ask for from providers that enter into service arrangements, such as GTL's contract with San Francisco, whereby incarcerated people receive free telephone service?

IV. Miscellaneous

In the *2021 ICS Order,* the Commission delegated to WCB/OEA the authority to ''require providers to submit any additional information that they deem necessary to help the Commission formulate permanent rate caps or to revise [the] rules governing ancillary service charges.'' WCB/OEA propose to require all providers to submit audited financial statements or reports, or similar documentation, for the relevant reporting period, to the extent they have been produced in the ordinary course of business. Are there other reports or documentation WCB/OEA should seek? Should WCB/OEA require providers to provide copies of all or a random sample of their ICS contracts to assist Commission staff in verifying or crosschecking data submitted in response to the Third Mandatory Data Collection?

Separately, in the *2021 ICS Order,* the Commission reasoned that the benefits of conducting a third data collection ''far outweigh any burden on providers'' given the ''adverse impact that unreasonably high rates and ancillary services charges have on incarcerated people and those family and loved ones they call.'' While WCB/OEA do not revisit this general finding, WCB/OEA do seek to maximize the benefits of this data collection while minimizing the costs to the extent WCB/OEA can. WCB/OEA therefore seek comment on whether these proposals will meet the Commission's objectives in requiring the data collection. If not, what additional questions should WCB/OEA ask to ensure the Commission has all the data it needs to set permanent rate caps, evaluate ancillary service fees, and adjust the caps for those fees, if necessary? Conversely, are there ways that WCB/OEA could minimize the burden on providers while still ensuring WCB/OEA collect all the data the Commission needs to meet its goals? If so, what specific changes do commenters propose in this regard? WCB/OEA also seek to ensure that smaller providers are not disproportionately burdened by this data collection, while recognizing that data from smaller providers is critical to the Commission's ratemaking process going forward. Do commenters have suggestions as to how WCB/OEA can get the information WCB/OEA need from smaller providers in a less burdensome way? If so, how?

In the *2021 Order,* the Commission eliminated the separate interim rate cap that had applied to interstate collect calls, an action that reflected a record establishing that collect calls now play only a limited role in the inmate calling services marketplace and that there is at most a relatively small difference between the costs of providing collect and non-collect inmate calling services calls. Consistent with that Commission action, the proposed instructions do not differentiate among debit, prepaid, and collect calls. WCB/OEA seek comment on whether the instructions should distinguish among these call types. If so, why and for which specific components of the proposed data collection?

Finally, as part of the Commission's continuing effort to advance communications equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, WCB/OEA invite comment on any equity-related considerations and benefits (if any) that may be associated with the upcoming Third Mandatory Data Collection. Section 1 of the Communications Act of 1934, as amended, provides that the Commission ''regulat[es] interstate and foreign commerce in communication by wire and radio so as to make [such service] available, so far as possible, to all the people of the United States, without discrimination on the basis of race, color, religion, national origin, or sex.'' WCB/OEA define the term ''equity'' consistent with Executive Order 13985 as the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. Specifically, WCB/OEA seek comment on how these proposals for that collection may promote or inhibit advances in diversity, equity, inclusion, and accessibility.

V. Procedural Matters

Filing of Comments and Replies. Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System. *See* FCC, Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (May 1, 1998). The Protective Order issued in this proceeding permits parties to designate certain material as confidential. Filings that contain confidential information should be appropriately redacted and filed pursuant to the procedure described therein.

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *https://www.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.
- Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701. U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.
- Effective March 19, 2020, and pending additional information, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect

the health and safety of individuals, and to mitigate the transmission of COVID–19.

Comments and reply comments must include a short and concise summary of the substantive arguments raised in the pleading. Comments and reply comments must also comply with section 1.49 and all other applicable sections of the Commission's rules. WCB/OEA direct all interested parties to include the name of the filing party and the date of the filing on each page of their comments and reply comments. All parties are encouraged to use a table of contents, regardless of the length of their submission. WCB/OEA also strongly encourage parties to track the organization set forth in the WCB/OEA document and the instructions in order to facilitate the internal review process.

People with Disabilities. WCB/OEA ask that requests for accommodations be made as soon as possible in order to allow the agency to satisfy such requests whenever possible. Send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530.

Ex Parte Presentations. This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in the prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with section 1.1206(b) of the Commission's rules. Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Supplemental Initial Regulatory Flexibility Act Analysis. As required by the RFA, the Commission has prepared a Supplemental Initial Regulatory Flexibility Analysis (Supplemental IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in the WCB/OEA document. The Commission requests written public comments on the Supplemental IRFA. Comments must be identified as responses to the Supplemental IRFA and must be filed by the deadlines for comments provided in this Notice. The Commission will send a copy of the WCB/OEA document, including this Supplemental IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, summaries of the WCB/OEA document and the Supplemental IRFA will be published in the **Federal Register**.

Final Paperwork Reduction Act Analysis. The WCB/OEA document contains new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other federal agencies are invited to comment on the new or modified information collection requirements contained in this proceeding. Contemporaneously with the publication of this Notice in the **Federal Register**, WCB/OEA will publish a notice in the **Federal Register** seeking comment pursuant to the PRA on the information collection requirements for the Mandatory Data Collection in the *2021 ICS Order* and this Public Notice. WCB/OEA will consider comments submitted in response to both **Federal Register** notices in finalizing this information collection for submission to OMB. In addition, WCB/OEA note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198; *see* 44 U.S.C. 3506(4), WCB/OEA previously sought comment on how the Commission will further reduce the information collection burden for small business concerns with fewer than 25 employees.

Additional Information. For further information, please contact Erik Raven-Hansen, Wireline Competition Bureau, Pricing Policy Division, at (202) 418–1532 or *erik.raven-hansen@fcc.gov, or Peter Bean,* Wireline Competition Bureau, Pricing Policy Division, at (202) 418–0786 or *peter.bean@fcc.gov.* Please copy *mandatorydatacollection@fcc.gov on any email correspondence.*

VI. Supplemental Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Wireline Competition Bureau (WCB) and the Office of Economics and Analytics (OEA) (collectively, WCB/OEA) have prepared this Supplemental Initial Regulatory Flexibility Analysis (Supplemental IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in the WCB/OEA document. WCB/OEA request written public comments on this Supplemental IRFA. Comments must be identified as responses to the Supplemental IRFA and must be filed by the deadlines for comments provided in this Public Notice. The Commission will send a copy of the WCB/OEA document, including this Supplemental IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the Public Notice and the Supplemental IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Data Collection

In this document, WCB/OEA seek comment on the contours and specific requirements of the forthcoming Third Mandatory Data Collection for inmate calling services (ICS). In 2020, the Commission sought comment on whether and how the Commission should proceed with any new data collection. In the *2021 ICS Order,* the Commission adopted a new data collection requirement. The Commission determined that this data collection would enable it to adopt permanent interstate and international rate caps, protect consumers against unjust and unreasonable ancillary service charges, and improve its continuing review of the inmate calling services marketplace.

Pursuant to their delegated authority, WCB/OEA have drafted proposed instructions and a template for the Third Mandatory Data Collection and are issuing the WCB/OEA document to seek comment on all aspects of these documents.

B. Legal Basis

The legal basis for any action that may be taken pursuant to the WCB/OEA document is contained in sections 1, 2, 4(i)–(j), 201(b), 218, 220, 276, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i)–(j), 201(b), 218, 220, 276, and 403.

C. Description and Estimate of the Number of Small Entities to Which the Third Mandatory Data Collection Will Apply

The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the Third Mandatory Data Collection. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.'' A ''small-business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

Regulatory Flexibility Analyses were incorporated in a 2020 document and the *2021 ICS Order*. In those analyses, the Commission described in detail the small entities that might be affected. Accordingly, in this document, for the Supplemental IRFA, WCB/OEA hereby incorporate by reference the descriptions and estimates of the number of small entities from these previous Regulatory Flexibility Analyses.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

The WCB/OEA document seeks comments on the specifics of the Third Mandatory Data Collection to ensure calling services rates, charges, and practices are just and reasonable. The Third Mandatory Data Collection requires ICS providers to submit, among other things, data and other information on calls, demand, operations, company and contract information, information about facilities served, revenues, site commission payments, and ancillary fees.

E. Steps Taken To Minimize the Significant Economic Impact on Small Entities and Significant Alternatives Considered

The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.'' WCB/OEA will consider all of these factors when WCB/OEA receive substantive comment from the public and potentially affected entities.

The Third Mandatory Data Collection is a one-time request and does not impose a recurring obligation on providers. Because the Commission's *2021 ICS Order* requires all ICS providers to comply with the mandatory data collection, the collection will affect smaller as well as larger ICS providers. The Commission has taken steps to ensure that the data collection template is competitively neutral and not unduly burdensome for any set of providers. Additionally, the WCB/OEA document asks whether there are ways of minimizing the burden of the data collection on providers while still ensuring that the Commission collects all the data needed to meet its goals.

WCB/OEA will consider the economic impact on small entities, as identified in comments filed in response to the WCB/OEA document and this Supplemental IRFA, in reaching its final conclusions and finalizing the instructions and the template for the Third Mandatory Data Collection.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

None.

Federal Communications Commission.

Daniel Kahn,

Associate Bureau Chief, Wireline Competition Bureau.

[FR Doc. 2021–21781 Filed 10–4–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No.: 210916–0190]

RIN 0648–BK68

Fisheries of the Northeastern United States; Atlantic Sea Scallop Fishery; Amendment 21

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to approve and implement through regulations measures included in Amendment 21 to the Atlantic Sea Scallop Fishery Management Plan, which the New England Fishery Management Council adopted and submitted to NMFS for approval. This action would allow for more controlled access to the scallop resource by the limited access and limited access general category fleets and increase monitoring to a growing directed scallop fishery in Federal waters, including the Northern Gulf of Maine Management Area. These proposed management measures are intended to promote conservation of the scallop resource in the Northern Gulf of Maine Management Area and to manage total removals from the area by all fishery components. Amendment 21 would also expand flexibility in the limited access general category individual fishing quota fishery to reduce impacts of potential decreases in ex-vessel price and increases in operating costs.

DATES: Comments must be received by November 4, 2021.

ADDRESSES: The Council has prepared a draft Environmental Assessment (EA) for this action that describes the proposed measures Amendment 21 to the Atlantic Sea Scallop Fishery Management Plan (FMP) and other considered alternatives and analyzes the impacts of the proposed measures and alternatives. The Council submitted a draft of the amendment to NMFS that includes the draft EA, a description of the Council's preferred alternatives, the Council's rationale for selecting each alternative, and a Regulatory Impact Review (RIR). Copies of supporting documents used by the New England Fishery Management Council, including the EA and RIR, are available from: Thomas A. Nies, Executive Director,

New England Fishery Management Council, 50 Water Street, Newburyport, MA 01950 and accessible via the internet in documents available at: *https://www.nefmc.org/library/amendment-21*.

You may submit comments, identified by NOAA–NMFS–2021–0065, by the following method:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov* and enter NOAA–NMFS–2021–0065 in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Travis Ford, Fishery Policy Analyst, (978) 281–9233, *travis.ford@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Atlantic sea scallop fishery is prosecuted along the east coast from Maine to Virginia, although most fishing activity takes place between Massachusetts and New Jersey. Management measures were first adopted in 1982, but there have been several major revisions to the management program in the subsequent decades.

Development of the Limited Access General Category Fishery

The Council established the general category component as an open access permit category in 1994 while developing a limited access program for qualifying vessels (now the limited access component). Through Amendment 11 to the Scallop FMP (73 FR 20090, April 14, 2008), the Council transitioned the general category component from open access to limited access in order to limit fishing mortality and control fleet capacity. The Council's vision for the Limited Access General Category (LAGC) component was a fleet made up of relatively small vessels, with possession limits to maintain the historical character of this fleet and provide opportunities to various participants, including vessels from smaller coastal communities. Amendment 11 established three LAGC permit categories, which allowed for continued participation in the general category fishery at varying levels. Vessels that met qualifying criteria were issued an LAGC individual fishing quota (IFQ) permit and allocated quota based on the 'contribution factor' (*i.e.* if they fished longer and landed more during the qualification period, they received a higher allocation). General category permit holders that did not meet the qualifying criteria for an LAGC IFQ permit were eligible to receive either an LAGC Northern Gulf of Maine (NGOM) permit or LAGC incidental permit. Limited access vessels that fished under general category rules and qualified under the same IFQ qualification criteria were issued LAGC IFQ permits and allocated a portion (0.5 percent) of the total scallop allocation. Unlike vessels with only LAGC IFQ permits, limited access vessels that also qualified for an LAGC IFQ permit were not allowed to transfer quota to or from other vessels.

Northern Gulf of Maine Management Area

The Council also established the Northern Gulf of Maine (NGOM) Management Area and permit category through Amendment 11. The area was established to enable continued fishing and address concerns related to conservation, administrative burden, and enforceability of scallop fishing within the Gulf of Maine. Amendment 11 authorized vessels with either an LAGC NGOM permit or LAGC IFQ permit to fish within the NGOM Management Area at a 200 lb per day (91 kg per day) trip limit until the fleet reaches the annual total allowable catch (TAC) for the area. The Council did not recommend restrictions on limited access vessels fishing in the NGOM because the improved management and abundance of scallops in the major resource areas on Georges Bank and in the Mid-Atlantic region made access to Gulf of Maine scallops less important for the limited access boats and general category boats from other regions. From 2008 through 2017, limited access vessels were able to operate in the NGOM management area under days-at-sea (DAS) management as long as the LAGC TAC had not been caught. The initial measures were intended to allow directed scallop fishing in the NGOM, and the Council envisioned that management of this area would be reconsidered if the scallop population and fishery in the NGOM grew in the future.

For each of the years 2009 through 2015, the NGOM TAC of 70,000 lb (31,751 kg) was not caught, and the fishery remained open for the entire year. In fishing years 2016 and 2017, there was a notable increase in effort in the NGOM management area by both LAGC and limited access vessels fishing the large year class of scallops on Stellwagen Bank, located mostly within the NGOM. Monitoring removals by the limited access component in the NGOM was challenging because vessels could fish both inside and outside NGOM management area while fishing under DAS management on the same trip.

In response to the increase in effort and landings in the NGOM area in 2016 and 2017, the Council developed the following problem statement for the Federal scallop fishery in the NGOM management area: Recent high landings and unknown biomass in the NGOM Scallop Management Area underscore the critical need to initiate surveys and develop additional tools to better manage the area and fully understand total removals.

Recent actions have developed measures that allow managers to track fishing effort and landings by all components from the NGOM management area. The NGOM TAC is now based on recent survey information, with separate TACs for the limited access and LAGC components. These measures were intended to be a short-term solution to allow controlled fishing in the NGOM management area until NGOM issues could be addressed more holistically, as this action proposes to do.

Limited Access General Category Individual Fishing Quota Possession Limits

The initial general category possession limit was set at 400 lb (181 kg) per trip through Amendment 4 (59 FR 2757; January 19, 1994). In 2007, Amendment 11 maintained the general category possession limit of 400 lb (181 kg) for qualifying IFQ vessels. Amendment 15 (76 FR 43746, July 21, 2011) increased the LAGC IFQ possession limit to 600 lb (272 kg) following concerns from industry

members that the 400-lb (181-kg) possession limit was not economically feasible due to increased operating costs. The 200-lb (91-kg) trip limit increase was not expected to change the nature of the ''day boat'' fishery and would keep the LAGC IFQ component consistent with the vision statement laid out by the Council in Amendment 11. The Council recently completed a program review of the LAGC IFQ fishery and analyzed the impacts of changes to IFQ trip limits. This review found that increasing the possession limit for IFQ trips would increase flexibility in fishing decisions, which could improve safety. Further, a higher possession limit would provide increased fishing revenue and vessel profit. The results of the program review are summarized in the Amendment 21 scoping document, which can be found at this website: *https://www.nefmc.org/library/amendment-21.*

Quota Transfers by Limited Access/LAGC IFQ Vessels

Amendment 15 allowed LAGC IFQ permit holders to permanently transfer some or all of their quota allocation to another LAGC IFQ permit holder while retaining the permit itself. During development of Amendment 15, the Council considered an option that would have included limited access permit holders that also have LAGC IFQ permits (combo vessels) in this allowance; however, the Council decided against this option so as not to change the overall 5-percent and 0.5-percent allocations specified in Amendment 11. For example, if a combo vessel permanently transferred quota to an LAGC IFQ-only vessel, the 5-percent allocation would be expected to increase and would have implications on quota accumulation caps that apply to LAGC IFQ-only permit holders (*i.e.* 5-percent maximum for owners, 2.5-percent maximum for individual vessels).

Summary of Amendment 21

The Council initiated Amendment 21 to consider adjusting the management of the NGOM to allow for more controlled access by the limited access and LAGC components, to increase monitoring to support a growing directed scallop fishery in Federal waters, and to consider adjusting the LAGC IFQ program to support overall economic performance while allowing for continued participation in the general category fishery at varying levels. To address these issues, the Council approved Amendment 21 at its September 2020 meeting. Amendment 21 would:

- Change the Annual Catch Limit (ACL) flow chart to account for biomass in the NGOM as part of the Overfishing Limit (OFL) and the Acceptable Biological Catch (ABC) to be consistent with other portions of scallop resource management;
- Develop landing limits for all permit categories in the NGOM and establish an 800,000-lb (362,874 kg) NGOM Set-Aside trigger for the NGOM directed fishery, with a sharing agreement for access by all permit categories for allocation above the trigger. Allocation above the trigger would be divided, with 5 percent for the NGOM fleet and 95 percent for limited access and LAGC IFQ fleets;
- Expand the scallop observer program to monitor directed scallop fishing in the NGOM by using a portion of the NGOM allocation to off-set monitoring costs;
- Allocate 25,000 lb (11,340 kg) of the NGOM allocation to increase the overall Scallop Research Set-Aside (RSA) and support Scallop RSA compensation fishing;
- Increase the LAGC IFQ possession limit to 800 lb (363 kg) per trip only for access area trips;
- Prorate the daily observer compensation rate in 12-hour increments for observed LAGC IFQ trips longer than 1 day; and
- Allow for temporary transfers of IFQ from limited access vessels with IFQ to LAGC IFQ-only vessels.

It is the Council's intent for Amendment 21 that the proposed measures become effective in concordance with updated specifications for fishing year 2022, which are currently under development through Framework Adjustment 34 to the Scallop FMP and have a target implementation date of April 1, 2022. If the implementation of Framework Adjustment 34 is delayed beyond April 1, 2022, the default measures, specifications, and possession limits for fishing year 2022 developed in Framework Adjustment 33 to the Scallop FMP (86 FR 27042, May 19, 2021) would still apply.

Proposed Measures

Accounting for the NGOM as Part of the ABC and ACL

Amendment 21 would modify the ACL flowchart to account for the scallop biomass in the NGOM as part of the legal limits in the fishery by adding biomass from the area into calculations of the OFL and ABC. This action would move the accounting of the NGOM ACL from only within the OFL into the OFL and ABC/ACL for the entire fishery (Figure 1). By including exploitable scallop biomass from the NGOM as part of the scallop OFL and ABC, the ACL and sub-ACLs for the limited access and LAGC IFQ, and the limited access Annual Catch Target (ACT) would increase. The observer set-aside would also increase with the NGOM as part of the OFL/ABC. The ABC/ACL would be reduced by the NGOM Set-Aside value, along with the Research and Observer Set-Asides and incidental catch (Figure 1). The Council would set specifications for the NGOM though future specifications actions.

The Council would use the following approach to include the NGOM in the ACL flowchart:

1. Exploitable biomass from surveyed areas of the NGOM would be estimated;

2. The contribution to the OFL would be calculated at the fishing mortality (F) rate equal to the estimate of F of Maximum Sustainable Yield (F_{MSY}) for Georges Bank from the most recent research or management track assessment, unless direct estimates of F_{MSY} for the Gulf of Maine are available; and

3. Combining OFL values from areas on Georges Bank/Mid Atlantic and the NGOM could be done in a single model (*e.g.,* add the NGOM to the Scallop Area Management Simulator model), or as separate calculations. The method would, in part, be determined by the available data.

Incorporating the NGOM into the ACL flowchart would have no impact on limited access DAS, or any other fishery allocation that is part of the Annual Projected Landings (APL).

Including the NGOM in the OFL and ABC would allow the fishery's overall limits to change with biomass in the NGOM. This would create a mechanism to increase the LAGC IFQ and limited access ACTs by accounting for biomass in the NGOM. In addition, incorporating the biomass from the NGOM into the ACL flowchart would increase the allocation that is available for the fishery's observer set-aside program.

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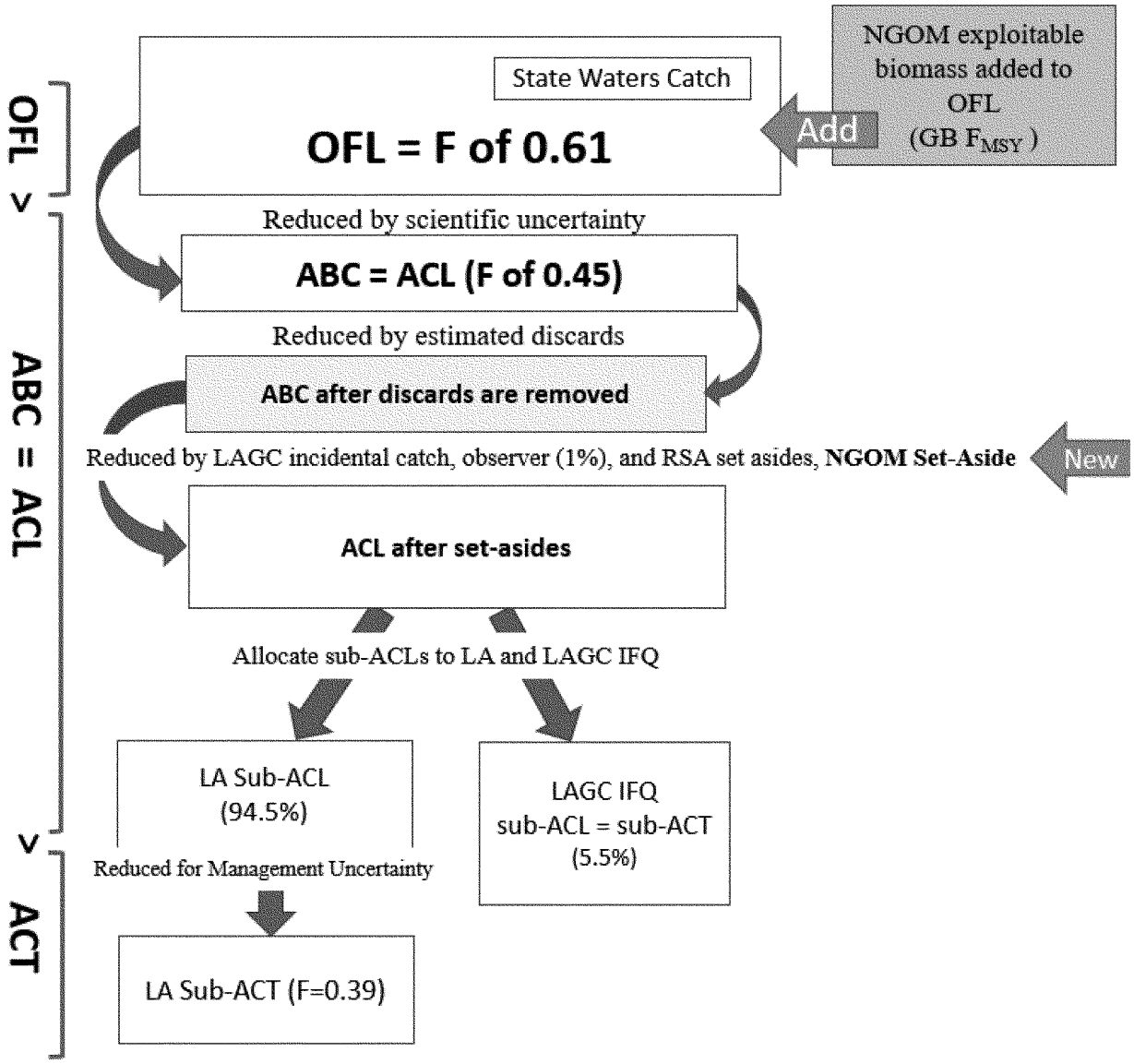

Figure 1 -- Example of Scallop Legal Limits (OFL, ABC, and ACL) With the NGOM Incorporated Into Estimates of the OFL and ABC.

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Creating the NGOM Total Allowable Limit

Amendment 21 would require that the Council set an overall Total Allowable Limit (TAL) for the NGOM management area for all permit categories. If NGOM survey data are available, the NGOM TAL would be developed using a projection method to estimate exploitable biomass in upcoming fishing years. The allowable landings would be set by applying an F rate ranging from F=0.15 to F=0.25 to exploitable biomass in open areas of the NGOM, as specified by the Council. A portion of the NGOM TAL would be added to the fishery wide RSA (described below). In addition, one percent of the NGOM's contribution to the fishery-wide ABC would be removed from the NGOM TAL to off-set monitoring costs (described below).

NGOM Set-Aside and NGOM Annual Projected Landings

The remaining portion of NGOM TAL after contributions to the fishery-wide observer and RSAs are removed would then be allocated to the NGOM Set-Aside up to the NGOM Set-Aside trigger (800,000 lb (362,874 kg)). The NGOM Set-Aside would support a directed LAGC fishery (including NGOM and LAGC IFQ permitted vessels) in the NGOM Management Area at a possession limit of 200 lb (91 kg) per vessel per day. If there is additional allocation available above the 800,000-lb (362,874-kg) trigger, the allocation above the trigger would be shared between the NGOM Set-Aside (5 percent of the allocation above the trigger) and the NGOM APL (95 percent of the allocation above the trigger) for allocating to the limited access and LAGC IFQ fleets. The NGOM APL would then be added to the overall APL to increase allocations for the limited access and LAGC IFQ fleets. If there is allocation above the NGOM Set-Aside trigger, the Council would determine the methods of how the NGOM APL

could be harvested by the limited access and LAGC IFQ components in a subsequent specifications package or framework adjustment.

The trip limit for LAGC vessels fishing the NGOM Set-Aside (*i.e.,* NGOM and IFQ vessels) would be 200 lb (91 kg) per vessel per day. Landings from LAGC IFQ vessels fishing the NGOM Set-Aside would be deducted from their IFQ as well as from the NGOM Set-Aside. LAGC vessels with incidental catch permits (LAGC Category C) would be permitted to land up to 40 lb (18 kg) per day while fishing on non-scallop trips in the NGOM if the area is open for LAGC vessels fishing against the NGOM Set-Aside. Scallop landings by vessels with LAGC incidental permits would not count against the NGOM Set-Aside. Incidental catch from the area would be tracked as part of the final year-end catch accounting.

For catch accounting purposes, all landings from the NGOM would be included in the review of year-end catch data.

NGOM Accountability Measures

Any overage of NGOM Set-Aside or NGOM APL allocations fished inside the NGOM Management Area would be subject to a pound-for-pound payback in a subsequent fishing year after an overage is determined. If reliable data are available to calculate an overage (Year 1), NMFS may implement these accountability measures (AMs) in the following fishing year (Year 2) through the rulemaking process for updated fishery specifications. If reliable data are not available in time for the start of the following fishing year, then the AMs would be implemented 2 years after the overage occurred (Year 3). Data may not be available by the start of the following fishing year because NMFS does not complete final catch accounting until June of the following fishing year. For example, if an overage occurred in fishing year 2021, NMFS would not have the final accounting data until June of fishing year 2022. The AMs could then be implemented at the April 1 start of fishing year 2023.

This approach to allocating the scallop resource in the NGOM would promote resource conservation by setting limits on total removals from the NGOM and implementing AMs for all permit categories fishing in the area. The NGOM Set-Aside approach, combined with options to grow the size of this set-aside with increasing biomass, would preserve and support a directed LAGC fishery in Federal waters in the NGOM, and distribute allocations to all permit types as the biomass in the area grows. This would allow for vessel-level allocations to the limited access and LAGC IFQ fleets, while setting aside allocation for LAGC NGOM permits to access the fishery on a first-come, first-serve basis. The set-aside approach would promote conservation in the management unit by setting a landings limit for all components of the fishery.

Expanding the Scallop Industry-Funded Observer Program to the NGOM

Amendment 21 would expand the observer call-in requirement to all scallop vessels operating in the NGOM, including NGOM-permitted vessels. This expansion of the call-in requirement would facilitate observer coverage in the NGOM Management Area.

This action would remove one percent of the NGOM ABC from the NGOM TAL to offset monitoring costs for vessels fishing in this area. This allocation would be removed from the NGOM TAL before allocating to the NGOM set-aside. This allocation could be used to support monitoring of all permit categories that have access to the NGOM Management Area. The NGOM monitoring set-aside would be added to the fishery-wide observer set-aside that is calculated as one percent of the ABC.

The scallop observer program would be expanded to cover directed scallop trips in Federal waters in the NGOM Management Area. Scallop trips by LAGC vessels in the NGOM are currently not covered by the observer program. This expanded program would utilize the cumulative allocation of the NGOM observer set-aside and the observer set-aside to support observer coverage in the scallop fishery. All compensation allocation for all observed trips would come out of the same pool, and NMFS would administer a single scallop observer program. At a minimum, observer coverage levels for the NGOM Management Area would be set to meet Standard Bycatch Reporting Methodology requirements.

The amount of daily compensation available for LAGC trips in the NGOM may vary from the daily compensation rate for LAGC IFQ vessels that have a higher trip limit. Vessels selected to carry an observer would be able to land the full amount of the daily observer compensation rate in addition to the NGOM trip limit. For example, if the daily compensation rate is set at 100 lb (45 kg), vessels with observers would be able to land 300 lb (136 kg) that trip.

Expanding the observer call-in requirement to the NGOM Management Area would facilitate the deployment of observers on directed scallop trips in Federal waters. Allowing vessels to land the daily observer compensation rate in addition to the trip limit is consistent with existing regulations for limited access and LAGC IFQ vessels when those vessels carry observers. Expanding the observer call-in requirement to directed scallop fishing in the NGOM means that monitoring requirements will be consistent for all scallop permit types across the entirety of the Atlantic sea scallop resource within the U.S. Exclusive Economic Zone.

NGOM Research Set-Aside

Amendment 21 would set-aside 25,000 lb (11,340 kg) from the NGOM TAL to support RSA compensation fishing in the NGOM management area and increase the overall allocation available for the scallop RSA program. The total amount of RSA available would be the sum of the NGOM RSA and the existing 1.25 million-lb (566,990-kg) fishery-wide RSA (*i.e.,* 1.275 million lb (573,330 kg)).

RSA compensation fishing in the NGOM management area would be allowed. Although, NGOM RSA will be combined with the overall RSA, RSA compensation fishing in the NGOM would be capped at the available NGOM RSA, *i.e.,* 25,000 lb (11,340 kg). Any vessels that are awarded NGOM RSA compensation would be required to declare into the area and fish exclusively within the NGOM Management Area. Compensation fishing in the NGOM Management Area could be done to support any research project awarded through the Scallop RSA. However, projects focusing on research in the NGOM would have the first opportunity to fish compensation allocation in the NGOM. NMFS would administer this process.

This action would not mandate that NGOM RSA be harvested strictly in the NGOM Management Area. Vessels allocated NGOM RSA would have an option to fish NGOM RSA in the NGOM or in any other area available to RSA compensation fishing.

Using a portion of the NGOM TAL to increase the size of the overall Scallop RSA program would allow for the funding of additional scallop-related research and provide opportunities for vessels to complete compensation fishing within the NGOM management unit. Limiting the amount of RSA compensation fishing that can occur in the NGOM is consistent with the goal of accurately monitoring catch in the management area.

Because 25,000 lb (11,340 kg) is a relatively small proportion of the current RSA, increasing the set-aside by this amount may have limited biological implications if the allocation can be

fished in any area open to compensation fishing. This would maintain some of the flexibility of the RSA program, while increasing the allocation available to support research. Further, a 25,000-lb (11,340-kg) set-aside is consistent with recent RSA awards that focused on research in the NGOM area.

Limited Access General Category Individual Fishing Quota Possession Limit

Amendment 21 would increase the LAGC IFQ possession limit to 800 lb (363 kg) for access area trips and maintain the 600-lb (172-kg) possession limit for open area trips. The LAGC IFQ component has been subject to a possession limit since the program's inception through Amendment 11. Interest in increasing the 600-lb (172-kg) trip limit through this action is based on the continued increase of operating expenses, which are principally driven by fuel costs associated with longer steam times. For LAGC IFQ vessels that elect to do so, transiting farther offshore to fish access areas with higher landings per unit of effort and improved meat yield leads to increased trip costs due to higher fuel expenses associated with longer steam times. Increasing the access area possession limit would reduce the overall number of trips and combined steam time needed to harvest quota from offshore access areas, thereby reducing overall trip costs (*i.e.,* fuel) and operating expenses (*i.e.,* vessel maintenance) relative to the current 600-lb (172-kg) limit. Increasing the access area possession limit could offer LAGC IFQ vessels more flexibility with regard to timing access area trips around weather conditions, which could potentially improve safety in this component of the fishery.

Observer Compensation Available for LAGC IFQ Vessels

Amendment 21 would make LAGC IFQ vessels eligible for additional compensation when carrying an observer on board and fishing trips longer than 1 day (24 hours). The daily compensation rate, as determined by NMFS, would be prorated at 12-hour increments for trips exceeding 24 hours. The amount of compensation a vessel could receive on one trip would be capped at 2 days (48 hours) and vessels fishing longer than 48 hours would not receive additional compensation allocation. For example, if the observer compensation rate is 200 lb/day (90.7 kg/day) and an LAGC IFQ vessel carrying an observer departs on July 1 at 2200 and lands on July 3 at 0100, the length of the trip would equal 27 hours, or 1 day and 3 hours. In this example, the LAGC IFQ vessel would be eligible for 1 day plus 12 hours of compensation allocation, *i.e.,* 300 lb (136 kg). An LAGC IFQ vessel would be able to harvest the trip limit and the daily compensation rate on the observed trip, or the vessel could harvest any unfished compensation on a subsequent trip while adhering to the commercial possession limit.

Aligning the amount that vessels can be compensated when carrying an observer with the length of a typical LAGC IFQ trip would reduce the risk of observer bias in the LAGC IFQ fishery. Currently, LAGC IFQ vessels are allowed 1 day of compensation for carrying an observer regardless of the length of a trip but are required to assume the cost of having the observer on board even when a trip exceeds the 1-day limit. Prorating in this method would make the level of compensation to a vessel more accurate with regard to the cost of carrying an observer on board for the full length of a trip. In addition, it would reduce the incentive for vessels to fish longer trips for the purpose of receiving additional compensation. Relieving vessels of the additional cost burden for trips of over 1 day would reduce the likelihood that fishing behavior would be different for observed trips versus unobserved trips.

Temporary Transfer of IFQ From Limited Access Vessels With IFQ (Combo Vessels) to LAGC IFQ-Only Vessels

Amendment 21 would allow temporary transfers of IFQ from combo vessels to LAGC IFQ-only permits and would maintain the existing prohibition on transferring quota in to combo vessels. This action would not change how IFQ is allocated. Quota accumulation caps would remain consistent with the limits established through Amendment 15 for LAGC IFQ-only permits, regardless of any additional quota that may become available through one-way, temporary transfers from combo vessels. An individual LAGC IFQ permit still would not be able to hold more than 2.5 percent of the IFQ allocated to the LAGC IFQ component in a year and an ownership entity still cannot hold more than 5 percent of the IFQ allocated to the LAGC IFQ component in a year.

Allowing one-way, temporary transfers from combo vessels to LAGC IFQ-only permits would increase the overall level of quota available to LAGC IFQ-only vessels, and it would not require changes to how allocations are estimated and distributed among the two fleets. Increasing the pool of quota that would be available to the LAGC IFQ-only fishery through temporary transfers could increase the level of participation for vessels currently in the fishery or potentially lead to more participation in terms of active vessels. Increasing potential harvest for existing participants and/or supporting additional vessels in the IFQ fishery would be expected to improve the overall performance of this component of the fishery. Allowing temporary transfers would give combo vessels the choice to lease out some or all of their quota on an annual basis.

Specifications and Framework Adjustment Process

The regulations at § 648.55 list management measures that may be changed or implemented through specifications or framework actions. During the development of Amendment 21, the Council identified a list of specific issues that may be addressed through future specifications actions or framework adjustments. The existing scallop regulations would not need to be expanded to address concepts that the Council would like to adjust through a specifications package or a framework adjustment in the future. The Council's list included:

1. § 648.55(f)(25) Set-asides for funding research;

a. Contribution of RSA percentage and/or assigned pounds from the NGOM allocation.

2. § 648.55(f)(31) Modifications to provisions associated with observer set-asides; observer coverage; observer deployment; observer service provider; and/or the observer certification regulations;

a. Observer set-aside percentage from the NGOM Allocation.

3. § 648.55(f)(35) Adjustments to the Northern Gulf of Maine scallop fishery measures;

a. Partition the NGOM into multiple sub-areas with separate allocations;

b. Partition the NGOM Set-Aside is multiple seasons;

c. Modify the F rate used to set the NGOM TAL; and

d. Harvest methods of the NGOM APL by the IFQ and limited access boats.

4. § 648.55(f)(37) Increases or decreases in the LAGC possession limit;

a. Accounting for access area trips in the LAGC IFQ fishery.

5. § 648.55(f)(38) Adjustments to aspects of ACL management, including accountability measures;

a. Modify how the NGOM is accounted for in the calculation of OFL, ABC, and ACLs.

In addition, the Council clarified that it could develop options for electronic monitoring to replace at-sea monitors in

a future framework based on existing language in these existing regulations:

1. § 648.55(f)(31) Modifications to provisions associated with observer set-asides; observer coverage; observer deployment; observer service provider; and/or the observer certification regulations;

2. § 648.55(g) *Industry-funded monitoring programs.* Fishery management plans (FMPs) managed by the New England Fishery Management Council (New England Council), including Atlantic Herring, Atlantic Salmon, Atlantic Sea Scallops, Deep-Sea Red Crab, Northeast Multispecies, and Northeast Skate Complex, may include industry-funded monitoring (IFM) programs to supplement existing monitoring required by the Standard Bycatch Reporting Methodology (SBRM), Endangered Species Act, and the Marine Mammal Protection Act. IFM programs may use observers, monitors, including at-sea monitors and portside samplers, and electronic monitoring to meet specified IFM coverage targets. The ability to meet IFM coverage targets may be constrained by the availability of Federal funding to pay NMFS cost responsibilities associated with IFM.

Identifying a list of changes that may be made to the FMP in subsequent specification packages or framework adjustments would give the Council flexibility to address specific issues without initiating an amendment to the FMP. This list is intended to capture the range of issues that could be taken up in a later action and was discussed during the development of Amendment 21, but is not intended to limit the range of issues that could be addressed under existing regulatory authority.

Regulatory Adjustments and Corrections Under Regional Administrator Authority

NMFS is proposing several changes consistent with section 305(d) of the Magnuson-Stevens Act, which provides that the Secretary of Commerce may promulgate regulations necessary to ensure that amendments to an FMP are carried out in accordance with the FMP and the Magnuson-Stevens Act. These adjustments do not make any substantive changes to the implications of the current regulations. First, NMFS would revise § 648.14(i) to more clearly define the prohibitions based on the scallop regulations at § 648 Subpart D. As a result, this proposed rule includes revisions to the regulatory text that would reorganize and condense references to possession limits and restrictions. The specific regulations being revised or removed are specified in Table 1. Second, in §§ 648.2, 648.14(i), 648.52, 648.55, and 648.59, NMFS would make revisions to consistently reference the Scallop Access Area Program throughout the regulations. Third, in § 648.14(i)(x), NMFS would clarify the presumption related to where scallops are caught (*i.e.,* Federal/state waters), not whether a vessel has a Federal scallop permit. Fourth, NMFS would update §§ 648.14(i)(x)(3)(iv)(B) and 648.52(a)(1) with a corrected reference to § 648.10(f). Fifth, in § 648.52(b), (c), (d), (e), (f), NMFS would add headings for consistency across paragraphs. Sixth, in § 648.52(f), NMFS would remove duplicative possession limit language for IFQ vessels. Seventh, in § 648.53(h)(3)(i)(A) and (B), NMFS would clarify that the IFQ accumulation cap applies to the annual IFQ allocation, not the IFQ sub-ACL. Eighth, in § 648.53(h)(5)(i) and (ii), NMFS would clarify that these regulations apply to IFQ permit holders regardless of whether the permit is in confirmation of permit history (CPH). Ninth, in § 648.59(b)(4), to promote safety at sea, NMFS would allow vessels to enter or exit a Scallop Access Area more than once per trip if there is a compelling safety reason.

Finally, due to the extensive regulatory changes in this action, we are updating references throughout the scallop regulations that will change based on the proposed regulatory adjustments. We have included a summary of all of the proposed regulatory changes in this rule in Table 1.

TABLE 1—SUMMARY OF PROPOSED REGULATORY CHANGES TO 50 CFR PART 648

Section	Authority	Summary of proposed changes
§§ 648.2, 648.14(i), 648.52, 648.55, 648.59	305(d)	Changing to consistently reference the Scallop Access Area Program throughout the regulations.
§ 648.14(i)(iii)	305(d)	Clarifying possession limits and restrictions which are already described in §§ 648.52 and 648.59.
§ 648.14(i)(x)	305(d)	Clarifying the presumption related to where scallops are caught (*i.e.,* Federal/state waters), not whether a vessel has a Federal scallop permit.
§ 648.14(i)(x)(3)(iii)(C) and (D)	305(d)	Clarifying possession limits and restrictions which are already described in § 648.52 for LAGC vessels in the NGOM are clearly stated later in the section specific to IFQ and NGOM vessels. Deleting to remove duplicative text.
§§ 648.14(i)(x)(3)(iv)(B), 648.52(a)(1)	305(d)	Updating with corrected reference to § 648.10(f).
§ 648.14(i)(x)(4)(i)(A)	305(d) and Amendment 21	Revising IFQ possession and landing regulations based on Amendment 21 measures. Clarify regulations by referencing IFQ possession limits for open and access areas in § 648.52(a).
§ 648.14(i)(x)(4)(i)(C)	Amendment 21	Updating NGOM landings and possession regulations with Amendment 21 language (*i.e.,* NGOM Set-Aside).
§ 648.14(i)(x)(4)(i)(D) and (G)	305(d)	Reducing duplicative language around possession and landing limits that are clearly stated later in § 648.52(a) and (c).
§ 648.14(i)(x)(5)(ii)	305(d)	Clarifying by cutting duplicative landings and possession prohibition, and referencing NGOM possession limit that is clearly stated in § 648.52(a).
§ 648.14(i)(x)(5)(iii)	Amendment 21	Updating NGOM regulations with Amendment 21 language (*i.e.,* NGOM Set-Aside).

TABLE 1—SUMMARY OF PROPOSED REGULATORY CHANGES TO 50 CFR PART 648—Continued

Section	Authority	Summary of proposed changes
§ 648.14(i)(x)(6)	305(d)	Clarifying regulations by removing duplicative landing and possession limit prohibition for incidental permits, and referencing incidental possession limit that is clearly stated in § 648.52.
§ 648.52(a)(1) and (2)	Amendment 21	Updating regulations with LAGC IFQ possession limits for open and access area trips.
§ 648.52(a)(2)	Amendment 21	Clarifying that default access area trips in fishing year 2022 will be subject to the 600-lb (272-kg) trip limit.
§ 648.52(b), (c), (d), (e), (f)	305(d)	Adding headings for consistency.
§ 648.52(a)(2)	Amendment 21	Making in-shell possession limit consistent with increased LAGC IFQ access area trip limit.
§ 648.52(b)	Amendment 21	Updating NGOM regulations with Amendment 21 language (*i.e.,* NGOM Set-Aside).
§ 648.52(f)	305(d)	Removing duplicative possession limit language for IFQ vessels.
§ 648.53(a)(3)(ii)	Amendment 21	Updating APL language to incorporate NGOM catch limit measures.
§ 648.53(a)(8)	Amendment 21	Adding language describing NGOM TAL and allocation structure.
§ 648.53(g)(1)	Amendment 21	Including NGOM contribution to observer set-aside.
§ 648.53(h)(3)(i)(A) and (B)	305(d)	Clarifying that the IFQ accumulation cap applies to the annual IFQ allocation, not the IFQ sub-ACL.
§ 648.53(h)(5)(i) and (ii)	305(d)	Clarifying that these regulations apply to IFQ permit holders regardless of whether permit is in CPH.
§ 648.53(h)(5)(i)(B)	Amendment 21	Specifying that temporary transfers from combo vessels to IFQ-only are allowed.
§ 648.53(h)(5)(ii)(A) and (iii)	Amendment 21	Clarifying that combo vessels are prohibited from permanently transferring or receiving IFQ.
§ 648.55(a)(1)	Amendment 21	Updating language to reflect NGOM catch limits.
§ 648.56(d)	Amendment 21	Including NGOM contribution to RSA.
§ 648.59(b)(4)	305(d)	Adjusting to promote safety at sea.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has made a preliminary determination that this proposed rule is consistent with the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Council for Regulation of the Department of Commerce certified to the Chief Council for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

During the development of preferred alternatives in Amendment 21, NMFS and the Council considered ways to reduce the regulatory burden on and provide flexibility to the regulated community. The measures that would be implemented by the preferred alternatives related to NGOM allocations and the LAGC IFQ possession limit in access areas, along with other Amendment 21 actions, would increase the economic benefits on small entities both in the short- and long-term. The proposed action for the NGOM allocation would adjust landing limits and related research and observer set-asides based on annual scallop surveys in the NGOM area, leading to increased harvest and wider fishery participation in the future. However, there would be no change to the LAGC IFQ allocation when increasing the LAGC IFQ possession limit in access areas.

Overall, the preferred alternatives in Amendment 21 would ensure that catch levels are sustainable, reduce the risk of overfishing, and maximize yield and economic benefits. The establishment of the NGOM Set-Aside and the increase to the LAGC IFQ access area possession limit are expected to have an immediate positive economic gain with potential for increased fishing participants/participation or effort, particularly in the NGOM area when there are more scallop fishing opportunities. The preferred alternatives in other actions of Amendment 21 also have overall positive economic effects benefitting both small and large entities.

As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This proposed rule contains a collection-of-information requirement subject to review and approval by Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). This rule revises the existing requirements for the collection of information OMB Control No. 0648–0546 by expanding the number of vessels required to carry observers and call-in to the observer program. Prior to Amendment 21, NGOM-permitted vessels were not required to carry observers. Amendment 21 would require that NGOM vessels call in to the observer program and, when selected, procure and carry an observer. Expanding the observer call-in requirement to directed scallop fishing in the NGOM means that monitoring requirements will be consistent for all scallop permit types across the entirety of the Atlantic sea scallop resource within the U.S. Exclusive Economic Zone. This proposed change would increase the number of respondents by 110 (512 respondents to 622 respondents). This would result in an additional 933 (5,252 hours to 6,185 hours) burden hours and an additional $5,608 ($44,937 to $50,545) in total annual cost burden to the respondents. Public reporting burden for calling into the observer program is estimated to average 10 minutes, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and

completing and reviewing the collection of information.

Public comment is sought regarding whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Submit comments on these or any other aspects of the collection of information at *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function and entering the OMB Control Number 0648–0546.

Notwithstanding any other provisions of the law, no person is required to respond or, nor shall any person by subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: September 16, 2021.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.2, revise the definition of ''Open areas'' to read as follows:

§ 648.2 Definitions.

* * * * *

Open areas, with respect to the Atlantic sea scallop fishery, means any area that is not subject to restrictions of the Scallop Access Area Program specified in §§ 648.59 and 648.60, the Northern Gulf of Maine Management Area specified in § 648.62, Habitat Management Areas specified in § 648.370, Dedicated Habitat Research areas specified in § 648.371, the Frank R. Lautenberg Deep-Sea Coral Protection Area described in § 648.372, or the New England Deep-Sea Coral Protection Area in § 648.373.

* * * * *

■ 3. Amend § 648.14 by:
■ a. Revising paragraphs (i)(1)(iii) and (x), (i)(2)(vi) introductory text, and (i)(2)(vi) (C), (D), and (E);
■ b. Removing paragraphs (i)(3)(iii)(C) and (D);
■ c. Revising paragraph (i)(3)(iv)(B), (i)(3)(v)(C) and (D), (i)(4)(i)(A);
■ d. Removing and reserving paragraph (i)(4)(i)(B);
■ e. Revising paragraph (i)(4)(i)(C);
■ f. Removing and reserving paragraph (i)(4)(i)(D);
■ g. Removing paragraphs (i)(4)(i)(G) and (H);
■ h. Revising paragraphs (i)(4)(ii)(A) and (B);
■ i. Removing and reserving paragraph (i)(5)(ii);
■ j. Revising paragraph (i)(5)(iii); and
■ k. Removing paragraph (i)(6).

The revisions read as follows:

§ 648.14 Prohibitions.

* * * * *

(i) * * *

(1) * * *

(iii) *Possession and landing.* Fish for, land, or possess on board a vessel per trip, or possess at any time prior to a transfer to another person for a commercial purpose, other than solely for transport on land in excess of any of the possession and/or landing limits described in §§ 648.52 and 648.59.

* * * * *

(x) *Presumption.* For purposes of this section, the following presumption applies: Scallops that are possessed or landed at or prior to the time when the scallops are received by a dealer, or scallops that are possessed by a dealer, are deemed to be harvested from the EEZ, unless the preponderance of evidence demonstrates that such scallops were harvested by a vessel fishing exclusively for scallops in state waters.

* * * * *

(2) * * *

(vi) *Scallop Rotational Area Management Program and Scallop Access Area Program requirements.*

(C) Fish for, possess, or land scallops in or from a Scallop Access Area in excess of the vessel's remaining specific allocation for that area as specified in § 648.59(b)(3) or the amount permitted to be landed from that area.

(D) Possess more than 50 bu (17.6 hL) of in-shell scallops outside the boundaries of a Scallop Access Area by a vessel that is declared into the Scallop Access Area Program as specified in § 648.59.

(E) Fish for, possess, or land scallops in or from any Scallop Access Area without an observer on board, unless the vessel owner, operator, or manager has received a waiver to carry an observer for the specified trip and area fished.

* * * * *

(3) * * *

(iv) * * *

(B) Fail to comply with any requirement for declaring in or out of the LAGC scallop fishery or other notification requirements specified in § 648.10(f).

* * * * *

(v) * * *

(C) Fish for or land per trip, or possess in excess of 40 lb (18.1 kg) of shucked scallops at any time in or from any Scallop Access Area specified at § 648.60, unless declared into the Scallop Access Area Program.

(D) Fish for, possess, or land scallops in or from any Scallop Access Area without an observer on board, unless the vessel owner, operator, or manager has received a waiver to carry an observer for the specified trip and area fished.

* * * * *

(4) * * *

(i) * * *

(A) Fish for or land per trip, or possess at any time, in excess of the possession and landing limits described in § 648.52(a).

* * * * *

(C) Declare into the NGOM scallop management area and fish against the NGOM Set-Aside after the effective date of a notification published in the **Federal Register** stating that after the NGOM Set-Aside has been harvested as specified in § 648.62, unless the vessel is fishing exclusively in state waters, declared a state-waters only NGOM trip, and is participating in an approved state waters exemption program as specified in § 648.54, or unless the vessel is participating in the scallop RSA program as specified in § 648.56.

* * * * *

(ii) * * *

(A) Have an ownership interest in vessels that collectively are allocated more than 5 percent of the total IFQ scallop APL as specified in § 648.53(a)(9).

(B) Have an IFQ allocation on an IFQ scallop vessel of more than 2.5 percent of the total IFQ scallop APL as specified in § 648.53(a)(9).

* * * * *

(5) * * *

(iii) Fish for, possess, or land scallops in state or Federal waters of the NGOM

management area after the effective date of notification in the **Federal Register** that the LAGC share of the NGOM Set-Aside has been harvested as specified in § 648.62, unless the vessel is fishing exclusively in state waters, declared a state-waters only NGOM trip, and is participating in an approved state waters exemption program as specified in § 648.54, or unless the vessel is participating in the scallop RSA program as specified in § 648.56.

* * * * *

■ 4. In § 648.52, revise paragraphs (a) through (f) to read as follows:

§ 648.52 Possession and landing limits.

(a) *IFQ trips.*

(1) *Open area trips.* A vessel issued an IFQ scallop permit that is declared into the IFQ scallop fishery in the open area, as specified in § 648.10(f), or on a properly declared NE multispecies, surfclam, or ocean quahog trip (or other fishery requiring a VMS declaration) and not fishing in a scallop access area, unless as specified in paragraph (g) of this section or exempted under the state waters exemption program described in § 648.54, may not possess or land, per trip, more than 600 lb (272 kg) of shucked scallops, or possess more than 75 bu (26.4 hL) of in-shell scallops shoreward of the VMS Demarcation Line. Such a vessel may land scallops only once in any calendar day. Such a vessel may possess up to 100 bu (35.2 hL) of in-shell scallops seaward of the VMS Demarcation Line on a properly declared IFQ scallop trip, or on a properly declared NE multispecies, surfclam, or ocean quahog trip, or other fishery requiring a VMS declaration, and not fishing in a scallop access area.

(2) *Access areas trips.* A vessel issued an IFQ scallop permit that is declared into the IFQ Scallop Access Area Program, as specified in § 648.10(f), may not possess or land, per trip, more than 800 lb (363 kg) of shucked scallops, or possess more than 100 bu (35.2 hL) of in-shell scallops shoreward of the VMS Demarcation Line. Such a vessel may land scallops only once in any calendar day. Such a vessel may possess up to 100 bu (35.2 hL) of in-shell scallops seaward of the VMS Demarcation Line on a properly declared IFQ scallop access area trip. Vessels fishing the 2022 default access area trips shall be subject to a 600-lb (272-kg) possession limit, as described in § 648.59(g)(3)(v).

(b) *NGOM trips.* A vessel issued an NGOM scallop permit, or an IFQ scallop permit that is declared into the NGOM scallop fishery and fishing against the NGOM Set-Aside as described in § 648.62, unless exempted under the state waters exemption program described under § 648.54, may not possess or land, per trip, more than 200 lb (90.7 kg) of shucked scallops, or possess more than 25 bu (8.81 hL) of in-shell scallops shoreward of the VMS Demarcation Line. Such a vessel may land scallops only once in any calendar day. Such a vessel may possess up to 50 bu (17.6 hL) of in-shell scallops seaward of the VMS demarcation line on a properly declared NGOM scallop fishery trip.

(c) *Incidental trips.* A vessel issued an Incidental scallop permit, or an IFQ scallop permit that is not declared into the IFQ scallop fishery or on a properly declared NE multispecies, surfclam, or ocean quahog trip or other fishery requiring a VMS declaration as required under § 648.10(f), unless exempted under the state waters exemption program described under § 648.54, may not possess or land, per trip, more than 40 lb (18.1 kg) of shucked scallops, or possess more than 5 bu (1.76 hL) of in-shell scallops shoreward of the VMS Demarcation Line. Such a vessel may land scallops only once in any calendar day. Such a vessel may possess up to 10 bu (3.52 hL) of in-shell scallops seaward of the VMS Demarcation Line.

(d) *Limited access vessel access area trips.* Owners or operators of vessels with a limited access scallop permit that have properly declared into the Scallop Access Area Program as described in § 648.59 are prohibited from fishing for or landing per trip, or possessing at any time, scallops in excess of any sea scallop possession and landing limit set by the Regional Administrator in accordance with § 648.59(b)(5).

(e) *Limited access vessel open area in-shell scallop possession limit.* Owners or operators of vessels issued limited access permits are prohibited from fishing for, possessing, or landing per trip more than 50 bu (17.6 hl) of in-shell scallops shoreward of the VMS Demarcation Line, unless when fishing under the state waters exemption specified under § 648.54.

(f) *Limited access vessel access area in-shell scallop possession limit.* A limited access vessel that is declared into the Scallop Area Access Program as described in § 648.59, may not possess more than 50 bu (17.6 hL) of in-shell scallops outside of the Access Areas described in § 648.60.

* * * * *

■ 5. Amend § 648.53 by:

■ a. Revising paragraphs (a)(3)(ii), (8), (g)(1), (h)(3)(i)(A) and (B), (5)(i), (5)(ii)(A), and (5)(iii); and

■ b. Adding paragraph (a)(9).

The revisions and addition read as follows:

§ 648.53 Overfishing limit (OFL), acceptable biological catch (ABC), annual catch limits (ACL), annual catch targets (ACT), annual projected landings (APL), DAS allocations, individual fishing quotas (IFQ).

(a) * * *

(3) * * *

(ii) *APL.* The APL shall be equal to the combined projected landings by the limited access and LAGC IFQ, in open areas, access areas, and Northern Gulf of Maine management area after set-asides (RSA, NGOM, and observer) and incidental landings are accounted for, for a given fishing year. Projected scallop landings are calculated by estimating the landings that will come from open area, access area, and Northern Gulf of Maine effort combined for both limited access and LAGC IFQ fleets. These projected landings shall not exceed the overall ABC/ACL and ACT, as described in paragraph (a) of this section.

* * * * *

(8) *Northern Gulf of Maine Total Allowable Landings (TAL).* The NGOM TAL is the landings available for harvest from the NGOM Management Area. The TAL shall be set by applying a fishing mortality rate of F=0.15 to F=0.25 to exploitable biomass estimated from open areas of the NGOM.

(i) *NGOM Observer Set-Aside.* The NGOM TAL shall be reduced by 1 percent to off-set monitoring costs for vessels fishing in this area. The NGOM monitoring set-aside would be added to the fishery-wide observer set-aside, as described in paragraph (g) of this section.

(ii) *NGOM Research Set-Aside.* The NGOM TAL shall be reduced by 25,000 lb (11,340 kg) to be added to the fishery-wide research set-aside, as described in § 648.56(d).

(iii) *Northern Gulf of Maine Set-Aside.* The NGOM Set-Aside shall be the portion of the NGOM TAL that is available for harvest by the LAGC IFQ and NGOM fleets at 200 lb (91 kg) per trip per day as set through specifications. After the observer and research set-asides are removed, the first 800,000 lb (362,874 kg) of the NGOM TAL shall be allocated to the NGOM Set-Aside. For all allocation above 800,000 lb (362,874 kg), 5 percent shall go to the NGOM Set-Aside, and 95 percent shall go to the NGOM Annual Projected Landings.

(iv) *NGOM APL.* The NGOM APL shall be the portion of the NGOM TAL that is available for harvest for the limited access and LAGC IFQ fleets set through specifications after the observer and research set-asides are removed and the first 800,000 lb (362,874 kg) of the

NGOM TAL are allocated to the NGOM Set-Aside. For all allocation above 800,000 lb (362,874 kg), 5 percent shall go to the NGOM set-aside, and 95 percent shall go to the NGOM APL. The method in which the limited access and LAGC IFQ components will access the NGOM APL will be determined in future specifications.

(9) *Scallop fishery catch limits.* The following catch limits will be effective for the 2021 and 2022 fishing years:

TABLE 1 TO PARAGRAPH (a)(9)—SCALLOP FISHERY CATCH LIMITS

Catch limits	2021 (mt)	2022 (mt) [1]
OFL	45,392	41,926
ABC/ACL (discards removed)	30,517	28,074
Incidental Catch	23	23
RSA	567	567
Observer Set-Aside	305	281
ACL for fishery	29,622	27,203
Limited Access ACL	27,993	25,707
LAGC Total ACL	1,629	1,496
LAGC IFQ ACL (5 percent of ACL)	1,481	1,360
Limited Access with LAGC IFQ ACL (0.5 percent of ACL)	148	136
Limited Access ACT	24,260	22,279
APL (after set-asides removed)	17,269	([1])
Limited Access APL (94.5 percent of APL)	16,319	([1])
Total IFQ Annual Allocation (5.5 percent of APL) [2]	950	712
LAGC IFQ Annual Allocation (5 percent of APL) [2]	863	648
Limited Access with LAGC IFQ Annual Allocation (0.5 percent of APL) [2]	86	65

[1] The catch limits for the 2022 fishing year are subject to change through a future specifications action or framework adjustment. This includes the setting of an APL for 2022 that will be based on the 2021 annual scallop surveys. The 2022 default allocations for the limited access component are defined for DAS in paragraph (b)(3) of this section and for access areas in § 648.59(b)(3)(i)(B).

[2] As specified in paragraph (a)(6)(iii)(B) of this section, the 2022 IFQ annual allocations are set at 75 percent of the 2021 IFQ Annual Allocations.

* * * * *

(g) * * *

(1) To help defray the cost of carrying an observer, 1 percent of the ABC/ACL defined in paragraph (a)(3) of this section and 1 percent of the NGOM ABC/ACL shall be set aside to be used by vessels that are assigned to take an at-sea observer on a trip. This observer set-aside is specified through the specifications or framework adjustment process defined in § 648.55.

* * * * *

(h) * * *

(3) * * *

(i) * * *

(A) Unless otherwise specified in paragraphs (h)(3)(i)(B) and (C) of this section, a vessel issued an IFQ scallop permit or confirmation of permit history shall not be issued more than 2.5 percent of the IFQ-only annual allocation to the IFQ scallop vessels as described in paragraph (a)(6) of this section.

(B) A vessel may be initially issued more than 2.5 percent of the IFQ-only annual allocation allocated to the IFQ scallop vessels as described in paragraph (a)(6) of this section, if the initial determination of its contribution factor specified in accordance with § 648.4(a)(2)(ii)(E) and paragraph (h)(2)(ii) of this section, results in an IFQ that exceeds 2.5 percent of the IFQ-only annual allocation to the IFQ scallop vessels as described in paragraph (a)(6) of this section. A vessel that is allocated an IFQ that exceeds 2.5 percent of the IFQ-only annual allocation to the IFQ scallop vessels as described in paragraph (a)(6) of this section, in accordance with this paragraph (h)(3)(i)(B), may not receive IFQ through an IFQ transfer, as specified in paragraph (h)(5) of this section. All scallops that have been allocated as part of the original IFQ allocation or transferred to a vessel during a given fishing year shall be counted towards the vessel cap.

* * * * *

(5) * * *

(i) *Temporary IFQ transfers.* (A) *IFQ-only vessels.* Subject to the restrictions in paragraph (h)(5)(iii) of this section, the owner of an IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit may temporarily transfer (*e.g.,* lease) its entire IFQ allocation, or a portion of its IFQ allocation, to another IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit. Temporary IFQ transfers shall be effective only for the fishing year in which the temporary transfer is requested and processed. IFQ can be temporarily transferred more than once (*i.e.,* re-transferred). For example, if a vessel temporarily transfers IFQ to a vessel, the transferee vessel may re-transfer any portion of that IFQ to another vessel. There is no limit on how many times IFQ can be re-transferred in a fishing year. The Regional Administrator has final approval authority for all temporary IFQ transfer requests.

(B) *Limited access vessels with LAGC IFQ.* Subject to the restrictions in paragraph (h)(5)(iii) of this section, the owner of a limited access vessel with LAGC IFQ (and/or a limited access permit with LAGC IFQ in confirmation of permit history) may temporarily transfer (*e.g.,* lease) its entire IFQ allocation, or a portion of its IFQ allocation, to an IFQ-only scallop vessel that does not have a limited access permit. Temporary IFQ transfers shall be effective only for the fishing year in which the temporary transfer is requested and processed. IFQ can be temporarily transferred more than once (*i.e.,* re-transferred). The Regional Administrator has final approval authority for all temporary IFQ transfer requests.

* * * * *

(ii) * * *

(A) Subject to the restrictions in paragraph (h)(5)(iii) of this section, the owner of an IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit may transfer IFQ permanently to or from another IFQ scallop vessel (and/or IFQ scallop

permit in confirmation of permit history) not issued a limited access scallop permit. Any such transfer cannot be limited in duration and is permanent as to the transferee, unless the IFQ is subsequently permanently transferred to another IFQ scallop vessel. IFQ may be permanently transferred to a vessel and then be re-transferred (temporarily transferred (*i.e.,* leased) or permanently transferred) by such vessel to another vessel in the same fishing year. There is no limit on how many times IFQ can be re-transferred in a fishing year. Limited access vessels with LAGC IFQ permits are prohibited from permanently transferring or receiving IFQ.

* * * * *

(iii) *IFQ transfer restrictions.* The owner of an IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit may transfer that vessel's IFQ to another IFQ scallop vessel, regardless of whether or not the vessel has fished under its IFQ in the same fishing year. Requests for IFQ transfers cannot be less than 100 lb (46.4 kg), unless that the transfer reflects the total IFQ amount remaining on the transferor's vessel, or the entire IFQ allocation. IFQ may be temporarily or permanently transferred to a vessel and then temporarily re-transferred (*i.e.,* leased) or permanently re-transferred by such vessel to another vessel in the same fishing year. There is no restriction on how many times IFQ can be re-transferred. A transfer of an IFQ may not result in the sum of the IFQs on the receiving vessel exceeding 2.5 percent of the allocation to IFQ-only scallop vessels. A transfer of an IFQ, whether temporary or permanent, may not result in the transferee having a total ownership of, or interest in, general category scallop allocation that exceeds 5 percent of the allocation to IFQ-only scallop vessels. Limited access scallop vessels that are also issued an IFQ scallop permit may not permanently transfer or receive IFQ. Further, they may not temporarily receive IFQ.

* * * * *

■ 6. In § 648.55, revise paragraphs (a)(1) and (f) introductory text to read as follows:

§ 648.55 Specifications and framework adjustments to management measures.

(a) * * *

(1) The Scallop Plan Development Team (PDT) shall meet at least every 2 years to assess the status of the scallop resource and to develop and recommend the following specifications for a period of up to 2 years, as well as second or third-year default measures, for consideration by the New England Fishery Management Council's Atlantic Sea Scallop Oversight Committee and Advisory Panel: OFL, overall ABC/ACL, sub-ACLs, sub-ACTs, DAS open area allocations, possession limits, modifications to rotational area management (*e.g.,* schedule, rotational closures and openings, seasonal restrictions, modifications to boundaries, etc.), access area limited access poundage allocations and LAGC IFQ fleet-wide trip allocations, annual incidental catch target TAC, and NGOM TAL.

* * * * *

(f) *Framework adjustments.* The Council may at any time initiate a framework adjustment to add or adjust management measures within the Scallop FMP if it finds that action is necessary to meet or be consistent with the goals and objectives of the FMP. The Council shall develop and analyze appropriate management actions over the span of at least two Council meetings. To address interactions between the scallop fishery and sea turtles and other protected species, such adjustments may include proactive measures including, but not limited to, the timing of Sea Scallop Access Area openings, seasonal closures, gear modifications, increased observer coverage, and additional research. The Council shall provide the public with advance notice of the availability of both the proposals and the analyses, and opportunity to comment on them prior to and at the second Council meeting. The Council's recommendation on adjustments or additions to management measures may include specifications measures specified in paragraph (a) of this section, which must satisfy the criteria set forth § 648.53(a) in order to prevent overfishing of the available biomass of scallops and ensure that OY is achieved on a continuing basis. Other measures that may be changed or implemented through framework action include:

* * * * *

■ 7. In § 648.56, revise paragraph (d) is to read as follows:

§ 648.56 Scallop research.

* * * * *

(d) Available RSA allocation shall be 1.275 million lb (578 mt) annually, which shall be deducted from the ABC/ACL specified in § 648.53(a) prior to setting ACLs for the limited access and LAGC fleets, as specified in § 648.53(a)(3) and (4), respectively. Approved RSA projects shall be allocated an amount of scallop allocation that can be harvested in open areas, available access areas, and the NGOM. The specific access areas that are open to RSA harvest and the amount of NGOM allocation to be landed through RSA harvest shall be specified through the framework process as identified in § 648.59(e)(1). In a year in which a framework adjustment is under review by the Council and/or NMFS, NMFS shall make RSA awards prior to approval of the framework, if practicable, based on total scallop allocation needed to fund each research project. Recipients may begin compensation fishing in open areas prior to approval of the framework, or wait until NMFS approval of the framework to begin compensation fishing within approved access areas.

* * * * *

■ 8. In § 648.59, revise the section title and paragraphs (a) introductory text, (a)(3), (b)(4), (g)(3)(i), and (4)(ii) to read as follows:

§ 648.59 Scallop Rotational Area Management Program and Scallop Access Area Program requirements.

(a) The Scallop Rotational Area Management Program consists of Scallop Rotational Areas, as defined in § 648.2. Guidelines for this area rotation program (*i.e.,* when to close an area and reopen it to scallop fishing) are provided in § 648.55(a)(6). Whether a rotational area is open or closed to scallop fishing in a given year, and the appropriate level of access by limited access and LAGC IFQ vessels, are specified through the specifications or framework adjustment processes defined in § 648.55. When a rotational area is open to the scallop fishery, it is called an Access Area and scallop vessels fishing in the area are subject to the Scallop Access Area Program Requirements specified in this section. Areas not defined as Scallop Rotational Areas specified in § 648.60, Habitat Management Areas specified in § 648.370, or areas closed to scallop fishing under other FMPs, are governed by other management measures and restrictions in this part and are referred to as Open Areas.

* * * * *

(3) *Transiting a Scallop Access Area.* Any sea scallop vessel that has not declared a trip into the Scallop Access Area Program may enter a Scallop Access Area, and possess scallops not caught in the Scallop Access Areas, for transiting purposes only, provided the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2. Any scallop vessel that has declared a trip into the Scallop Area Access Program may not enter or be in another Scallop Access Area on the

same trip except such vessel may transit another Scallop Access Area provided its gear is stowed and not available for immediate use as defined in § 648.2, or there is a compelling safety reason to be in such areas without such gear being stowed. A vessel may only transit the Closed Area II Scallop Rotational Area, as defined in § 648.60(d), if there is a compelling safety reason for transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2.

* * * * *

(b) * * *

(4) *Area fished.* While on a Scallop Access Area trip, a vessel may not fish for, possess, or land scallops in or from areas outside the Scallop Access Area in which the vessel operator has declared the vessel will fish during that trip, and may not enter or exit the specific declared Scallop Access Area more than once per trip unless there is a compelling safety reason. A vessel on a Scallop Access Area trip may not enter or be in another Scallop Access Area on the same trip except such vessel may transit another Scallop Access Area as provided for under paragraph (a)(3) of this section.

* * * * *

(g) * * *

(3) * * *

(i) An LAGC scallop vessel authorized to fish in the Scallop Rotational Areas specified in § 648.60 or in paragraph (g)(3)(iv) of this section may land scallops, subject to the possession limit specified in § 648.52(a)(2), unless the Regional Administrator has issued a notice that the number of LAGC IFQ access area trips have been or are projected to be taken. All LAGC IFQ access area trips must be taken in the fishing year that they are allocated (*i.e.,* there are no carryover trips). The total number of LAGC IFQ trips in an Access Area is specified in the specifications or framework adjustment processes defined in § 648.55.

* * * * *

(4) * * *

(ii) *Other species.* Unless issued an LAGC IFQ scallop permit and fishing under an approved NE multispecies SAP under NE multispecies DAS, an LAGC IFQ vessel fishing in the Closed Area I, Closed Area II, Closed Area II Extension, and Nantucket Lightship Rotational Areas specified in § 648.60, and the Nantucket Lightship North Scallop Access Area specified in paragraph (g)(3)(iv) of this section is prohibited from possessing any species of fish other than scallops and monkfish, as specified in § 648.94(c)(8)(i). Such a vessel may fish in an approved SAP under § 648.85 and under multispecies DAS in the scallop access area, provided that it has not declared into the Scallop Access Area Program. Such a vessel is prohibited from fishing for, possessing, or landing scallops.

* * * * *

[FR Doc. 2021–20462 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 86, No. 190
Tuesday, October 5, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Proposed New Fee Sites

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of proposed new fee sites.

SUMMARY: The Humboldt-Toiyabe National Forest (Forest) is proposing to charge new fees at one group campground, two campgrounds, and one new horse campground. These sites are currently in use by the public but are not currently charging fees for use. Funds from fees would be used for the continued operation and maintenance of these recreation sites. Fees are assessed based on the level of amenities and services provided, cost of operation and maintenance, market assessment, and public comment. Significant capital improvements made in the past few years, coupled with increased visitation, support a fee. A review of visitor use data and fee collection information for existing fee campgrounds and group campgrounds on the Forest demonstrate public need and demand for the variety of recreation opportunities these facilities provide.

DATES: If approved, the new fee would be implemented no earlier than six months following the publication of this notice in the **Federal Register**.

ADDRESSES: Humboldt-Toiyabe National Forest, Attention: Erin Rajala, 825 Avenue E, Ely, Nevada 89301 or *erin.rajala@usda.gov.*

FOR FURTHER INFORMATION CONTACT: Erin Rajala, Recreation and Wilderness Program Manager at 775–289–5129. Information about proposed fee changes can also be found on the Humboldt-Toiyabe National Forest website: *https://www.fs.usda.gov/htnf.*

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, Pub. L. 108–447) directed the Secretary of Agriculture to publish a six-month advance notice in the **Federal Register** whenever new recreation fee areas are established. A market analysis indicated that the proposed fees are both reasonable and acceptable for the type of recreation experience they provide.

The fees are only proposed at this time and will be determined upon further analysis and public comment. The following campground and group campground are included in this proposal for new fees: Horse Campground for $10 per night and Kalamazoo and White River Campgrounds for $5 per night. Bird Creek Campground is proposing a new double campsite fee for $15 per night and group sites at $20 and $45 per night.

Once public involvement is complete, these new fees will be reviewed and approved by a Recreation Resource Advisory Committee prior to a final decision and implementation.

Dated: September 29, 2021.

Sandra Watts,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2021–21571 Filed 10–4–21; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Proposed New Fee Sites

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of proposed new fee sites.

SUMMARY: The Okanogan-Wenatchee National Forest is proposing to charge new fees at 23 recreation sites listed in **SUPPLEMENTARY INFORMATION** of this notice. Many sites have recently been reconstructed or amenities are being added to improve services and experiences. Fees are assessed based on the level of amenities and services provided, cost of operation and maintenance, market assessment, and public comment. Funds from fees would be used for the continued operation and maintenance of these recreation sites.

DATES: If approved, the new fees would be implemented no earlier than six months following the publication of this notice in the **Federal Register**.

ADDRESSES: ATTN: Recreation Fee Proposals, Okanogan-Wenatchee National Forest, 215 Melody Lane, Wenatchee, WA 98801.

FOR FURTHER INFORMATION CONTACT: Suzanne Cable, Recreation Fee Coordinator, 509–664–9394, or *SM.FS.FeeProposal@usda.gov.*

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, Pub. L. 108–447) directed the Secretary of Agriculture to publish a six-month advance notice in the **Federal Register** whenever new recreation fee areas are established.

As part of this proposal, Mystery Campground, Three Creek Campground, Nice Campground, and North Fork Campground would be converted to group campgrounds offering a new opportunity for the public and available to reserve at $40–$75/night. A $5 day-use fee at Lower Echo Trailhead, Spillway Day Use Area, Upper Echo Trailhead, Blackpine Lake Picnic Area, Swiftwater Picnic Area, Conrad Meadows Trailhead, Crater Creek Trailhead, Foggy Dew Trailhead, Goat Peak Trailhead, Lower Mad River Trailhead, Penstock Trailhead, Pot Peak Trailhead, Rattlesnake Creek Trailhead, and Chickadee Trailhead would be added to improve services and facilities, and recreation passes would be honored. This proposal would also implement new fees at eight campgrounds (Antilon Lake, Crawfish Lake, Grasshopper Meadow, Lake Creek, Napeequa Crossing, North Summit Horse Camp, Rainy Creek, and White River Falls), all proposed at $10 per night. In addition, this proposal would implement new fees at four recreation rentals: Tyee Lookout proposed at $90 a night; two yurts at Lake Creek Campground (Entiat Ranger District), proposed at $75 a night; and Steliko Lookout, proposed at $75 a night. New fees would provide increased visitor opportunities, as well as increased staffing to address operations and maintenance needs and enhance customer service.

Advanced reservations for campgrounds and cabins will be available through *www.recreation.gov* or by calling 1–877–444–6777. The reservation service charges an $8.00 fee for reservations.

These new fees will be reviewed by a Recreation Resource Advisory

Committee prior to a final decision and implementation.

Dated: September 29, 2021.

Sandra Watts,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2021–21569 Filed 10–4–21; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Intent To Establish Secure Rural Schools Resource Advisory Committees

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of intent to establish Secure Rural Schools Resource Advisory Committees.

SUMMARY: The Forest Service, United States Department of Agriculture (USDA), intends to establish the following: The Greater Rocky Mountain Resource Advisory Committee (RAC) in the Rocky Mountain Region (R2) by consolidating the Saguache-Upper Rio Grande, Rocky Mountain, and San Juan RACs; the Rural Nevada RAC in the Intermountain Region (R4) by consolidating the White Pine-Nye and Humboldt NV RACs; the National Forests in Mississippi RAC in the Southern Region (R8) by consolidating the Delta-Bienville, DeSoto, Holly Springs-Tombigbee, and Southwest Missippippi RACs; the Ottawa RAC in the Eastern Region (R9) by consolidating the Gogebic and Ontonagon RACs; the North Tongass RAC in the Alaska Region (R10) by consolidating the Juneau, Lynn Canal-Icy Strait, Yakutat, and Sitka RAC; and the South Tongass RAC in the Alaska Region (R10) by consolidating the Wrangell-Petersburg, Prince of Wales, and Ketchikan RACs. Secure Rural Schools (SRS) RACs are established pursuant to the Secure Rural Schools and Community Self-Determination Act (the Act), as amended, and most recently authorized in accordance to the Agricultural Improvement Act of 2018 (Pub. L. 115–334). The SRS RACs will operate in compliance with the Federal Advisory Committee Act (FACA). The purpose of the SRS RACs is to improve collaborative relationships among people who use and care for National Forests. The Secretary has determined that the work of the SRS RACs are in the public's interest and relevant to the duties of the Department of Agriculture. The SRS RACs are statutory committees. Additional information concerning the SRS RACs can be found by visiting the SRS RACs website at: *http://www.fs.usda.gov/pts/.*

FOR FURTHER INFORMATION CONTACT: Comments concerning this notice should be addressed to Juana Rosas, National Partnership Coordinator, National Partnership Office, USDA Forest Service, Yates Building, 1400 Independence Avenue, Mailstop #1158, Washington, DC 20250. Comments also may be submitted by email to: Juana Rosas at *juana.rosas@usda.gov.* Individuals who use telecommunication devices for the deaf/hard-of-hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the provisions of FACA, the Secretary of Agriculture intends to establish SRS RACs to provide advice and recommendations to the Forest Service concerning projects and funding consistent with SRS Title II of the Act. The duties of SRS RACs include monitoring projects, advising the Secretary on the progress and results of monitoring efforts, and making recommendations to the Forest Service for any appropriate changes or adjustments to the projects being monitored by the SRS RACs.

SRS RACs Membership

The SRS RACs will be comprised of no more than 15 members and no fewer than 9 members in accordance with the Agricultural Improvement Act of 2018, also known as the 2018 Farm Bill. Members will be approved by the Secretary of Agriculture or their designee except for RACs located in the states of Arizona and Montana where they will be approved by the Regional Forester and each will serve a 4-year term. SRS RAC memberships will be balanced in terms of the points of view represented and functions to be performed. The SRS RACs shall include representation from the following interest areas:

(1) Five persons who represent:

(a) Organized Labor or Non-Timber Forest Product Harvester Groups,

(b) Developed Outdoor Recreation, Off Highway Vehicle Users, or Commercial Recreation Activities,

(c) Energy and Mineral Development, or Commercial or Recreational Fishing Interests,

(d) Commercial Timber Industry, or

(e) Federal Grazing or Other Land Use Permits, or Represent Non-industrial Private Forest Land Owners within the area for which the committee is organized.

(2) Five persons who represent:

(a) Nationally Recognized Environmental Organizations,

(b) Regionally or Locally Recognized Environmental Organizations,

(c) Dispersed Recreational Activities,

(d) Archaeological and Historical Interests, or

(e) Nationally or Regionally Recognized Wild Horse and Burro Interest Groups, Wildlife or Hunting Organizations, or Watershed Associations.

(3) Five persons who represent:

(a) State Elected Office (or a designee),

(b) County or Local Elected Office,

(c) American Indian Tribes within or adjacent to the area for which the committee is organized,

(d) Area School Officials or Teachers, or

(e) Affected Public at Large.

Of these members, one will become the Chairperson who is recognized for their ability to lead a group in a fair and focused manner and who has been briefed on the mission of the RAC. A chairperson is selected by a majority of RAC members. The Committee will meet on an annual basis or as needed and determined by the Forest Service.

In the event that a vacancy arises, the Designated Federal Officer (DFO) may fill the vacancy in the manner in which the original appointments were made. In accordance with the SRS Act, members of the SRS RAC shall serve without compensation. SRS RAC members may be allowed travel and per diem expenses for attendance at committee meetings, subject to approval of the DFO responsible for administrative support to the SRS RAC.

Equal opportunity practices in accordance with USDA policies shall be followed in all appointments to the RACs. To help ensure that the recommendations of the RACs have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals representing minorities, women, and persons with disabilities. USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability or age. Additionally, discrimination based on political beliefs, income derived from a public assistance program, marital status, family/parental status, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA is also prohibited by

statutes enforced by USDA (not all bases apply to all programs).

Dated: September 30, 2021.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2021–21683 Filed 10–4–21; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Proposed New Fee Site

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of proposed new fee site.

SUMMARY: The San Juan National Forest (Forest) proposes to charge new fees at the Chimney Rock National Monument. These sites are currently in use by the public, but the Forest Service is not currently charging a fee for their use. Funds from fees would be used for the continued operation and maintenance of these recreation sites. Fees are assessed based on the level of amenities and services provided, cost of operation and maintenance, market assessment, and public comment. Significant capital improvements made in the past few years, coupled with increased visitation, support a fee. A review of visitor use data and fee collection information for existing fee campgrounds and group campgrounds on the Forest demonstrate public need and demand for the variety of recreation opportunities these facilities provide.

DATES: If approved, the new fee would be implemented no earlier than six months following the publication of this notice in the **Federal Register**.

ADDRESSES: Pagosa Ranger District, Chimney Rock Fee Change Proposal, P.O. Box 310, Pagosa Springs, CO 81147, or by emailing Paul Blackman at *paul.blackman@usda.gov.*

FOR FURTHER INFORMATION CONTACT: Paul Blackman, District Recreation Staff, 970–264–1505 or *paul.blackman@usda.gov.* Information about proposed fee changes can also be found on the San Juan National Forest's website: *https://www.fs.usda.gov/sanjuan.*

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, Pub. L. 108–447) directed the Secretary of Agriculture to publish a six-month advance notice in the **Federal Register** whenever new recreation fee areas are established. Fees are based on the level of amenities and services provided, the cost of operations and maintenance, and the market assessment of similar types of opportunities within the geographic area.

The current fee is $12–$16 per adult and $6–$8 per child which is charged by the Chimney Rock Interpretive Association. The proposal will establish a new Forest Service fee of $20 per vehicle for five days and $10 per motorcycle for five days. Revenue from these fees will help the Forest Service and its partner, Chimney Rock Interpretive Association, to provide services and amenities so visitors can continue to access and enjoy a unique and high-quality monument experience. Revenue would be directed primarily towards infrastructure maintenance and repairs, as well as Forest Service activities such as managing parking, maintaining trails, providing education, protecting cultural resources, and providing other visitor services.

Once public involvement is complete, these new fees will be reviewed and approved by the Rocky Mountain Regional Office prior to a final decision and implementation.

Dated: September 29, 2021.

Sandra Watts,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2021–21570 Filed 10–4–21; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

[Docket Number: RUS–21–Electric–0020]

Badger State Solar, LLC: Notice of Intent To Prepare an Environmental Impact Statement and Hold a Virtual Public Scoping Meeting on October 26, 2021

AGENCY: Rural Utilities Service, Agriculture (USDA).

ACTION: Notice of intent to prepare an Environmental Impact Statement and hold a virtual public scoping meeting.

SUMMARY: The Rural Utilities Service (RUS) announces its intent to prepare an Environmental Impact Statement (EIS) and hold a virtual public scoping meeting in connection with possible impacts related to the Badger State Solar, LLC's Alternating Current solar project (Project). The Project consists of a 149-megawatt photovoltaic Alternating Current solar energy generating facility located on approximately 1,750 acres in the Townships of Jefferson and Oakland, in Jefferson County, Wisconsin. RUS is considering funding this application, thereby making the proposed Project an undertaking subject to review under the National Historic Preservation Act (NHPA). RUS has determined that a loan for the Project would be a federal action and is, therefore, subject to National Environmental Policy Act (NEPA) review.

DATES: The public scoping meeting webinar will be held on October 26, 2021 at 7 p.m. EST via Zoom. Those wishing to attend the webinar are invited to register online at the virtual scoping meeting room website *https://badgerstatesolar.consultation.ai.* An email will be sent to registrants with information for how to access the webinar. Attendees will be able to provide spoken comments during the webinar. The virtual scoping meeting room is an interactive website which will be available throughout the public scoping period. Attendees will be able to submit written comments through the virtual scoping meeting room website. Written comments may also be submitted to *BadgerStateSolarEIS@usda.gov.*

Written requests to participate as a ''consulting party'' or to provide comments for consideration during the scoping process for the proposed Project must be received on or before November 4, 2021.

ADDRESSES: To request ''consulting party'' status, submit comments, or for further information, please contact: *BadgerStateSolarEIS@usda.gov.*

Project-related information will be available at RUS's and Badger State Solar's websites located at: *https://www.rd.usda.gov/resources/environmental-studies/impact-statements, https://badgerstatesolar.consultation.ai,* and *https://www.badgerstatesolar.com.* This includes the Alternative Evaluation and Site Selection Studies prepared for the project. Project information will also be available at the Jefferson Public Library in Jefferson, WI; the Cambridge Community Library in Cambridge, WI and the Lake Mills Library in Lake Mills, WI.

Due to the COVID 19 pandemic, electronic communication is preferred because delivery of hard copies by mail may not be delivered in a timely manner.

SUPPLEMENTARY INFORMATION: RUS is the lead federal agency, as defined at 40 CFR 1508.1(o), for preparation of the EIS. With this notice, federal and state agencies and federally recognized Tribes with jurisdiction or special expertise are invited to be cooperating agencies. Such agencies or tribes may make a request to RUS to be a cooperating agency by contacting the RUS contact provided in this notice. Designated cooperating

agencies have certain responsibilities to support the NEPA and scoping process, as specified at 40 CFR 1501.8.

In addition, with this notice, RUS invites any affected federal, state, and local agencies, Tribes, and other interested persons to comment on the scope, alternatives, and significant issues to be analyzed in depth in the EIS.

Throughout the scoping period a virtual public scoping meeting room will be available online at *https://badgerstatesolar.consultation.ai.* The virtual public scoping meeting room is an interactive website which will include information about the project, the NEPA process, and next steps in the process. Interested parties will also be able to register to attend the October 26 webinar on Zoom through the virtual scoping meeting room website.

Public participation is an integral component of the environmental review process for federal actions. Public participation will be especially important during the scoping phase of the proposed Project. RUS will be seeking information, comments, and assistance from federal, State, and local agencies, Tribes, and other individuals who may be interested in or affected by the proposed Project. This input will be used in preparing the Draft EIS. Comments submitted during the scoping process should be in writing. The comments should describe as clearly and completely as possible any issues, concerns, or input commenters may have so that they can be addressed appropriately in the EIS.

RUS is considering funding this application, thereby making the proposed Project an undertaking subject to review under Section 106 of the National Historic Preservation Act (NHPA), 16 U.S.C. 470(f), and its implementing regulation, ''Protection of Historic Properties'' (36 CFR part 800). Any party wishing to participate directly with RUS as a ''consulting party'' in Section 106 review may submit a written request to the RUS contact provided below. Pursuant to 36 CFR 800.3(f)(3), RUS will consider, and provide a timely response to any and all requests for consulting party status.

Badger State Solar proposes to construct, install, operate, and maintain a 149-megawatt photovoltaic Alternating Current solar energy generating facility on a site in the Townships of Jefferson and Oakland, in Jefferson County, Wisconsin. The proposed project is approximately 1,750 acres located on the north and south sides of U.S. Highway 18, approximately 2-miles west of the City of Jefferson and west of State Highway 89. The collector substation would be located in the Primary Development Area. Site land cover is predominantly agricultural crops and pasture, with some forest and wetland.

Construction involves the installation on leased lands of 127,752 single-axis tracking PV panels in the Primary Project area. The PV panels would be mounted on a steel racking frame. Supporting facilities include an electrical substation. The lease agreement allows for an operating period of 40 years. A power purchase agreement (PPA) has been executed with Dairyland Power Cooperative for the entire output of the Project. The proposed site is near the point of interconnection to the grid at the American Transmission Company Jefferson substation near the intersection of State Trunk Highway 89 and U.S. Highway 18.

Construction equipment would include graders, bulldozers, excavators, forklifts, trailers, plows, trenchers, pile drivers, and directional boring rigs. Vehicles for transporting construction materials and components primarily would be legal load over-the road flatbed and box trucks. Transport would use existing regional roads, bridges, and intersections. Laydown areas would be established within the Project site. Internal site access roads would be required. The site would be fenced. Overhead collector circuits would not be required.

Badger State has submitted an Application for a Certificate of Public Convenience and Necessity (CPCN) to the Public Service Commission of Wisconsin (PSC). Consultations have been conducted with the Wisconsin Department of Natural Resources (WDNR) and an endangered resource review (ER) has been submitted to the agency. Consultations with other agencies include the Federal Aviation Administration (FAA), Natural Resources Conservation Service (NRCS), U.S. Environmental Protection Agency (USEPA), and informal consultation with the U.S. Fish and Wildlife Service (USFWS). Badger State has consulted property owners, local town and county officials and staff, state elected representatives, Wisconsin Department of Agriculture Trade and Consumer Protection, and engaged the general public.

Among the alternatives that RUS will address in the EIS is the No Action alternative, under which the proposal would not be undertaken or if RUS did not fund the proposed Project, and any reasonable alternatives defined as a result of the scoping process. In the EIS, the effects of the proposal will be compared to the existing conditions in the affected area of the proposal. Public health and safety, environmental impacts, socio-economic, and engineering aspects of the proposal will also be considered in the EIS.

As part of its broad environmental review process, RUS must take into account the effect of the proposal on historic properties in accordance with Section 106 of the National Historic Preservation Act (Section 106) and its implementing regulation, ''Protection of Historic Properties'' (36 CFR part 800). Pursuant to 36 CFR 800.2(d)(3), RUS is using its procedures for public involvement under NEPA to meet its responsibilities to solicit and consider the views of the public during Section 106 review. Accordingly, comments submitted in response to this Notice will inform RUS decision-making during Section 106 review.

From information provided in the studies mentioned above, and using input provided by government agencies, tribes, and the public, RUS will prepare a Draft EIS. The Draft EIS will be filed with the U.S. Environmental Protection Agency (USEPA) and will be available for public comment by the Fall 2021. At that time, the RUS and USEPA will publish a notice of the availability of the Draft EIS and notice of receipt, respectively, in the **Federal Register**. In addition, the Badger State Solar will publish notices in local newspapers and any online local news sources. The comment period for the DEIS will be 45 days from the date the EPA publishes its **Federal Register** notice announcing receipt of the Draft EIS.

To assist the involved federal agencies in identifying and considering issues and concerns on the proposal, comments on the Draft EIS should be as specific as possible. It is also helpful if the comments refer to the specific pages or chapters of the Draft EIS. Comments may also address the adequacy of the Draft EIS or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the CEQ's regulations at 40 CFR 1503.3 in addressing these points. After the comment period ends on the Draft EIS, the comments will be analyzed, considered, and responded to by the agencies involved in preparing the Final EIS.

The public will again have the opportunity to review and comment on the Final EIS. Upon completion of a 30-day public comment period, the RUS will document its decision regarding the proposed Project and reasons for the decision in a Record of Decision. A public notice announcing the availability of the Record of Decision

will be published in the **Federal Register** and local newspapers.

Any final action by RUS related to the proposal will be subject to, and contingent upon, compliance with all relevant executive orders and federal, state, and local environmental laws and regulations in addition to the completion of the environmental review requirements as prescribed in RUS Environmental Policies and Procedures, 7 CFR part 1970.

Christopher A. McLean,

Acting Administrator, Rural Utilities Service, U.S. Department of Agriculture.

[FR Doc. 2021–21579 Filed 10–4–21; 8:45 am]

BILLING CODE 3410–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Kentucky Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Kentucky Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a meeting on Thursday, October 14, 2021, at 12:00 p.m. Eastern Time. The Committee will discuss civil rights concerns in the state.

DATES: The meeting will take place on Thursday, October 14, 2021, from 12:00 p.m.–1:00 p.m. Eastern Time.

ADDRESSES:

Online Registration (Audio/Visual): https://bit.ly/3AQUdmE.

Telephone (Audio Only): Dial 800–360–9505 USA Toll Free; Access code: 433 716 81.

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez, DFO, at *bdelaviez@usccr.gov* or (202) 376–8473.

SUPPLEMENTARY INFORMATION: Members of the public can listen to these discussions. Committee meetings are available to the public through the above call-in number. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov*. Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Kentucky Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

Roll Call
Introduction of Liliana Schiller
Post-Report Gate—Discussion about distribution of Report on Bail Reform
Concept Stage—orientation/reminder of Stage Gate Process
Next Steps
Open Comment
Adjourn

Dated: Monday, September 30, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–21680 Filed 10–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Boundary and Annexation Survey

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on Tuesday, May 18, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Commerce.

Title: Boundary and Annexation Survey.

OMB Control Number: 0607–0151.

Form Number(s): BAS–1, BAS–2, BAS–3, BAS–5, BAS–6, BASSC–1L, BASSC–3L, BASSC–4L.

Type of Request: Regular submission, Request for a Revision of a Currently Approved Collection.

Number of Respondents: 40,000 governments.

Average Hours per Response: 7.5 hours. This estimate is based on an average of 5 hours for a no change participant and 10 hours for a participant with changes.

Burden Hours: 300,000 hours.

Needs and Uses: The Boundary and Annexation Survey (BAS) provides tribal, state, and local governments an opportunity to review the Census Bureau's legal boundary data to ensure the Census Bureau has the correct boundary, name, and status information. BAS also allows participants to review and provide updates to Census Designated Places (CDPs). BAS fulfills the agency's responsibility as part of the National Spatial Data Infrastructure, for which the Office of Management and Budget (OMB) Circular A–16 designates the Census Bureau as the lead federal agency for maintaining national data about legal government boundaries, as well as statistical and administrative boundaries. BAS supports the spatial data steward responsibilities of the *OMB E-Gov*, *Data.gov*, the National Map, and Geographic Names Information System.

The Census Bureau uses the boundaries collected in BAS to tabulate data for various censuses and surveys including the decennial census, American Community Survey (ACS), and Population Estimates Program (PEP). It also uses the legal boundaries collected through BAS to support several other programs such as Congressional and State Legislative redistricting, the Economic Census, the Geographic Update Population Certification Program, and the Special Census program.

Numerous federal programs also rely on accurate boundaries collected through BAS. The U.S. Geological

Survey's National Map is updated annually to depict the legal boundaries provided by BAS. The Department of Housing and Urban Development uses legal boundaries to determine jurisdictional eligibility for various grant programs, such as the Community Development Block Grant program. In addition, the Department of Agriculture uses legal boundaries to determine eligibility for various rural housing and economic development programs.

The following collection methods allow the Census Bureau to coordinate among various levels of governments to obtain the most accurate legal boundary, CDPs, and contact information:

- BAS
  - Annual Response
  - Submissions—Digital and Paper
  - Non-Response Follow-Up
  - State Agreements
  - Consolidated BAS (CBAS) Agreements
- State Certification
- Boundary Quality

The following changes have been made since the BAS 60-day notification was published on Tuesday, May 18, 2021.

- The paper BAS annual response form (ARF) will no longer be included in the late-January annual response mailing. Participants will be instructed to complete the online response form or provide their response via email.
- BAS participants requesting CD/DVD will no longer receive state specific inserts or paper forms. State specific insert information will move to the online form. The paper forms are specific to the paper response method and will not be included with CD/DVD requests.
- BAS participants requesting paper maps will no longer receive state specific inserts. State specific insert information will move to the online form.
- BAS participants requesting paper maps will receive an insert that includes a list of materials included in the packet. This insert was omitted from the 60-day notification in error.
- The governor's letter for state certification will be replaced by an email. A non-response follow-up email was also added.
- The state certifying official letter will be replaced by an email. A non-response follow-up email was also added.

BAS

The Census Bureau collects legal boundary, CDP, and contact updates from tribal, state, and local governments during BAS. Governments are first contacted during annual response where they are asked if they have legal boundary, CDP, or contact updates to report. Those indicating they have updates to provide can choose to create a submission using an approved response method. Those governments that do not respond to annual response or those governments that indicate they have updates to provide are followed up with during BAS non-response follow-up. The BAS schedule is outlined below.

- January 1—Boundary updates must be legally in effect on or before this date to be reported in the current survey year.
- January to May—Tribal, state, and local governments respond during annual response or non-response follow-up indicating if they have legal boundary, CDP, or contact updates to report. Those with boundary updates to report download or request materials to create a submission to return to the Census Bureau.
- Early January—The Census Bureau sends the annual response email. Tribal, state, and local governments are contacted through email to determine if they have legal boundary, CDP, or contact updates to report.
- Late January—The Census Bureau sends the annual response letter. Tribal, state, and local governments that do not have an email address on file with the Census Bureau or did not respond to the annual response email are contacted through mail to determine if they have legal boundary, CDP, or contact updates to report.
- Mid-February—The Census Bureau conducts BAS non-response follow-up through email. Governments that have not responded to annual response, along with those that indicated they have boundary changes to report, are contacted through email.
- March 1—Boundary updates returned by this date will be reflected in the ACS and PEP data and in next year's BAS materials.
- March to May—The Census Bureau conducts BAS non-response telephone follow-up. Governments that did not respond to the annual response email, letter, and non-response email are contacted over the phone to determine if they have any legal boundary, CDP, or contact updates to report.
- May 31—Boundary updates returned by this date will be reflected in next year's BAS materials.

BAS—Annual Response

The Census Bureau first contacts tribal, state, and local governments during annual response. During this phase, the Census Bureau contacts all eligible governments through email and mail. The BAS annual response email includes program information and directs governments to respond through an online form if they have legal boundary, CDP, or contact updates to report. Only those governments that do not have an email address on file with the Census Bureau or did not respond to the annual response email are contacted through mail. The mailed package consists of a letter and program flyer.

Through annual response, participants are instructed to review the legal boundary, name, and status information, along with the contact information that the Census Bureau has on file for their government. BAS participants are also able to review CDP boundaries. Eligible governments can review their boundaries using the Census Bureau's TIGERweb online GIS viewer, partnership shapefiles, or PDF maps.

Participants respond if they have legal boundary, CDP, or contact updates to report through an online form, email, fax, or mail. Those indicating they have updates to provide can choose to create a submission using the Census Bureau's Geographic Update Partnership Software (GUPS) tool, their own GIS, or on paper maps. Participants can request to receive the materials to create their submission through download, by mail on CD/DVD or on large format paper maps.

The Census Bureau uses email and encourages participants to use the online form to respond to annual response to reduce cost and participant burden.

BAS—Submissions

Tribal, state, and local governments with boundary updates can choose to create a submission using either digital or paper response methods during annual response. The data provided to the partners, by the Census Bureau, are derived from its Master Address File and Topologically Integrated Geographic Encoding and Reference (MAF/TIGER) System. The boundary data reflects updates reported by partners through the prior year's BAS.

BAS—Digital Submission Methods

The Census Bureau offers participants two digital submission methods. Governments with boundary updates can create a submission using the GUPS tool or their own GIS. When completing annual response, participants select one of the following options:

- CD/DVD. Participants can choose to receive GUPS and the partnership shapefiles through mail on CD/DVD.

• Download. Participants can choose to download GUPS and partnership shapefiles, or partnership shapefiles only to use in their own GIS. The Census Bureau also offers a partnership toolbox that can be used in the partner's own GIS.

Those partners that elect to receive digital materials on CD/DVD will receive a package through the mail containing the following materials:

• Letter.
• CD or DVD containing GUPS tool.
• CD or DVD containing partnership shapefiles, respondent guides, and a readme text file.

Governments that elect to download materials can find the software, partnership shapefiles, respondent guides, and other information included in the letter on the BAS website.

Tribal, state, and local governments use GUPS or their own GIS to create a submission with legal boundaries updates, and optionally, CDPs, linear features, and landmarks updates. Partners return these updates electronically using the Census Bureau's SWIM file transfer module. Governments selecting one of the digital response methods during annual response will receive SWIM access information through email.

BAS—Paper Submission Method

The Census Bureau also provides partners a paper map option to create a submission with legal boundary, CDP, linear feature, and landmark updates. When completing annual response, partners select the following option:

• Paper maps. Participants can choose to receive large format paper maps through mail. Those partners that elect to receive paper maps will receive a package through the mail containing the following materials:

• Letter.
• Insert listing materials included in the package.
• Form specific to the government type.
  ○ BAS–1—Incorporated places and consolidated cities.
  ○ BAS–2—Counties and county equivalent governments.
  ○ BAS–3—Minor civil divisions.
  ○ BAS–5—Federally recognized tribal reservations and off-reservation trust lands.
• Large format paper maps covering the extent of the government.
• Supplies to update the paper maps.
• Respondent guide.
• Postage-paid return envelope.

Tribal, state, and local governments use the provided supplies to annotate legal boundaries updates, and optionally, CDPs, linear features, and landmarks updates on paper maps. Partners return these updates using the Census Bureau provided postage-paid return envelope.

BAS—Non-Response Follow-Up

Tribal, state, and local governments that do not respond to annual response or those governments that indicate they have updates to provide are followed up with during BAS non-response follow-up. Non-response follow-up is conducted through email and over the phone.

Governments that have not responded to annual response, along with those that indicated they have boundary changes to report, are first contacted through email. The email reminds participants to respond through an online form if they have legal boundary, CDP, or contact updates to report. Those governments that indicated they have boundary updates to report are requested to submit those updates to the Census Bureau by the BAS program deadline.

Partners that still have not responded are contacted by phone later in the program cycle. Governments are requested to provide a response over the phone on whether they have legal boundary, CDP, or contact updates to report. Again, those governments that indicated they have boundary updates to report are reminded to submit those updates to the Census Bureau by the program deadline.

State Agreements

BAS state agreements allow for the coordination and sharing of information and resources between the Census Bureau and state governments in collecting boundary information for local governments. Through this agreement with state governments, the Census Bureau aims to reduce the duplication of effort across various levels of governments as well as the cost and time burden associated with participating in BAS. To facilitate a state agreement, the Census Bureau may enter a Memorandum of Understanding (MOU) with the state. States interested in establishing a state agreement MOU can do so when there is state legislation requiring local governments to report all legal boundary updates to a state agency.

The Census Bureau currently maintains two types of state agreements. In the first type of agreement, the state reports boundary changes for all local governments within its jurisdiction during BAS. Local governments in this type of agreement are notified about BAS, however, do not receive materials to participate, and are instructed to report all boundary updates to the state so that they are reported to the Census Bureau. Under the second type of agreement, the state provides the Census Bureau with a list of local governments that reported boundary changes. The Census Bureau uses the list to target those local governments during BAS. States have the option to report the list of governments with known legal boundary changes to the Census Bureau.

Consolidated BAS (CBAS) Agreements

The Census Bureau offers CBAS agreements to counties or county equivalent governments that are interested in submitting boundary updates for legal governments within their jurisdiction. CBAS agreements help ensure collection of complete and accurate boundary data, reduces duplication of effort between local and county governments and the Census Bureau, and reduces the cost and time burden on local governments. Once entered into a CBAS agreement, local governments are notified about BAS, however, do not receive materials to participate, and are instructed to report all boundary updates to the county or county equivalent government so that they are reported to the Census Bureau.

State Certification

The state certification program provides an annual opportunity for state agencies to verify that the legal boundary, name, and status information received through BAS updates were reported in accordance with state law. The Census Bureau requests that each state governor designate a state certifying official (SCO) to participate in the program. The SCO reviews listings of legal boundary changes, as well as government names and statuses that were submitted through the previous year's BAS. These listings include the attribute information for new incorporations, dissolutions, mergers, consolidations, and legal boundary changes. The listings also include the names and functional statuses of all local governments within the state's jurisdiction. The SCO can request that the Census Bureau edit the attribute data, add missing records, or remove invalid records. Invalid records only are removed if the state government maintains an official record of all changes to legal boundaries and governments as mandated by state law. The state certification schedule is as follows:

• October—The Census Bureau sends an email to governors requesting the state appoint an SCO to participate in the program. Non-response emails are sent to governors that do not respond.

• December—The Census Bureau distributes the SCO emails. The SCO email contains information required by the SCO to participate in the program. Non-response emails are sent to SCOs that do not respond.

• March—The Census Bureau distributes discrepancy emails to local governments based on feedback from the SCO.

The state certification materials include emails to the governor, general emails to convey any additional information, respondent guide, legal boundary change, and government name and status listings to the SCO, and discrepancy emails to local governments. The listings and respondent guide are provided on the BAS website. The SCO returns all updates electronically through the SWIM file transfer module.

Boundary Quality

The Boundary Quality project is designed to assess, analyze, and improve the spatial quality of legal, statistical, and administrative boundaries within the Census Bureau's MAF/TIGER System. Ensuring quality boundaries is a critical component of the geographic preparations for each decennial census and the Census Bureau's ongoing geographic programs. In addition, the improvement of boundary quality is an essential element of the Census Bureau's commitment as the responsible agency for legal boundaries under OMB Circular A–16.

The Boundary Quality project represents an effort to systematically target and assess boundary quality within the Census Bureau's MAF/TIGER System. Historically, it has relied exclusively on geographic programs such as BAS and the Participant Statistical Areas Program (PSAP) to obtain updates to tribal, state, local government, and CDP boundaries. While programs like BAS play an essential role in improving boundary quality, the goal of boundary quality activities is to establish a more accurate baseline for legal boundaries and CDPs within an entire state or county. BAS would build on this baseline by collecting individual legal boundary changes and optionally associated addresses, and CDP updates, on a transaction basis as they occur over the years.

Affected Public: Tribal, state, and local governments in all 50 states and District of Columbia.

Frequency: Annual.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, U.S.C., Section 6.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–0151.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–21732 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–67–2021]

Foreign-Trade Zone (FTZ) 7—Mayaguez, Puerto Rico, Notification of Proposed Production Activity, AbbVie Ltd. (Pharmaceutical Products), Barceloneta, Puerto Rico

AbbVie Ltd. (AbbVie) submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Barceloneta, Puerto Rico within Subzone 7I. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on September 24, 2021.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status materials and specific finished products described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.* The proposed finished products and materials would be added to the production authority that the Board previously approved for the operation, as reflected on the Board's website.

The proposed finished products include UBRELVY® tablets, ATOGEPANT® tablets and atogepant and ubrelvy extrudates (duty-free).

The proposed foreign-status materials include ubrogepant and atogepant active pharmaceutical ingredients (duty rate 6.5%). The request indicates both materials are subject to duties under section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is November 15, 2021.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Christopher Wedderburn at *Chris.Wedderburn@trade.gov.*

Dated: September 30, 2021.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2021–21655 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–45–2021]

Foreign-Trade Zone (FTZ) 281—Miami-Dade County, Florida, Authorization of Production Activity, Intel Corporation (Kitting, Assembly and Packaging of Computer Electronics), Miami, Florida

On June 2, 2021, ModusLink Corporation, an operator within FTZ 281, submitted a notification of proposed production activity to the FTZ Board on behalf of Intel Corporation for its facility within FTZ 281.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (86 FR 31695, June 15, 2021). On September 30, 2021, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14. Textile bags must be admitted in privileged foreign status (19 CFR 146.41).

Dated: September 30, 2021.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2021–21656 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–843, A–570–029, A–533–865, A–588–873, A–580–881, A–412–824]

Cold-Rolled Steel Flat Products From Brazil, China, India, Japan, Republic of Korea, and United Kingdom: Final Results of the Expedited Sunset Reviews of the Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of these expedited sunset reviews, the Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) orders on certain cold-rolled steel flat products (cold-rolled steel) from Brazil, China, India, Japan, Republic of Korea (Korea), and the United Kingdom would be likely to lead to continuation or recurrence of dumping as indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Reginald Anadio, Abdul Alnoor, or Thomas Hanna, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2000, (202) 482–4554, or (202) 482–0835, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 14 and September 20, 2016, Commerce published in the **Federal Register** the *China and Japan Orders* and the *Brazil, India, Korea, and United Kingdom Orders,* respectively (collectively, *Orders*).[1] On June 1, 2021, Commerce published the notice of initiation of the sunset reviews of the *Orders* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] In accordance with 19 CFR 351.218(d)(1)(i) and (ii), Commerce received notices of intent to participate in these sunset reviews from Cleveland-Cliffs Inc.,[3] Nucor Corporation, California Steel Industries,[4] Steel Dynamics Inc., and United States Steel Corporation (collectively, the domestic interested parties) within 15 days after the date of publication of the *Initiation Notice.*[5] The domestic interested parties claimed interested party status under section 771(9)(C) of the Act. Commerce received adequate substantive responses to the *Initiation Notice* from the domestic interested parties within the 30-day period specified in 19 CFR 351.218(d)(3)(i).[6] Commerce did not receive a substantive response from any respondent interested party and no hearing was requested. On July 22, 2021, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from any respondent interested party.[7]

[1] *See Certain Cold-Rolled Steel Flat Products from Japan and the People's Republic of China: Antidumping Duty Orders,* 81 FR 45956 (July 14, 2016) (*China and Japan Orders*); *see also Certain Cold-Rolled Steel Flat Products from Brazil, India, the Republic of Korea, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Brazil and the United Kingdom and Antidumping Duty Orders,* 81 FR 64432 (September 20, 2016) (*Brazil, India, Korea, and United Kingdom Orders*).

[2] *See Initiation of Five-Year (Sunset) Review,* 86 FR 29239 (June 1, 2021) (*Initiation Notice*).

[3] Cleveland-Cliffs acquired AK Steel and the majority of the U.S. operations of Arcelor Mittal USA LLC, two firms that were among the domestic producing petitioners in the original investigations. *See, e.g.,* Domestic Interested Parties' Letter, ''First Five-Year (''Sunset'') Review of the Antidumping Order on Cold-Rolled Steel Flat Products from Brazil: Domestic Industry's Substantive Response to Notice of Initiation,'' dated July 1, 2021.

[4] California Steel Industries is a domestic interested party for all proceedings except for Brazil and Japan. *See* Domestic Interested Parties' Letters, ''First Five-Year (''Sunset'') Review of the Antidumping Order on Cold-Rolled Steel Flat Products from Brazil: Domestic Industry's Substantive Response to Notice of Initiation,'' dated July 1, 2021; *see also* ''Cold-Rolled Steel Flat Products from the People's Republic of China: Substantive Response of the Domestic Interested Parties to Commerce's Notice of Initiation of Five-Year (''Sunset'') Reviews,'' dated July 1, 2021; ''First Five-Year (''Sunset'') Review of the Antidumping Order on Cold-Rolled Steel Flat Products from India: Domestic Industry's Substantive Response to Notice of Initiation,'' dated July 1, 2021; ''Cold-Rolled Steel Flat Products from Japan: Substantive Response of the Domestic Interested Parties to Commerce's Notice of Initiation of Five-Year (''Sunset'') Reviews,'' dated July 1, 2021; ''Certain Cold-Rolled Steel Flat Products from the Republic of Korea: Substantive Response to Notice of Initiation of Sunset Review,'' dated July 1, 2021; and ''Five-Year (''Sunset'') Review of Antidumping Duty Order On Cold-Rolled Flat Products From the United Kingdom: Domestic Industry Substantive Response,'' dated July 1, 2021 (collectively, Substantive Responses).

[5] *See* Cleveland-Cliffs Inc.'s Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Cold-Rolled Steel Flat Products from Brazil: Notice of Intent to Participate in Sunset Review,'' dated June 14, 2021; *see also* United States Steel Corporation's Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Cold-Rolled Steel Flat Products from Brazil: Notice of Intent to Participate,'' dated June 16, 2021; Steel Dynamics Inc.'s Letter, ''Notice of Intent to Participate in the First Five-Year Review of the Antidumping Duty Order on Cold-Rolled Steel Flat Products from Brazil,'' dated June 16, 2021; Nucor Corporation's Letter, ''Certain Cold-Rolled Steel Flat Products from Brazil: Notice of Intent to Participate in Sunset Review,'' dated June 16, 2021; Cleveland-Cliffs Inc.'s Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Cold-Rolled Steel Flat Products From China: Notice of Intent to Participate in Sunset Review,'' dated June 14, 2021; United States Steel Corporation's Letter, ''Five-Year (''Sunset'') Review of Antidumping and Countervailing Duty Orders on Cold-Rolled Steel Flat Products from China: Notice of Intent to Participate,'' dated June 16, 2021; California Steel Industries' and Steel Dynamics Inc.'s Letter, ''Notice of Intent to Participate in the First Five-Year Review of the Antidumping Duty Order on Cold-Rolled Steel Flat Products from the People's Republic of China,'' dated June 16, 2021; Nucor Corporation's Letter, ''Certain Cold-Rolled Steel Flat Products from the People's Republic of China: Notice of Intent to Participate in Sunset Review,'' dated June 16, 2021; Cleveland-Cliffs Inc.'s Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Cold-Rolled Steel Flat Products From India: Notice of Intent to Participate in Sunset Review,'' dated June 14, 2021; United States Steel Corporation's Letter, ''Five-Year (''Sunset'') Review of Antidumping and Countervailing Duty Orders on Cold-Rolled Steel Flat Products from India: Notice of Intent to Participate,'' dated June 16, 2021; California Steel Industries' and Steel Dynamics Inc.'s Letter, ''Notice of Intent to Participate in the First Five-Year Review of the Antidumping Duty Order on Cold-Rolled Steel Flat Products from India,'' dated June 16, 2021; Nucor Corporation's Letter, ''Certain Cold-Rolled Steel Flat Products from India: Notice of Intent to Participate in Sunset Review,'' dated June 16, 2021; Cleveland-Cliffs Inc.'s Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Cold-Rolled Steel Flat Products From Japan: Notice of Intent to Participate in Sunset Review,'' dated June 14, 2021; United States Steel Corporation's Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Cold-Rolled Steel Flat Products from Japan: Notice of Intent to Participate,'' dated June 16, 2021; Steel Dynamics Inc.'s Letter, ''Notice of Intent to Participate in the First Five-Year Review of the Antidumping Duty Order on Cold-Rolled Steel Flat Products from Japan,'' dated June 16, 2021; Nucor Corporation's Letter, ''Certain Cold-Rolled Steel Flat Products from Japan: Notice of Intent to Participate in Sunset Review,'' dated June 16, 2021; Cleveland-Cliffs Inc.'s Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Cold-Rolled Steel Flat Products From the Republic of Korea: Notice of Intent to Participate in Sunset Review,'' dated June 14, 2021; United States Steel Corporation's Letter, ''Five-Year (''Sunset'') Review of Antidumping and Countervailing Duty Orders on Cold-Rolled Steel Flat Products from South Korea: Notice of Intent to Participate,'' dated June 16, 2021; California Steel Industries' and Steel Dynamics Inc.'s Letter, ''Notice of Intent to Participate in the First Five-Year Review of the Antidumping Duty order on Cold-Rolled Steel Flat Products from the Republic of Korea,'' dated June 16, 2021; Nucor Corporation's Letter, ''Certain Cold-Rolled Steel Flat Products from the Republic of Korea: Notice of Intent to Participate in Sunset Review,'' dated June 16, 2021; Cleveland-Cliffs Inc.'s Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Cold-Rolled Steel Flat Products From the United Kingdom: Notice of Intent to Participate in Sunset Review,'' dated June 14, 2021; United States Steel Corporation's Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Cold-Rolled Steel Flat Products from the United Kingdom: Notice of Intent to Participate,'' dated June 16, 2021; California Steel Industries' and Steel Dynamics Inc.'s Letter, ''Notice of Intent to Participate in the First Five-Year Review of the Antidumping Duty order on Cold-Rolled Steel Flat Products from the United Kingdom,'' dated June 16, 2021; Nucor Corporation's Letter, ''Certain Cold-Rolled Steel Flat Products from the United Kingdom: Notice of Intent to Participate in Sunset Review,'' dated June 16, 2021 (collectively, Notices of Intent to Participate).

[6] *See* Substantive Responses.

[7] *See* Commerce's Letter, ''Sunset Reviews Initiated on June 1, 2021,'' dated July 22, 2021.

In accordance with section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted expedited, *i.e.,* 120-day, sunset reviews of the *Orders.*

Scope of the Orders: Brazil, India, Korea, the United Kingdom, and China

The products covered by the orders on cold-rolled steel from Brazil, India, Korea, the United Kingdom, and China are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings: 7209.15.0000, 7209.16.0030, 7209.16.0060, 7209.16.0070, 7209.16.0091, 7209.17.0030, 7209.17.0060, 7209.17.0070, 7209.17.0091, 7209.18.1530, 7209.18.1560, 7209.18.2510, 7209.18.2520, 7209.18.2580, 7209.18.6020, 7209.18.6090, 7209.25.0000, 7209.26.0000, 7209.27.0000, 7209.28.0000, 7209.90.0000, 7210.70.3000, 7211.23.1500, 7211.23.2000, 7211.23.3000, 7211.23.4500, 7211.23.6030, 7211.23.6060, 7211.23.6090, 7211.29.2030, 7211.29.2090, 7211.29.4500, 7211.29.6030, 7211.29.6080, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7225.50.6000, 7225.50.8080, 7225.99.0090, 7226.92.5000, 7226.92.7050, and 7226.92.8050.

The products subject to the orders on cold-rolled steel from Brazil, India, Korea, the United Kingdom, and China may also enter under the following HTSUS subheadings: 7210.90.9000, 7212.50.0000, 7215.10.0010, 7215.10.0080, 7215.50.0016, 7215.50.0018, 7215.50.0020, 7215.50.0061, 7215.50.0063, 7215.50.0065, 7215.50.0090, 7215.90.5000, 7217.10.1000, 7217.10.2000, 7217.10.3000, 7217.10.7000, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.19.0000, 7226.19.1000, 7226.19.9000, 7226.99.0180, 7228.50.5015, 7228.50.5040, 7228.50.5070, 7228.60.8000, and 7229.90.1000. The HTSUS subheadings are provided for convenience and customs purposes. A full description of the scope of the orders on cold-rolled steel from Brazil, India, Korea, the United Kingdom, and China is contained in the Issues and Decision Memorandum.[8] The written description is dispositive.

Scope of the Order: Japan[9]

The products covered by the order on cold-rolled steel from Japan are currently classified in the HTSUS under subheadings: 7209.15.0000, 7209.16.0030, 7209.16.0040, 7209.16.0045, 7209.16.0060, 7209.16.0070, 7209.16.0091, 7209.17.0030, 7209.17.0040, 7209.17.0045, 7209.17.0060, 7209.17.0070, 7209.17.0091, 7209.18.1530, 7209.18.1560, 7209.18.2510, 7209.18.2520, 7209.18.2580, 7209.18.6020, 7209.18.6090, 7209.25.0000, 7209.26.0000, 7209.27.0000, 7209.28.0000, 7209.90.0000, 7210.70.3000, 7211.23.1500, 7211.23.2000, 7211.23.3000, 7211.23.4500, 7211.23.6030, 7211.23.6060, 7211.23.6090, 7211.29.2030, 7211.29.2090, 7211.29.4500, 7211.29.6030, 7211.29.6080, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7225.50.6000, 7225.50.8080, 7225.99.0090, 7226.92.5000, 7226.92.7050, and 7226.92.8050.

The products subject to the order on cold-rolled steel from Japan may also enter under the following HTSUS subheadings: 7210.90.9000, 7212.50.0000, 7215.10.0010, 7215.10.0080, 7215.50.0016, 7215.50.0018, 7215.50.0020, 7215.50.0061, 7215.50.0063, 7215.50.0065, 7215.50.0090, 7215.90.5000, 7217.10.1000, 7217.10.2000, 7217.10.3000, 7217.10.7000, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.19.0000, 7226.19.1000, 7226.19.9000, 7226.99.0180, 7228.50.5015, 7228.50.5040, 7228.50.5070, 7228.60.8000, and 7229.90.1000. The HTSUS subheadings are provided for convenience and customs purposes. A full description of the scope of the order on cold-rolled steel from Japan is contained in the Issues and Decision Memorandum.[10] The written description is dispositive.

Analysis of Comments Received

All issues raised in this review are addressed in the Issues and Decision Memorandum, including the likelihood of continuation or recurrence of dumping in the event of revocation and the magnitude of dumping margins likely to prevail if the order was revoked. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in the Issues and Decision Memorandum, which is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be found at *http://enforcement.trade.gov/frn/index.html.*

Final Results of Sunset Review

Pursuant to sections 751(c) and 752(c) of the Act, Commerce determines that revocation of the *Orders* would be likely to lead to continuation or recurrence of dumping and the magnitude of the margins of dumping likely to prevail would be weighted-average margins up to the following percentages:

Country	Weighted-average margin (percent)
Brazil	35.43
China	265.79
India	7.60
Japan	71.35
Korea	28.42
United Kingdom	25.17

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.221(c)(5)(ii).

[8] *See* Memorandum, ''Issues and Decision Memorandum for the Expedited Sunset Reviews of the Antidumping Duty Orders on Cold-Rolled Steel Flat Products from Brazil, China, India, Japan, South Korea, and United Kingdom,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[9] As discussed in the accompanying Issues and Decision Memorandum, a result of the changed circumstances review, Commerce modified the scope of the order on cold-rolled steel from Japan to specify an exclusion on certain cold-rolled steel from Japan. *See Certain Cold-Rolled Steel Flat Products From Japan: Final Results of Changed Circumstances Review, and Revocation of Antidumping Duty Order, in Part,* 82 FR 12337 (March 2, 2017); *see also* Issues and Decision Memorandum.

[10] *See* Issues and Decision Memorandum.

Dated: September 29, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2021–21658 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–825]

Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes From the Republic of Turkey: Preliminary Results and Rescission in Part of Countervailing Duty Administrative Review; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the countervailing duty (CVD) order on heavy walled rectangular welded carbon steel pipes and tubes (HWR pipes and tubes) from the Republic of Turkey (Turkey) for the period January 1, 2019, through December 31, 2019. Commerce preliminarily determines that Ozdemir Boru Profil San. Ve Tic. Ltd. Sti. (Ozdemir), the sole producer/exporter of HWR pipes and tubes from Turkey subject to this review, received *de minimis* countervailable subsidies. In addition, we are also rescinding this review with regard to eight companies for which the request for review was timely withdrawn by Nucor Tubular Products Inc. (the petitioner).

DATES: Applicable October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Janae Martin or Jaron Moore, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0238 or (202) 482–3640, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 30, 2020, Commerce received a timely request for an administrative review of several companies from the petitioner, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b).[1] Commerce received no other requests for administrative review of these companies. On October 30, 2020, Commerce published a notice of initiation of an administrative review of the CVD order on HWR pipes and tubes from Turkey.[2]

On January 28, 2021, the petitioner timely withdrew its request for an administrative review with respect to the following eight companies: Agir Haddecilik A.S., Cag Celik Demir ve Celik Endustri A.S., Cinar Boru Profil San Ve Tic. A.S., Mescier Dis Ticaret Ltd. Sti., MTS Lojistik ve Tasimacilik Hizmetleri TIC A.C. Istanbul, Noksel Celik Boru Sanayi A, SEBA Dis Ticaret AS., and Tosyali Toyo Celik A.S.[3] As a result, the only company for which the request for review was not withdrawn is Ozdemir.

On May 18, 2021, Commerce extended the deadline for the preliminary results to September 30, 2021.[4]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5] A list of topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Scope of the Order

The merchandise covered by the order is HWR pipes and tubes from Turkey. For a complete description of the scope of the order, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(A) of the Act. For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a government financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[6] For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested a review withdraws the request within 90 days of the publication date of the notice of initiation of the requested review. On October 30, 2020, Commerce published the notice of initiation of the requested review in the **Federal Register**.[7] The petitioner's withdrawal request was timely submitted,[8] and no other interested party requested an administrative review of the eight companies named above. Therefore, in accordance with 19 CFR 351.213(d)(1), we are rescinding this administrative review of the CVD order on HWR pipes and tubes from Turkey, in part, with respect to the aforementioned eight companies.

Preliminary Results of Review

Commerce preliminarily determines that the following countervailable subsidy rate exists for Ozdemir for the period January 1, 2019, through December 31, 2019:

[1] *See* Petitioner's Letter, ''Request for Administrative Review,'' dated September 30, 2020.

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 68840 (October 30, 2020).

[3] *See* Petitioner's Letter, ''Partial Withdrawal of Request for Administrative Review,'' dated January 28, 2021.

[4] *See* Memorandum, ''Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey: Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review; 2019,'' dated May 18, 2021.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results: Administrative Review of the Countervailing Duty Order on Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey; 2019,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 68840 (Oct. 30, 2020).

[8] *See* Petitioner's Letter, ''Partial Withdrawal of Request for Administrative Review,'' dated January 28, 2021.

Company	Subsidy rate (percent)
Ozdemir Boru Profil San. Ve Tic. Ltd. Sti	*0.26

* (*de minimis*).

Assessment Rate

Consistent with section 751(a)(2)(C) of the Act, upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. If the assessment rate calculated in the final results is zero or *de minimis,* we will instruct CBP to liquidate all appropriate entries without regard to countervailing duties. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

With respect to the companies for which this administrative review is rescinded (*i.e.,* Agir Haddecilik A.S., Cag Celik Demir ve Celik Endustri A.S., Cinar Boru Profil San Ve Tic. A.S., Mescier Dis Ticaret Ltd. Sti., MTS Lojistik ve Tasimacilik Hizmetleri TIC A.C. Istanbul, Noksel Celik Boru Sanayi A, SEBA Dis Ticaret AS., and Tosyali Toyo Celik A.S.), countervailing duties shall be assessed at rates equal to the cash deposit rate required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2019, through December 31, 2019, in accordance with 19 CFR 351.212(c)(1)(i).

Cash Deposit Rate

Pursuant to section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amount indicated for Ozdemir with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review, except, where the rate calculated in the final results is zero or *de minimis,* no cash deposit will be required. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit instructions, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We will disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results.[9] Interested parties may submit written comments (case briefs) within 30 days of publication of the preliminary results and rebuttal comments (rebuttal briefs) within seven days after the time limit for filing case briefs.[10] Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs. Parties who submit arguments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[11]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary for Enforcement and Compliance using Enforcement and Compliance's ACCESS system.[12] Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce will inform parties of the scheduled date of the hearing which will be held at a time and date to be determined.[13] Issues addressed during the hearing will be limited to those raised in the briefs.[14] Parties should confirm the date and time of the hearing two days before the scheduled date.

Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5 p.m. Eastern Time on the due date. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[15]

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) and 19 CFR 351.213(h), unless this deadline is extended.

Notification to Interested Parties

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: September 29, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2021–21654 Filed 10–4–21; 8:45 am]

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[9] *See* 19 CFR 351.224(b).

[10] *See* 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1).

[11] *See* 19 CFR 351.309(c)(2) and 351.309(d)(2).

[12] *See* 19 CFR 351.310(c).

[13] *See* 19 CFR 351.310.

[14] *See* 19 CFR 351.310(c).

[15] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements); *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–864]

Certain Corrosion-Resistant Steel Products From India: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on certain corrosion-resistant steel products (CORE) from India would be likely to lead to the continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Nathan James, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5305.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 2016, Commerce published in the **Federal Register** the CVD order on CORE from India.[1] On July 1, 2021, Commerce published the notice of initiation of the first sunset review of the CVD order on CORE from India, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] In June 2021, Commerce received timely notices of intent to participate from California Steel Industries (CSI), Cleveland-Cliffs Inc., Nucor Corporation (Nucor), Steel Dynamics Inc. (SDI), and United States Steel Corporation (U.S. Steel) (collectively, domestic interested parties).[3] The companies claimed interested party status under section 771(9)(C) of the Act as domestic producers of CORE.

On July 1, 2021, Commerce received a timely and adequate substantive response from the domestic interested parties.[4] We received no substantive responses from any other interested parties, including the Government of India, nor was a hearing requested. On July 22, 2021, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, pursuant to 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the CVD order on CORE from India.

Scope of the Order

The product covered by the order is CORE. For a full description of the scope, *see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

All issues raised in this sunset review are addressed in the accompanying Issues and Decision Memorandum, which is hereby adopted by this notice. The issues discussed in the Issues and Decision Memorandum are the likelihood of continuation or recurrence of a countervailable subsidy, the net countervailable subsidy rate likely to prevail if the order were revoked, and the nature of the subsidy programs. A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice.

The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, Commerce determines that revocation of the CVD order on CORE from India would be likely to lead to the continuation or recurrence of countervailable subsidies at the rates listed below:

Producer/exporter	Net subsidy rate (percent)
JSW Steel Limited and JSW Steel Coated Products Limited	6.69
Uttam Galva Steels Limited and Uttam Value Steels Limited	530.74
All Others	6.12

Notification Regarding Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: September 29, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2021–21660 Filed 10–4–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–870]

Certain Oil Country Tubular Goods From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that certain oil country tubular goods (OCTG) from the Republic of Korea (Korea) were sold in the United States at prices below normal value. The period of review (POR) is September 1, 2019, through August 31, 2020. Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Davina Friedmann, Mark Flessner, or Frank Schmitt, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0698, (202) 482–6312, or (202) 482–4880, respectively.

SUPPLEMENTARY INFORMATION:

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[1] *See Certain Corrosion-Resistant Steel Products from India, Italy, Republic of Korea and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 86 FR 29239 (June 1, 2021).

[3] *See* Cleveland-Cliffs' Letter, ''Five-Year (''Sunset'') Review of Countervailing Duty Order On Corrosion-Resistant Steel Products From India: Notice Of Intent To Participate In Sunset Review,'' dated June 14, 2021; U.S. Steel's Letter, ''Five-Year (''Sunset'') Review of Antidumping and Countervailing Duty Orders on Corrosion-Resistant Steel Products from India: Notice of Intent to Participate,'' dated June 16, 2021; CSI/SDI's Letter, ''Notice of Intent to Participate in the First Five-Year Review of the Countervailing Duty Order on Certain Corrosion-Resistant Steel Products from India,'' dated June 16, 2021; and Nucor's Letter, ''Certain Corrosion-Resistant Steel Products from India: Notice of Intent to Participate in Sunset Review,'' dated June 16, 2021.

[4] *See* Domestic Interested Parties' Letter, ''First Five-Year (''Sunset'') Review of Countervailing Duty Order on Corrosion-Resistant Steel Products from India: Domestic Industry's Substantive Response to Notice of Initiation,'' dated July 1, 2021.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on June 1, 2021,'' dated July 22, 2021.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Countervailing Duty Order on Certain Corrosion-Resistant Steel Products from India,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Background

These preliminary results are made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this administrative review on October 30, 2020.[1] Commerce selected Hyundai Steel Company (Hyundai Steel) and SeAH Steel Corporation (SeAH) as the two mandatory respondents in this review.[2] On April 29, 2021, in accordance with section 751(a)(3)(A) of the Act, Commerce extended the preliminary results of review by 120 days, until September 30, 2021.[3]

For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.[4] A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Scope of the Order

The product covered by the *Order*[5] is OCTG from Korea. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(2) of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value (NV) is calculated in accordance with section 773 of the Act. Commerce preliminarily does not find that a cost-based particular market situation existed in Korea during the POR.[6] For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Determination of No Shipments

On November 25, 2020, HiSteel Co., Ltd. (HiSteel) submitted a letter certifying that it had no exports or sales of subject merchandise into the United States during the POR.[7] U.S. Customs and Border Protection (CBP) did not have any information to contradict this claim of no shipments during the POR.[8] Therefore, we preliminarily determine that HiSteel did not have any shipments of subject merchandise during the POR. Consistent with Commerce's practice, we will not rescind the review with respect to HiSteel but will complete the review and issue instructions to CBP based on the final results.[9]

Rates for Non-Examined Companies

The statute and Commerce's regulations do not address the rate to be applied to companies not selected for examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In this review, we preliminarily calculated dumping margins for the two mandatory respondents, Hyundai Steel and SeAH, of 19.38 and 3.85 percent, respectively, and we have assigned to the non-selected companies a rate of 11.62 percent, which is the simple average of Hyundai Steel's and SeAH's margins.[10]

Preliminary Results of Review

Commerce preliminarily finds that, for the period September 1, 2019, through August 31, 2020, the following weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Hyundai Steel Company	19.38
SeAH Steel Corporation	3.85
Non-examined companies[11]	11.62

Disclosure, Public Comment, and Opportunity to Request a Hearing

We intend to disclose the calculations performed for these preliminary results of review to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, the content of which is limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[12] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[13] Executive summaries should be limited to five pages total, including footnotes. Case and rebuttal briefs should be filed

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 68840 (October 30, 2020).

[2] *See* Memorandum, ''2019–2020 Administrative Review of the Antidumping Duty Order on Oil Country Tubular Goods from the Republic of Korea: Respondent Selection,'' dated December 18, 2020.

[3] *See* Memorandum, ''Oil Country Tubular Goods from the Republic of Korea: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review, 2019–20,'' dated April 29, 2021.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2019–2020 Administrative Review of Oil Country Tubular Goods from the Republic of Korea'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value,* 79 FR 53691 (September 10, 2014) (*Order*).

[6] For a complete discussion, *see* Preliminary Decision Memorandum at 15–28.

[7] *See* HiSteel's Letter, ''Administrative Review of the Antidumping Order on Oil Country Tubular Goods from Korea for the 2019–20 Review Period—No Shipments Letter,'' dated November 25, 2020.

[8] *See* Memorandum, ''Certain Oil Country Tubular Goods from the Republic of Korea 2019–20: No Shipment Inquiry for HiSteel Co., Ltd., During the Period 09/01/2019 through 08/31/2020,'' dated September 27, 2021.

[9] *See, e.g., Certain Frozen Warmwater Shrimp from Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013,* 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012–2013,* 79 FR 51306, 51307 (August 28, 2014).

[10] Commerce was unable to compare a simple average to a weighted-average relative to publicly available data because public data for volume of U.S. sales were not available for both respondents.

[11] *See* Appendix II.

[12] *See* 19 CFR 351.309(d).

[13] *See* 19 CFR 351.309(c)(2) and (d)(2).

using ACCESS [14] and must be served on interested parties.[15] An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time on the date that the document is due.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via Commerce's electronic records system, ACCESS. An electronically filed request must be received successfully in its entirety by 5:00 p.m. Eastern Time within 30 days of the date of publication of this notice.[16] Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined.[17] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

Pursuant to Section 751(a)(2)(B)(iv) of the Act and 19 CFR 351.213(h)(2), Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any case or rebuttal briefs, no later than 120 days after the date of publication of this notice, unless extended.[18]

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[19]

For any individually examined respondents whose weighted-average dumping margin is above *de minimis* (*i.e.,* greater than or equal to 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the examined sales to that importer, and we will instruct CBP to assess antidumping duties on all appropriate entries covered by this review. For entries of subject merchandise during the POR produced by each respondent for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[20] Where the individually-selected respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For the companies which were not selected for individual review, we intend to assign an assessment rate based on the methodology described in the ''Rates for Non-Examined Companies'' section. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review where applicable.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**.[21] If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for the companies listed in the final results of review will be equal to the weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 5.24 percent, the all-others rate established in the less-than-fair-value investigation.[22] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

The preliminary results of this administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: September 29, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Rates for Non-Examined Companies
V. Preliminary Determination of No Shipments
VI. Affiliation
VII. Discussion of the Methodology
VIII. Currency Conversion
IX. Recommendation

Appendix II—List of Companies Not Individually Examined

1. AJU Besteel Co., Ltd.
2. DB Inc.
3. Dong-A Steel Co., Ltd.
4. FM Oilfield Services Solutions LLC
5. Hengyang Steel Tube Group International Trading Inc.
6. Husteel Co., Ltd.
7. Hyundai Corporation
8. Hyundai Heavy Industries Co., Ltd.

[14] *See generally* 19 CFR 351.303.

[15] *See* 19 CFR 351.303(f).

[16] *See* 19 CFR 351.310(c).

[17] *See* 19 CFR 351.310(d).

[18] *See* section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

[19] *See* 19 CFR 351.212(b)(1).

[20] For a full discussion of this clarification, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[21] *See Notice of Discontinuation of Policy to Issue Liquidation Instructions After 15 Days in Applicable Antidumping and Countervailing Duty Administrative Proceedings,* 86 FR 884 (January 15, 2021).

[22] *See Certain Oil Country Tubular Goods from the Republic of Korea: Notice of Court Decision Not in Harmony With Final Determination,* 81 FR 59603 (August 30, 2016).

9. ILJIN Steel Corporation
10. K Steel Corporation
11. KASCO
12. Kenwoo Metals Co., Ltd.
13. Kukje Steel Co., Ltd.
14. Kumkang Kind Co., Ltd.
15. Kumsoo Connecting Co., Ltd.
16. Master Steel Corporation
17. NEXTEEL Co., Ltd.
18. POSCO International Corporation
19. Pusan Coupling Corporation
20. Pusan Fitting Corporation
21. Sang Shin Industrial Co., Ltd. (a.k.a. SIC Tube Co., Ltd.)
22. SeAH Changwon Integrated Special Steel Co., Ltd.
23. Shin Steel Co., Ltd.
24. Sichuan Y&J Industries Co. Ltd.
25. Steel-A Co., Ltd.
26. Sungwon Steel Co., Ltd.
27. TGS Pipe Co., Ltd.
28. TJ Glovsteel Co., Ltd.
29. TPC Co., Ltd.
30. T-Tube Co., Ltd.

[FR Doc. 2021–21659 Filed 10–4–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB379]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Office of Naval Research's Arctic Research Activities in the Beaufort and Chukchi Seas (Year 4)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an IHA to the U.S. Navy's Office of Naval Research (ONR) to incidentally harass, by Level B harassment only, marine mammals during oceanographic research activities associated with the Arctic Research Activities (Year 4) in the Beaufort and eastern Chukchi Seas. The Navy's activities are considered military readiness activities pursuant to the MMPA, as amended by the National Defense Authorization Act for Fiscal Year 2004 (NDAA).

DATES: This Authorization is effective from October 5, 2021 through October 4, 2022.

FOR FURTHER INFORMATION CONTACT: Kelsey Potlock, Office of Protected Resources, NMFS, (301) 427–8401.

Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-office-naval-research-arctic-research-activities-beaufort-1.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth.

The NDAA (Pub. L. 108–136) removed the ''small numbers'' and ''specified geographical region'' limitations indicated above and amended the definition of ''harassment'' as it applies to a ''military readiness activity.'' The activity for which incidental take of marine mammals is being requested addressed here qualifies as a military readiness activity. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

Summary of Request

On June 4, 2021, NMFS received a request from the Office of Naval Research (ONR) for an IHA to take marine mammals incidental to oceanographic research activities, known as Arctic Research Activities, in the Beaufort and eastern Chukchi Seas. The application was deemed adequate and complete on August 4, 2021. ONR's request is for take of beluga whales (*Delphinapterus leucas;* two stocks) and ringed seals (*Pusa hispida hispida*) by Level B harassment only. Neither ONR nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

This IHA will cover the fourth year of a larger project for which ONR obtained prior IHAs (83 FR 48799, September 27, 2018; 84 FR 50007, September 24, 2019; 85 FR 53333, August 28, 2020) and may request take authorization for subsequent facets of the overall project. This IHA will be valid for a period of one year, October 5, 2021 to October 4, 2022. The larger project involves several scientific objectives that support the Arctic and Global Prediction Program, as well as the Ocean Acoustic Program and the Naval Research Laboratory, for which ONR is the parent command. ONR has complied with all the requirements (*e.g.,* mitigation, monitoring, and reporting) of the previous IHAs (83 FR 48799, September 27, 2018; 84 FR 50007, September 24, 2019; 85 FR 53333, August 28, 2020).

Description of Activities

Overview

ONR's Arctic Research Activities include scientific experiments to be conducted in support of the following programs: The Arctic and Global Prediction Program, the Ocean Acoustic Program, and the Naval Research Laboratory (NRL), for which ONR is the parent command. Specifically, the project includes the Arctic Mobile Observing System (AMOS), Ocean Acoustics field work, and NRL experiments in the Beaufort and Chukchi Seas. Project activities involve acoustic testing during cruises (two planned) and a multi-frequency navigation system concept test using left-behind active acoustic sources. More specifically, these experiments involve the deployment of moored, drifting, and ice-tethered active acoustic sources as well as a towed source (see details in the proposed notice (86 FR 47065; August 23, 2021) on the Shallow Water Integrate Mapping System) from the Research Vessel (R/V) *Sikuliaq* and another vessel, most likely the U.S. Coast Guard Cutter (CGC) HEALY. Underwater sound from the acoustic sources may result in behavioral harassment of marine mammals.

A detailed description of the planned Arctic Research Activities is provided in the **Federal Register** notice of the proposed IHA (86 FR 47065; August 23, 2021). Since that time, no changes have been made to the project activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specified activities.

Comments and Responses

A notice of NMFS's proposal to issue an IHA to ONR was published in the **Federal Register** on August 23, 2021 (86 FR 47065). That proposed notice described, in detail, ONR's activities, the marine mammal species that may be affected by the activities and the anticipated effects on marine mammals. During this period, NMFS received two non-substantive public comments that did not present relevant information and did not change our determinations or any aspects of the IHA as described in the proposed **Federal Register** notice (86 FR 47065; August 23, 2021).

Changes From the Proposed IHA to Final IHA

NMFS notes one correction to information provided in the notice of proposed IHA (86 FR 47065; August 23, 2021). The location of the activity was described in error as being potentially as close as 110 miles from Alaska. The correct distance is 110 nautical miles (nm; 204 km).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*https://www.fisheries.noaa.gov/find-species*).

Table 1 lists all species or stocks for which take is expected and is authorized for this action, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2021). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's 2020 Alaska SARs (Muto *et al.,* 2021). All values presented in Table 1 are the most recent available at the time of publication and are available in the 2020 SARs (Muto *et al.,* 2021) and available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.*

TABLE 1—SPECIES EXPECTED TO OCCUR IN THE PROJECT AREA

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacean—Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Monodontidae						
Beluga whale	*Delphinapterus leucas.*	Beaufort Sea [4]	-,-; N	39,258 (0.229, N/A, 1992)	[4] UND	102
Beluga whale	*Delphinapterus leucas.*	Eastern Chukchi	-,-; N	13,305 (0.51, 8,875, 2012)	178	55
Order Carnivora—Superfamily Pinnipedia						
Family Phocidae (earless seals)						
Ringed seal [5]	*Pusa hispida hispida*	Arctic	T, D; Y	171,418	5,100	6,459

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance.

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[4] The 2016 guidelines for preparing SARs state that abundance estimates older than 8 years should not be used to calculate PBR due to a decline in the reliability of an aged estimate. Therefore, the PBR for this stock is considered undetermined.

[5] Abundance and associated values for ringed seals are for the U.S. population in the Bering Sea only.

A detailed description of the species likely to be affected by the Arctic Research Activities, including brief information regarding population trends and threats, and information regarding local occurrence, were provided in the

Federal Register notice for the proposed IHA (86 FR 47065; August 23, 2021). Since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for those descriptions. Please also refer to NMFS's website (*https://www.fisheries.noaa.gov/find-species*) for generalized species accounts.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 2.

TABLE 2—MARINE MAMMAL HEARING GROUPS (NMFS, 2018)

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Two marine mammal species (1 cetacean and 1 pinniped (1 phocid) species) have the reasonable potential to co-occur with the survey activities. Please refer to Table 1. Beluga whales are classified as mid-frequency cetaceans.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from the deployed acoustic sources have the potential to result in behavioral harassment of marine mammals in the vicinity of the study area. The **Federal Register** notice for the proposed IHA (86 FR 47065; August 23, 2021) included a discussion of the effects of anthropogenic noise on marine mammals and their habitat, therefore that information is not repeated here; please refer to the **Federal Register** notice (86 FR 47065; August 23, 2021) for that information.

Estimated Take

This section provides an estimate of the number of incidental takes authorized through this IHA, which will inform NMFS' consideration of the negligible impact determination.

Harassment is the only type of take expected to result from these activities. For this military readiness activity, the MMPA defines ''harassment'' as (i) Any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) Any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where the behavioral patterns are abandoned or significantly altered (Level B harassment).

Authorized takes are by Level B harassment only, in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to acoustic transmissions. Based on the nature of the activity, Level A harassment is neither anticipated nor authorized.

As described previously, no mortality is anticipated or authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) and the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). For this IHA, ONR employed a sophisticated model known as the Navy Acoustic Effects Model (NAEMO) for assessing the impacts of underwater sound. Below, we describe the factors considered here in more detail and present the authorized take.

Acoustic Thresholds

Using the best available science, NMFS recommends the use of acoustic

thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (*e.g.,* hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS typical generalized acoustic thresholds are received levels of 120 dB of 1 microPascal (re 1 μPa; rms) for continuous (*e.g.,* vibratory pile-driving, drilling) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. In this case, NMFS has adopted the Navy's approach to estimating incidental take by Level B harassment from the active acoustic sources for this action, which includes use of the dose response functions described below.

The Navy's dose response functions were developed to estimate take from sonar and similar transducers. Multi-year research efforts have conducted sonar exposure studies for odontocetes and mysticetes (Miller *et al.,* 2012; Sivle *et al.,* 2012). Several studies with captive animals have provided data under controlled circumstances for odontocetes and pinnipeds (Houser *et al.,* 2013a; Houser *et al.,* 2013b). Moretti *et al.,* (2014) published a beaked whale dose-response curve based on passive acoustic monitoring of beaked whales during U.S. Navy training activity at Atlantic Underwater Test and Evaluation Center during actual Anti-Submarine Warfare exercises. This new information necessitated the update of the behavioral response criteria for the U.S. Navy's environmental analyses.

Southall *et al.,* (2007), and more recently Southall *et al.,* (2019), synthesized data from many past behavioral studies and observations to determine the likelihood of behavioral reactions at specific sound levels. While in general, the louder the sound source the more intense the behavioral response, it was clear that the proximity of a sound source and the animal's experience, motivation, and conditioning were also critical factors influencing the response (Southall *et al.,* 2007; Southall *et al.,* 2019). After examining all of the available data, the authors felt that the derivation of thresholds for behavioral response based solely on exposure level was not supported because context of the animal at the time of sound exposure was an important factor in estimating response. Nonetheless, in some conditions, consistent avoidance reactions were noted at higher sound levels depending on the marine mammal species or group allowing conclusions to be drawn. Phocid seals demonstrated avoidance reactions at or below 190 dB re 1 μPa at 1m; thus, seals may actually receive levels adequate to produce TTS before avoiding the source.

Odontocete behavioral criteria for non-impulsive sources were updated based on controlled exposure studies for dolphins and sea mammals, sonar, and safety (3S) studies where odontocete behavioral responses were reported after exposure to sonar (Antunes *et al.,* 2014; Houser *et al.,* 2013b); Miller *et al.,* 2011; Miller *et al.,* 2014; Miller *et al.,* 2012). For the 3S study, the sonar outputs included 1–2 kilohertz (kHz) up- and down-sweeps and 6–7 kHz up-sweeps; source levels were ramped up from 152–158 dB re 1 μPa to a maximum of 198–214 re 1 μPa at 1 meter (m). Sonar signals were ramped up over several pings while the vessel approached the mammals. The study did include some control passes of ships with the sonar off to discern the behavioral responses of the mammals to vessel presence alone versus active sonar.

The controlled exposure studies included exposing the Navy's trained bottlenose dolphins to mid-frequency sonar while they were in a pen. Mid-frequency sonar was played at 6 different exposure levels from 125–185 dB re 1 μPa (rms). The behavioral response function for odontocetes resulting from the studies described above has a 50 percent probability of response at 157 dB re 1 μPa. Additionally, distance cutoffs (20 km for mid-frequency (MF) cetaceans) were applied to exclude exposures beyond which the potential of significant behavioral responses is considered to be unlikely.

The pinniped behavioral threshold was updated based on controlled exposure experiments on the following captive animals: Hooded seal, gray seal (*Halichoerus grypus*), and California sea lion (Götz *et al.,* 2010; Houser *et al.,* 2013a; Kvadsheim *et al.,* 2010). Hooded seals were exposed to increasing levels of sonar until an avoidance response was observed, while the grey seals were exposed first to a single received level multiple times, then an increasing received level. Each individual California sea lion was exposed to the same received level ten times. These exposure sessions were combined into a single response value, with an overall response assumed if an animal responded in any single session. The resulting behavioral response function for pinnipeds has a 50 percent probability of response at 166 dB re 1 μPa. Additionally, distance cutoffs (10 km for pinnipeds) were applied to exclude exposures beyond which the potential of significant behavioral responses is considered to be unlikely.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). ONR's activities involve only non-impulsive sources.

These thresholds are provided in Table 3 below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6:* $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10:* $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 µPa, and cumulative sound exposure level (L_E) has a reference value of 1µPa²s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Quantitative Modeling

The Navy performed a quantitative analysis to estimate the number of marine mammals that could be exposed to underwater acoustic transmissions above the previously described threshold criteria during ONR's action. Inputs to the quantitative analysis included marine mammal density estimates obtained from the Navy Marine Species Density Database, marine mammal depth occurrence distributions (U.S. Department of the Navy, 2017b), oceanographic and environmental data, marine mammal hearing data, and criteria and thresholds for levels of potential effects. The quantitative analysis consists of computer modeled estimates and a post-model analysis to determine the number of potential animal exposures. The model calculates sound energy propagation from the non-impulsive acoustic sources, the sound received by animat (virtual animal) dosimeters representing marine mammals distributed in the area around the modeled activity, and whether the sound received by animats exceeds the thresholds for effects.

The Navy developed a set of software tools and compiled data for estimating acoustic effects on marine mammals without consideration of behavioral avoidance or mitigation. These tools and data sets serve as integral components of NAEMO. In NAEMO, animats are distributed non-uniformly based on species-specific density, depth distribution, and group size information and animats record energy received at their location in the water column. A fully three-dimensional environment is used for calculating sound propagation and animat exposure in NAEMO. Site-specific bathymetry, sound speed profiles, wind speed, and bottom properties are incorporated into the propagation modeling process. NAEMO calculates the likely propagation for various levels of energy (sound or pressure) resulting from each source used during the training event.

NAEMO then records the energy received by each animat within the energy footprint of the event and calculates the number of animats having received levels of energy exposures that fall within defined impact thresholds. Predicted effects on the animats within a scenario are then tallied and the highest order effect (based on severity of criteria; *e.g.,* PTS over TTS) predicted for a given animat is assumed. Each scenario, or each 24-hour period for scenarios lasting greater than 24 hours is independent of all others, and therefore, the same individual marine mammal (as represented by an animat in the model environment) could be impacted during each independent scenario or 24-hour period. In few instances, although the activities themselves all occur within the study location, sound may propagate beyond the boundary of the study area. Any exposures occurring outside the boundary of the study area are counted as if they occurred within the study area boundary. NAEMO provides the initial estimated impacts on marine species with a static horizontal distribution (*i.e.,* animats in the model environment do not move horizontally).

There are limitations to the data used in the acoustic effects model, and the results must be interpreted within this context. While the best available data and appropriate input assumptions have been used in the modeling, when there is a lack of definitive data to support an aspect of the modeling, conservative modeling assumptions have been chosen (*i.e.,* assumptions that may result in an overestimate of acoustic exposures):

- Animats are modeled as being underwater, stationary, and facing the source and therefore always predicted to receive the maximum potential sound level at a given location (*i.e.,* no porpoising or pinnipeds' heads above water);
- Animats do not move horizontally (but change their position vertically within the water column), which may overestimate physiological effects such as hearing loss, especially for slow moving or stationary sound sources in the model;
- Animats are stationary horizontally and therefore do not avoid the sound source, unlike in the wild where animals would most often avoid exposures at higher sound levels, especially those exposures that may result in PTS;
- Multiple exposures within any 24-hour period are considered one continuous exposure for the purposes of calculating potential threshold shift, because there are not sufficient data to estimate a hearing recovery function for the time between exposures; and
- Mitigation measures were not considered in the model. In reality, sound-producing activities would be reduced, stopped, or delayed if marine mammals are detected by visual monitoring.

Because of these inherent model limitations and simplifications, model-estimated results should be further analyzed, considering such factors as the range to specific effects, avoidance, and the likelihood of successfully implementing mitigation measures. This analysis uses a number of factors in addition to the acoustic model results to

predict acoustic effects on marine mammals.

For the other non-impulsive sources, NAEMO calculates the SPL and SEL for each active emission during an event. This is done by taking the following factors into account over the propagation paths: Bathymetric relief and bottom types, sound speed, and attenuation contributors such as absorption, bottom loss, and surface loss. Platforms such as a ship using one or more sound sources are modeled in accordance with relevant vehicle dynamics and time durations by moving them across an area whose size is representative of the testing event's operational area.

Table 4 provides range to effects for noise produced through use of the acoustic sources to mid-frequency cetacean and pinniped-specific criteria. Range to effects is important information in predicting non-impulsive acoustic impacts. Therefore, the ranges in Table 4 provide realistic maximum distances over which the specific effects from the use of non-impulsive sources during ONR's action will be possible.

TABLE 4—RANGE TO PTS, TTS, AND BEHAVIORAL EFFECTS IN THE PROJECT AREA BASED ON CUTOFF DISTANCES FOR NON-IMPULSIVE ACOUSTIC SOURCES

Source type	Range to behavioral effects (meters)		Range to TTS effects (meters) [c]		Range to PTS effects (meters) [c]	
	MF cetacean	Pinniped	MF cetacean	Pinniped	MF cetacean	Pinniped
On-site drifting sources [b]	[a] 10,000	[a] 10,000	0	0	0	0
Fixed sources	[a] 20,000	[a] 5,000	0	0	0	0

[a] Cutoff distance applied (U.S. Department of the Navy, 2017a).
[b] Assessed under the assumption that some of the on-site drifting sources would become closer together.
[c] No effect (and therefore, no distance from source) is anticipated based on the NAEMO modeling.

A behavioral response study conducted on and around the Navy range in Southern California (SOCAL BRS) observed reactions to sonar and similar sound sources by several marine mammal species, including Risso's dolphins (*Grampus griseus*), a mid-frequency cetacean (DeRuiter *et al.,* 2013; Goldbogen *et al.,* 2013; Southall *et al.,* 2011; Southall *et al.,* 2012; Southall *et al.,* 2013). In a preliminary analysis, none of the Risso's dolphins exposed to simulated or real mid-frequency sonar demonstrated any overt or obvious responses (Southall *et al.,* 2012, Southall *et al.,* 2013). In general, although the responses to the simulated sonar were varied across individuals and species, none of the animals exposed to real Navy sonar responded; these exposures occurred at distances beyond 10 km, and were up to 100 km away (DeRuiter *et al.,* 2013). These data suggest that most odontocetes (not including beaked whales (Family *Ziphiidae*) and harbor porpoises (*Phocoena phocoena*)) likely do not exhibit significant behavioral reactions to sonar and other transducers beyond approximately 10 km. Therefore, the Navy uses a cutoff distance for odontocetes of 10 km for moderate source level, single platform training, and testing events, and 20 km for all other events, including ONR's action (U.S. Department of the Navy, 2017a). NMFS has adopted this approach in support of this final IHA.

Southall *et al.,* (2007) reported that pinnipeds do not exhibit strong reactions to SPLs up to 140 dB re 1 µPa from non-impulsive sources. While there are limited data on pinniped behavioral responses beyond about 3 km in the water, the Navy used a distance cutoff of 2.7 nm (5 km) for moderate source level, single platform training and testing events, and 5.4 nm (10 km) for all other events, including the Arctic Research Activities (U.S. Department of the Navy, 2017a).

Regardless of the received level at the cutoff distances described above, take is not estimated to occur beyond 10 and 20 km from the source for pinnipeds and cetaceans, respectively. No instances of PTS were modeled for any species or stock; as such, no take by Level A harassment is anticipated or is authorized. Further information on cutoff distances can be found in Section 6.5.1 in ONR's 2021–2022 IHA application on NMFS' website: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

The marine mammal density numbers utilized for quantitative modeling are from the Navy Marine Species Density Database (U.S. Department of the Navy, 2014). Density estimates are based on habitat-based modeling by Kaschner *et al.,* (2006) and Kaschner (2004). While density estimates for the two stocks of beluga whales are equal (Kaschner *et al.,* 2006; Kaschner 2004), take has been apportioned to each stock proportional to the abundance of each stock. Table 5 shows the exposures expected for the beluga whale and ringed seal based on NAEMO modeled results.

TABLE 5—QUANTITATIVE MODELING RESULTS OF POTENTIAL EXPOSURES

Species	Density (animals/km^2)	Level B harassment (behavioral)	Level B harassment (TTS)	Total take	Percentage of stock taken [1]
Cetacean (odontocete)					
Beluga Whale (Beaufort Sea stock) [1]	0.0087	375	0	375	0.96
Beluga Whale (Chukchi Sea stock) [1]	.....	125	0	125	0.94

TABLE 5—QUANTITATIVE MODELING RESULTS OF POTENTIAL EXPOSURES—Continued

Species	Density (animals/km^2)	Level B harassment (behavioral)	Level B harassment (TTS)	Total take	Percentage of stock taken [1]
Pinniped (phocid)					
Ringed Seal	0.3958	6,050	0	6,050	3.53

[1] Acoustic exposures to beluga whales were not modeled at the stock level. Take of beluga whales in each stock was based on the proportion of each stock in relation to the total number of beluga whales. Therefore, 75 percent of the calculated take was apportioned to the Beaufort Sea stock, and 25 percent of the calculated take was apportioned to the Eastern Chukchi Sea stock.

Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses. NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)). The NDAA for FY 2004 amended the MMPA as it relates to military readiness activities and the incidental take authorization process such that ''least practicable impact'' shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Mitigation for Marine Mammals and Their Habitat

Ships operated by or for the Navy have personnel assigned to stand watch at all times, day and night, when moving through the water. While in transit, ships must use extreme caution and proceed at a safe speed (1–3 knots in ice; <10 knots in open ice-free waters) such that the ship can take proper and effective action to avoid a collision with any marine mammal and can be stopped within a distance appropriate to the prevailing circumstances and conditions.

While underway, the ships (including non-Navy ships operating on behalf of the Navy) utilizing active acoustics and towed in-water devices will have at least one watch person during activities. While underway, watch personnel must be alert at all times and have access to binoculars.

During mooring or UUV deployment, visual observation will start 15 minutes prior to and continue throughout the deployment within an exclusion zone of 180 feet (ft; 55 m, roughly one ship length) around the deployed mooring. Deployment will stop if a marine mammal is visually detected within the exclusion zone. Deployment will re-commence if any one of the following conditions are met: (1) The animal is observed exiting the exclusion zone, (2) the animal is thought to have exited the exclusion zone based on its course and speed, or (3) the exclusion zone has been clear from any additional sightings for a period of 15 minutes for pinnipeds and 30 minutes for cetaceans.

Ships will avoid approaching marine mammals head-on and will maneuver to maintain an exclusion zone of 500 yards (yd; 457 m) around observed whales, and 200 ft (183 m) around all other marine mammals, provided it is safe to do so in ice-free waters.

All personnel conducting on-ice experiments, as well as all aircraft operating in the study area, are required to maintain a separation distance of 1,000 ft (305 m) from any observed marine mammal.

These requirements do not apply if a vessel's safety is at risk, such as when a change of course would create an imminent and serious threat to safety, person, vessel, or aircraft, and to the extent that vessels are restricted in their ability to maneuver. No further action is necessary if a marine mammal other than a whale continues to approach the vessel after there has already been one maneuver and/or speed change to avoid the animal. Avoidance measures should continue for any observed whale in order to maintain an exclusion zone of 500 yd (457 m).

Based on our evaluation of the Navy's measures, NMFS has determined that the mitigation measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for subsistence uses.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the action area. Effective reporting is critical, both to compliance as well as to ensure that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS

should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density).
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas).
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors.
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks.
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat).
- Mitigation and monitoring effectiveness.

While underway, the ships (including non-Navy ships operating on behalf of the Navy) utilizing active acoustics will have at least one watch person during activities. Watch personnel undertake extensive training in accordance with the U.S. Navy Lookout Training Handbook or civilian equivalent, including on the job instruction and a formal Personal Qualification Standard program (or equivalent program for supporting contractors or civilians), to certify that they have demonstrated all necessary skills (such as detection and reporting of floating or partially submerged objects). Additionally, watch personnel have taken the Navy's Marine Species Awareness Training. Their duties may be performed in conjunction with other job responsibilities, such as navigating the ship or supervising other personnel. While on watch, personnel employ visual search techniques, including the use of binoculars, using a scanning method in accordance with the U.S. Navy Lookout Training Handbook or civilian equivalent. A primary duty of watch personnel is to detect and report all objects and disturbances sighted in the water that may be indicative of a threat to the ship and its crew, such as debris, or surface disturbance. Per safety requirements, watch personnel also report any marine mammals sighted that have the potential to be in the direct path of the ship as a standard collision avoidance procedure.

The U.S. Navy has coordinated with NMFS to develop an overarching program plan in which specific monitoring will occur. This plan is called the Integrated Comprehensive Monitoring Program (ICMP) (U.S. Department of the Navy, 2011). The ICMP has been developed in direct response to Navy permitting requirements established through various environmental compliance efforts. As a framework document, the ICMP applies by regulation to those activities on ranges and operating areas for which the Navy is seeking or has sought incidental take authorizations. The ICMP is intended to coordinate monitoring efforts across all regions and to allocate the most appropriate level and type of effort based on a set of standardized research goals, and in acknowledgement of regional scientific value and resource availability.

The ICMP is focused on Navy training and testing ranges where the majority of Navy activities occur regularly as those areas have the greatest potential for being impacted. ONR's Arctic Research Activities in comparison is a less intensive test with little human activity present in the Arctic. Human presence is limited to a minimal amount of days for source operations and source deployments, in contrast to the large majority (greater than 95 percent) of time that the sources will be left behind and operate autonomously. Therefore, a dedicated monitoring project is not warranted. However, ONR will record all observations of marine mammals, including the marine mammal's location (latitude and longitude), behavior, and distance from project activities.

The Navy is committed to documenting and reporting relevant aspects of research and testing activities to verify implementation of mitigation, comply with permits, and improve future environmental assessments. If any injury or death of a marine mammal is observed during the 2021–2022 Arctic Research Activities, the Navy will immediately halt the activity and report the incident to the Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinator, NMFS. The following information must be provided:

- Time, date, and location of the discovery;
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal(s) was discovered (*e.g.,* deployment of moored or drifting sources, during on-ice experiments, or by transiting vessel).

ONR will provide NMFS with a draft exercise monitoring report within 90 days of the conclusion of the activity. The draft exercise monitoring report will include data regarding acoustic source use and any mammal sightings or detection will be documented. The report will include the estimated number of marine mammals taken during the activity. The report will also include information on the number of shutdowns recorded. If no comments are received from NMFS within 30 days of submission of the draft final report, the draft final report will constitute the final report. If comments are received, a final report must be submitted within 30 days after receipt of comments.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status

of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

Underwater acoustic transmissions associated with the Arctic Research Activities, as outlined previously, have the potential to result in Level B harassment of beluga seals and ringed seals in the form of behavioral disturbances. No serious injury, mortality, or Level A harassment are anticipated to result from these described activities.

Effects on individuals that are taken by Level B harassment could include alteration of dive behavior, alteration of foraging behavior, effects to breathing rates, interference with or alteration of vocalization, avoidance, and flight. More severe behavioral responses are not anticipated due to the localized, intermittent use of active acoustic sources. Most likely, individuals will simply be temporarily displaced by moving away from the acoustic source. As described previously in the behavioral effects section, seals exposed to non-impulsive sources with a received sound pressure level within the range of calculated exposures (142–193 dB re 1 μPa), have been shown to change their behavior by modifying diving activity and avoidance of the sound source (Götz *et al.,* 2010; Kvadsheim *et al.,* 2010). Although a minor change to a behavior may occur as a result of exposure to the sound sources associated with ONR's action, these changes will be within the normal range of behaviors for the animal (*e.g.,* the use of a breathing hole further from the source, rather than one closer to the source, will be within the normal range of behavior). Thus, even repeated Level B harassment of some small subset of the overall stock is unlikely to result in any significant realized decrease in fitness for the affected individuals, and will not result in any adverse impact to the stock as a whole.

The project is not expected to have significant adverse effects on marine mammal habitat. While the activities may cause some fish to leave the area of disturbance, temporarily impacting marine mammals' foraging opportunities, this will encompass a relatively small area of habitat leaving large areas of existing fish and marine mammal foraging habitat unaffected. As such, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No injury, serious injury, or mortality is anticipated or authorized;
- Impacts will be limited to Level B harassment only;
- TTS is not expected or predicted to occur; only temporary behavioral modifications are expected to result from these activities; and
- There will be no permanent or significant loss or modification of marine mammal prey or habitat.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from these activities will have a negligible impact on all affected marine mammal species or stocks.

Unmitigable Adverse Impact Analysis and Determination

Impacts to subsistence uses of marine mammals resulting from the planned action are not anticipated (as described in greater detail in the proposed notice of the IHA (86 FR 47065; August 23, 2021)). The closest active acoustic source (fixed or drifting) within the project site that is likely to cause Level B harassment take is approximately 110 nm (204 km) from land and outside of known subsistence use areas. However, almost all leave-behind sources that will constitute most of the Level B harassment take will be approximately 240 mi (386 km) from shore. In comparison with IHAs issued to ONR for their previous Arctic Research Activities, this project is further north; therefore, there is no spatial overlap between known subsistence harvest sites and the activities contained herein. Furthermore, and as stated above, the range to effects for non-impulsive acoustic sources in this experiment is much smaller than the distance from shore, with acoustic sources that could constitute take being located far away from known subsistence hunting areas. Lastly, the action will not remove individuals from the population.

Based on this information, NMFS has determined that there will be no unmitigable adverse impact on subsistence uses from ONR's planned activities.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally, in this case with the NMFS Alaska Regional Office (AKR), whenever we propose to authorize take for endangered or threatened species.

The AKR issued a Biological Opinion on September 29, 2021, which concluded that ONR's Arctic Research Activities and NMFS's issuance of an IHA for those activities are not likely to jeopardize the continued existence of the Arctic ringed seal or adversely modify any designated critical habitat.

National Environmental Policy Act

In compliance with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), as implemented by the regulations published by the Council on Environmental Quality (CEQ; 40 CFR parts 1500–1508), ONR prepared an Supplemental Overseas Environmental Assessment (SOEA) to consider the direct, indirect, and cumulative effects to the human environment resulting from the Arctic Research Activities. NMFS made ONR's SOEA available to the public for review and comment, concurrently with the publication of the proposed IHA (86 FR 47065; August 23, 2021), on the NMFS website (*https://www.fisheries.noaa.gov/action/incidental-take-authorization-office-naval-research-arctic-research-activities-beaufort-1*), in relation to its suitability for adoption by NMFS in order to assess the impacts to the human environment of issuance of an IHA to ONR. In addition, in compliance with NEPA and the CEQ regulations, as well as NOAA Administrative Order 216–6, NMFS has reviewed ONR's SOEA and determined it to be sufficient. NMFS has subsequently adopted that EA (SOEA) and signed a Finding of No Significant Impact (FONSI) on September 23, 2021.

Authorization

As a result of these determinations, NMFS has issued an IHA to ONR for conducting oceanographic research activities in the Beaufort and eastern Chukchi Seas from October 5, 2021 through October 4, 2022, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: September 30, 2021.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–21672 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB459]

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of one scientific research permit.

SUMMARY: Notice is hereby given that NMFS has issued a scientific research permit (Permit 19571–2R) to the NMFS Southwest Fisheries Science Center in La Jolla, California, under the Endangered Species Act (ESA). The research is intended to increase knowledge of black abalone listed under the ESA and to help guide management, conservation, and recovery efforts.

ADDRESSES: The permit and related documents are available for review upon written request via email to *nmfs.wcr-apps@noaa.gov* (please include the permit number in the subject line of the email).

FOR FURTHER INFORMATION CONTACT: Susan Wang, Long Beach, California, phone: 562–980–4199, email: *Susan.Wang@noaa.gov.*

SUPPLEMENTARY INFORMATION: Notice was published in the **Federal Register** on February 16, 2021, that a request for a permit renewal had been submitted by NMFS's Southwest Fisheries Science Center. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the research, go to *www.federalregister.gov* and search on the permit number and **Federal Register** notice information provided in the table below.

TABLE 1—ISSUED PERMITS

Permit No.	RTID	Applicant	Previous **Federal Register** notice	Issuance date
19571–2R	0648–XA872 ..	NMFS Southwest Fisheries Science Center—8901 La Jolla Shores Drive, La Jolla, CA 92037 (Responsible Party: Kristen Koch).	86 FR 9489; February 16, 2021.	September 16, 2021.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Authority

Scientific research permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR parts 222–226). NMFS issues permits based on finding that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Dated: September 30, 2021.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–21714 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB460]

Marine Mammals; File No. 25794

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Jennifer Burns, Ph.D., Texas Tech University, Biology Department, 2901 Main Street Lubbock, TX 79409–3131 has applied in due form for a permit to import and export specimens of gray seals (*Halichoerus grypus*) for scientific research.

DATES: Written, telefaxed, or email comments must be received on or before November 4, 2021.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 25794 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 25794 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Sara Young, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to import and export of parts collected from gray seals at Sable Island, Nova Scotia for the purpose of studying the role of maternal iron transfer in the development of heme stores and aerobic diving capacity in gray seal pups. Samples will be imported and exported from up to 35 males, 51 females and 16 pups (of either sex) per year. In addition, the applicant is proposing to opportunistically import and export of samples from 100 gray seals from Canada DFO archives and organs opportunistically salvaged from up to 20 deceased gray seals in Canada. Samples would include blood, milk, whiskers, nails, fur, blubber, muscle, scat, spew, saliva, and urine. Samples

will be imported from Canada through Houston/Dallas (Texas Tech University), Boston (Woods Hole), or Los Angeles/Seattle/Anchorage (University of Alaska Fairbanks). Samples may also be re-exported back to Canada. A permit is requested for a duration of five years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: September 30, 2021.

Benjamin Laws,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–21647 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB442]

Caribbean Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Caribbean Fishery Management Council's (Council) District Advisory Panels (DAPs) will hold public virtual meetings to address the items contained in the tentative agenda included in the **SUPPLEMENTARY INFORMATION**.

DATES: The DAPs public virtual meetings will be held as follows: St. Thomas/St. John DAP, October 26, 2021, from 9 a.m. to 5 p.m.; and Puerto Rico DAP, October 27, 2021, from 10 a.m. to 5 p.m. All meetings will be at Atlantic Standard Time (AST).

ADDRESSES: You may join the DAPs public virtual meetings (via Zoom) from a computer, tablet or smartphone by entering the following addresses:

DAP–STT/STJ

Join Zoom Meeting
https://us02web.zoom.us/j/86262657165?pwd=aGQ4U25rME92d1p1TWo4d3Y3RGFrdz09
Meeting ID: 862 6265 7165
Passcode: 901759
One tap mobile
+17879451488,,86262657165#,,,,*901759# Puerto Rico
+17879667727,,86262657165#,,,,*901759# Puerto Rico
Dial by your location
+1 787 945 1488 Puerto Rico
+1 787 966 7727 Puerto Rico
+1 939 945 0244 Puerto Rico
Meeting ID: 862 6265 7165
Passcode: 901759

DAP–PR

Join Zoom Meeting
https://us02web.zoom.us/j/86222659918?pwd=UitRcnBJRXQyMUpWaEtISEZ6elVvQT09
Meeting ID: 862 2265 9918
Passcode: 623876
One tap mobile
+19399450244,,86222659918#,,,,*623876# Puerto Rico
+17879451488,,86222659918#,,,,*623876# Puerto Rico
Dial by your location
+1 939 945 0244 Puerto Rico
+1 787 945 1488 Puerto Rico
+1 787 966 7727 Puerto Rico
Meeting ID: 862 2265 9918
Passcode: 623876

FOR FURTHER INFORMATION CONTACT: Miguel Rolón, Executive Director, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918–1903; telephone: (787) 398–3717.

SUPPLEMENTARY INFORMATION: The items included in the tentative agenda are:

Call to Order
Roll Call
Adoption of Agenda
Discussion of Possible Compatible Regulations between Federal and Local Governments for the Island-Based Fishery Management Plans
Other Business

All meetings will be discussing the same agenda items.

Other than the starting date and time, the order of business may be adjusted as necessary to accommodate the completion of agenda items, at the discretion of the Chair. The meetings will begin on October 26, 2021 at 9 a.m. AST, and will end on October 27, 2021, at 5 p.m. AST.

Special Accommodations

Simultaneous interpretation will be provided for the DAP–PR, on October 27, 2021.

For simultaneous interpretation English-Spanish-English follow your Zoom screen instructions. You will be asked which language you prefer when you join the meeting.

For any additional information on this public virtual meeting, please contact Diana Martino, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918–1903, telephone: (787) 226–8849.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 30, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21734 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; NOAA Coastal Ocean Program Grants Proposal Application Package

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Revised Notice of Information Collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for an additional 30 days of public comment preceding submission of the collection to OMB. A 60-day notice of request for comment on the extension of this collection was published in the **Federal Register** on June 8, 2021. This additional notice alerts the public that NOAA intends to revise the information.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before December 6, 2021.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *Adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0384 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or

specific questions related to collection activities should be directed to Laurie Golden, Grants Administrator, 240–533–0285 or *laurie.golden@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a revision and extension of a currently approved information collection. The National Oceanic and Atmospheric Administration's Coastal Ocean Program (COP), now known as the Competitive Research Program (CRP) under the National Centers for Coastal Ocean Science, provides direct financial assistance through grants and cooperative agreements for research supporting the management of coastal ecosystems and the NOAA RESTORE Science Program (RSP). The statutory authority for COP is Public Law 102–567 Section 201 (Coastal Ocean Program). NOAA was authorized to establish and administer the Restore Science Program, in consultation with the U.S. Fish and Wildlife Service, by the Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies (RESTORE) of the Gulf States Act of 2012 (Pub. L. 112–141, Section 1604). Identified in the RESTORE Act as the Gulf Coast Ecosystem restoration Science, Observation, Monitoring, and Technology Program, the Program is commonly known as the NOAA RESTORE Science Program. In addition to standard government application requirements, applicants for financial assistance are required to submit a project summary form, current and pending form, and a key contacts form for both programs. CRP recipients are required to file annual progress reports and a project final report using CRP formats. The RSP are required to file semi-annual progress reports, a final report, and a Gantt chart showing project milestones using RSP formats. All of these requirements are needed for better evaluation of proposals and monitoring of awards.

Several revisions are being requested for this information collection. The approved annual and final reports for CRP will be revised to include the request for publication digital object identifiers (DOIs). The RSP semi-annual and final reports will be revised to include end-user details. Finally, the Current and Pending Support form is being updated to require applicants disclose all sources of current and pending research support, contractual or otherwise, direct and indirect, including current and pending private and public sources of funding or income, both foreign and domestic. Other support should include all resources made available to a Covered Person in support of and/or related to all of their professional research and development efforts, including resources provided directly to the Covered Person rather than through the research institution, and regardless of whether they have monetary value (*e.g.,* even if the support received is only in-kind, such as office/laboratory space, equipment, supplies, or employees). This should include resource and/or financial support from all foreign and domestic entities, including but not limited to, gifts provided with terms or conditions, financial support for laboratory personnel, and participation of student and visiting researchers supported by other sources of funding.

II. Method of Collection

Respondents have a choice of either electronic or paper forms.

III. Data

OMB Control Number: 0648–0384.

Form Number: None.

Type of Review: Regular submission (revision/extension of a currently approved collection).

Affected Public: Non-profit institutions; State, local, or tribal government; business or other for-profit organizations.

Estimated Number of Respondents: 1,200.

Estimated Time per Response: 30 minutes each for a project summary, key contacts and current and pending federal support; 6 hours for a semi-annual report; 6 hours for an annual report, 10.5 hours for a CRP final report, 10.5 hours for the RSP final report; and 1 hour for the milestone Gantt chart.

Estimated Total Annual Burden Hours: 1,875.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

Respondent's Obligation: Mandatory.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–21645 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–JS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB488]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council's is convening its Scientific and Statistical Committee (SSC) via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Monday, October 25, 2021, beginning at 9 a.m. Webinar registration information: *https://attendee.gotowebinar.com/register/7720008007096709389.*

Call in information: +1 (562) 247–8422, Access Code: 206–777–773.

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Scientific and Statistical Committee will meet to review recent stock assessment information from the 2021 Groundfish Management Track Assessments and information provided by the Council's Groundfish Plan Development Team (PDT), and recommend the overfishing limits and acceptable biological catch (ABC) for Georges Bank (GB) cod, and Gulf of Maine (GOM) cod for fishing years 2022–24. They will review information presented by the Groundfish PDT and consider recommending revised OFLs/ABCs for GB haddock and GOM haddock for fishing year 2022. Also on the agenda is to review information presented by the Groundfish PDT and consider recommending revised OFLs/ABCs for white hake under the recently implemented rebuilding plan for this stock. They will consider other business as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: September 30, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21736 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB479]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Long Beach Cruise Terminal Improvement Project in the Port of Long Beach, California

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of incidental harassment authorization.

SUMMARY: NMFS has received a request from the Carnival Corporation & PLC (Carnival) for the re-issuance of a previously issued incidental harassment authorization (IHA) with the only change being effective dates. The initial IHA authorized take of five species of marine mammals, by Level A and Level B harassment, incidental to construction associated with the Port of Long Beach Cruise Terminal Improvement Project in Port of Long Beach, California. The project has been delayed and none of the work covered in the initial IHA has been conducted. The initial IHA was effective from November 19, 2019, through November 18, 2020, and was re-issued with new effective dates of December 10, 2020 through December 9, 2021. The scope of the activities and anticipated effects remain the same, authorized take numbers are not changed, and the required mitigation, monitoring, and reporting remains the same as included in the initial IHA. NMFS is, therefore, issuing a third identical IHA to cover the incidental take analyzed and authorized in the initial IHA.

DATES: This authorization is effective from December 10, 2021, through December 9, 2022.

ADDRESSES: An electronic copy of the final 2019 IHA previously issued to Carnival, Carnival's application, and the **Federal Register** notices proposing and issuing the initial IHA may be obtained by visiting *https://www.fisheries.noaa.gov/action/incidental-take-authorization-cruise-terminal-improvement-project-port-long-beach-ca.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the Marine Mammal Protection Act (MMPA; 16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On November 25, 2019, NMFS published final notice of our issuance of an IHA authorizing take of marine mammals incidental to the Port of Long Beach Cruise Terminal Improvement Project (84 FR 64833). The effective dates of that IHA were November 19, 2019 through November 18, 2020. On November 24, 2020, Carnival informed NMFS that the project was delayed. Carnival submitted a request that we reissue an identical IHA that would be effective from December 10, 2020

through December 9, 2021, in order to conduct the construction work that was analyzed and for which take was authorized in the previously issued IHA. That IHA was issued on December 9, 2020. On September 20, 2021, Carnival notified NMFS that the project had remained delayed due to COVID–19 impacts, and requested that we re-issue an identical IHA, with effective dates from December 10, 2021 through December 9, 2022. None of the pile driving considered in the initial IHA has occurred. Therefore, reissuance of the IHA is appropriate.

Summary of Specified Activity and Anticipated Impacts

The planned activities (including mitigation, monitoring, and reporting), authorized incidental take, and anticipated impacts on the affected stocks are the same as those analyzed and authorized through the previously issued IHA.

The purpose of Carnival's project is to make improvements to its existing berthing facilities at the Long Beach Cruise Terminal in order to accommodate a new, larger class of cruise ships. Implementation of the project requires pile driving to install two high-capacity mooring dolphins, fenders, and a new passenger bridge system, and dredging at the existing berth and the immediate surrounding area. The location, timing, and nature of the activities, including the types of equipment planned for use, are identical to those described in the initial IHA. The mitigation, monitoring, and reporting measures are also identical to those prescribed in the initial IHA.

Species that are expected to be taken by the specified activity include short-beaked common dolphin (*Delphinus delphis*), long-beaked common dolphin (*Delphinus capensis*), bottlenose dolphin (*Tursiops truncatus*), California sea lion (*Zalophus californianus*) and harbor seal (*Phoca vitulina*). A description of the methods and inputs used to estimate take anticipated to occur and, ultimately, the take that was authorized is found in the previous documents referenced above. The data inputs and methods of estimating take are identical to those used in the initial IHA. NMFS has reviewed recent Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature, and determined that no new information affects our original analysis of impacts or take estimate under the initial IHA.

Determinations

Carnival will conduct activities as analyzed in the initial 2019 IHA. As described above, the number of authorized takes of the same species and stocks of marine mammals are identical to the numbers that were found to meet the negligible impact and small numbers standards and authorized under the initial IHA and no new information has emerged that would change those findings. The re-issued 2021 IHA includes identical required mitigation, monitoring, and reporting measures as the initial IHA, and there is no new information suggesting that our analysis or findings should change.

Based on the information contained here and in the referenced documents, NMFS has determined the following: (1) The required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; and (4) Carnival's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action with respect to environmental consequences on the human environment.

Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review. This action is consistent with categories of activities identified in CE B4 of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Because the only change to the IHA are effective dates, the CE on record for issuance of the initial IHA applies to this action.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

However, no incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Authorization

NMFS has issued an IHA to Carnival for in-water construction activities associated with the specified activity from December 10, 2021 through December 9, 2022. All previously described mitigation, monitoring, and reporting requirements from the initial 2019 IHA are incorporated.

Dated: September 30, 2021.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–21717 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB487]

Endangered and Threatened Species; Announcement of Workshop To Inform Recovery Planning for ESA Listed Rice's Whale (Balaenoptera Ricei)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: We, NMFS, are convening a workshop to solicit information from experts to inform recovery planning for Rice's whale (*Balaenoptera ricei*) under section 4(f) of the Endangered Species Act (ESA). This workshop will be open to the public.

DATES: *Workshop dates and information:* We will hold the recovery planning workshop for the Rice's whale virtually over the course of 5 sessions in October and November 2021.

- Monday, October 18, 11 a.m.–4 p.m. Eastern Daylight Savings Time (EDT)
- Monday, November 1, 12 p.m.–4 p.m. EDT
- Wednesday, November 10, 12 p.m.–4 p.m. Eastern Standard Time (EST)
- Tuesday, November 16, 12 p.m.–4 p.m. EST
- Thursday, November 18, 12 p.m.–4 p.m. EST

ADDRESSES: If you plan to attend the workshop as an interested member of the public, please register for each session that you would like to observe:

- *Session 1: ttps://bit.ly/RIWH-Wkshp1-Oct18-RSVP*
- *Session 2: https://bit.ly/RIWH-Wkshp2-Nov1-RSVP*
- *Session 3: https://bit.ly/RIWH-Wkshp3-Nov10-RSVP*
- *Session 4: https://bit.ly/RIWH-Wkshp4-Nov16-RSVP*
- *Session 5: https://bit.ly/RIWH-Wkshp5-Nov18-RSVP*

FOR FURTHER INFORMATION CONTACT: Barb Zoodsma, (727) 824–5312, NMFS Southeast Regional Office (SERO), Protected Resources Division, *Barb.Zoodsma@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On April 15, 2019, we published a final rule listing the Gulf of Mexico Bryde's whale (*Balaenoptera edeni*; a subspecies of Bryde's whales) as endangered under the Endangered Species Act (ESA) (84 FR 15446). In 2021, a published study in a peer-reviewed journal (Rosel *et al.,* 2021) provided evidence for and described the individuals referred to as the Gulf of Mexico Bryde's whales as an entirely new species (not just subspecies) of baleen whale. The new species is described as the Rice's whale (*Balaenoptera ricei*). Consequently, on August 23, 2021, we published a direct final rule to update the taxonomic classification, description, and common name of species included in the list of endangered species maintained at 50 CFR 224.101 to reflect the updated science (86 FR 47022). The direct final rule changes the common name of the listed entity from Bryde's whale (Gulf of Mexico subspecies) to Rice's whale, the scientific name from *B. edeni* (unnamed subspecies) to *B. ricei,* and the description of the listed entity from Bryde's whales that breed and feed in the Gulf of Mexico to the entire species. The direct final rule and these changes will be effective on October 22, 2021. The direct final rule ensures that the list of endangered species reflects the best available scientific information. Although the changes to the enumeration of listed species are not yet effective, we are referring to the species using the updated scientific understanding. Therefore, this rule will refer to the individuals as Rice's whale or *B. ricei,* as appropriate. The species' status and legal protections under the ESA remain the same despite the forthcoming changes.

The final listing rule (84 FR 15446; April 15, 2019) describes the background of the listing action for this species and provides a summary of our conclusions regarding its status. For additional background and information about this species, the reader is referred to the status review report, final listing rule, and our species web pages (available at *https://www.fisheries.noaa.gov/species/rices-whale*).

NMFS is required by section 4(f) of the ESA to develop and implement recovery plans for the conservation and survival of federally-listed species unless the Secretary finds that such a plan will not promote the conservation of the species. Recovery means that the status of a listed species has improved to the point at which the protections of the ESA are no longer necessary. The ESA specifies that recovery plans are to include (1) a description of site-specific management actions necessary to achieve the plan's goal for the conservation and survival of the species; (2) objective, measurable criteria which, when met, would result in the species being removed from the list; and (3) estimates of the time and costs required to carry out the actions needed to achieve the plan's conservation and survival goal and to achieve intermediate steps toward that goal. Under section 4(f) of the ESA, public notice and an opportunity for public review and comment also are provided during recovery plan development.

This notice serves as a public notice and opportunity for public attendance in the recovery workshop. Once a recovery plan has been drafted, it will be announced in the **Federal Register** and available on our website for public review and comment before being finalized.

Recovery Planning Workshop Announcement

NMFS will hold a virtual workshop in five sessions to help inform our recovery planning for Rice's whale. The first session will be held on Monday, October 18, 2021, and the last session will be held Thursday, November 18, 2021 (see **DATES** section). We invited experts and stakeholders in specific topic areas, including the species' biology and ecology, threats to the species and the species' habitat, the recovery planning process itself, and cetacean conservation and management. These experts and stakeholders will help us identify potential actions to address the threats to the species, identify gaps in knowledge and associated research needs, as well as begin developing recovery criteria for the species. Identified experts and stakeholders include representatives of Federal and State agencies, scientific experts, individuals from industry, and individuals from conservation partners and nongovernmental organizations.

NMFS has contracted a facilitator to manage the workshop as well as note takers to document input received. We are seeking information; we will not be asking for consensus recommendations on how to recover the Rice's whale species. A summary of the workshop will be prepared, noting the main points raised by the participants.

This workshop will be open to the public, and a public comment period will be provided at the end of each session. If you plan to attend the workshop as an interested member of the public, please register via the website addresses listed in the **ADDRESSES** section, so we can ensure sufficient online connectivity for participants and interested parties during our logistics planning.

Schedule of Workshops

- *Session 1: Workshop Series Kick-Off*—October 18—Session 1 will focus on general background and orientation to Rice's whale recovery process
- *Session 2: Entanglement, Prey, and Climate Change*—November 1—Session 2 will focus on entanglement, prey, and climate change
- *Session 3: Marine Debris and Environmental Pollutants*—November 10—Session 3 will focus on marine debris and environmental pollutants (oil spills, contaminants and disease)
- *Session 4: Anthropogenic Noise and Acoustic Habitat, Vessel Strikes, Marine Structures*—November 16—Session 4 will focus on anthropogenic noise and acoustic habitat, vessel strikes, and marine structures (offshore renewable energy, sediment diversion and aquaculture)
- *Session 5: Recovery Criteria Discussion*—November 18—Session 5 will focus on bringing workshop takeaways together and deeper dive into recovery criteria

Workshops are accessible to persons with disabilities. Send requests for auxiliary aids at least five business days in advance of the start date of the session to Barb Zoodsma at *Barb.Zoodsma@noaa.gov.*

Authority: 16 U.S.C. 1531 *et seq.*

Dated: September 30, 2021.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–21661 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Technical Information Service

National Technical Information Service Advisory Board

AGENCY: National Technical Information Service, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: This notice announces the next meeting of the National Technical Information Service (NTIS) Advisory Board (the Advisory Board).

DATES: The Advisory Board will meet on Wednesday, October 27, 2021 from 1:00 p.m. to approximately 4:30 p.m., Eastern Time, via teleconference.

ADDRESSES: The Advisory Board meeting will be via teleconference. Please note attendance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Elizabeth Shaw, (703) 605–6136, *eshaw@ntis.gov* or Steven Holland at *sholland@ntis.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Board is established by Section 3704b(c) of Title 15 of the United States Code. The charter has been filed in accordance with the requirements of the Federal Advisory Committee Act, as amended (5 U.S.C. app.). The Advisory Board reviews and makes recommendations to improve NTIS programs, operations, and general policies in support of NTIS' mission to advance Federal data priorities, promote economic growth, and enable operational excellence by providing innovative data services to Federal agencies through joint venture partnerships with the private sector.

The meeting will focus on a review of the progress NTIS has made in implementing its data mission and strategic direction. A final agenda and summary of the proceedings will be posted on the NTIS website as soon as they are available (*https://www.ntis.gov/about/advisorybd/index.xhtml*).

The teleconference will be via controlled access. Members of the public interested in attending via teleconference or speaking are requested to contact Ms. Shaw at the contact information listed in the **FOR FURTHER INFORMATION CONTACT** section above not later than Friday, October 22, 2021. If there are sufficient expressions of interest, up to one-half hour will be reserved for public oral comments during the session. Speakers will be selected on a first-come, first-served basis. Each speaker will be limited to five minutes. Questions from the public will not be considered during this period.

Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend are invited to submit written statements by emailing Ms. Shaw at the email address provided in the **FOR FURTHER INFORMATION CONTACT** section above.

Dated: September 29, 2021.

Gregory Capella,

Director.

[FR Doc. 2021–21576 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–04–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Matters Related to First Inventor To File

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0071 (Matters Relating to First Inventor to File). The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before December 6, 2021.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0071 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Parikha Mehta, Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–3248; or by email to *Parikha.Mehta@uspto.gov* with ''0651–0071 comment'' in the subject line of the message. Additional information about this information collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent System uses a 'first to file' system, as introduced by the Leahy-Smith America Invents Act (AIA) which was enacted into law on September 16, 2011. To determine the first inventor to file, information is needed in order to identify the inventorship and ownership, or obligation to assign ownership, of each claimed invention on its effective filing date. Section 3 of the AIA, *inter alia,* amended 35 U.S.C. 102 and 103 consistent with the objectives of the AIA, including the conversion of the United States patent system from a ''first to invent'' system to a ''first inventor to file'' system. The changes in section 3 of the AIA went into effect on March 16, 2013, but apply only to certain applications filed on or after March 16, 2013.

This information collection covers information required by 37 CFR 1.55(k), 1.78(a)(6), and 1.78(d)(6) to assist the USPTO in determining whether an application is subject to 35 U.S.C. 102 and 103 as amended by Section 3 of the AIA, or 35 U.S.C. 102 and 103, in effect on March 15, 2013.

II. Method of Collection

The items in this information collection may be submitted by mail, facsimile, hand delivery, or via the Patent Electronic Systems (EFS-Web or Patent Center).

III. Data

OMB Control Number: 0651–0071.
Form Number(s): None.
Type of Review: Extension and revision of a currently approved information collection.
Affected Public: Private sector; individuals or households.
Estimated Number of Respondents: 99 respondents per year.
Estimated Number of Responses: 144 responses per year.
Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public 2 hours to complete. This

includes the time to gather the necessary information, create the document, and submit the completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 288 hours.

Estimated Total Annual Respondent Hourly Cost Burden: $115,200.

TABLE 1—TOTAL HOURLY BURDEN FOR PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents	Responses per respondent	Estimated annual responses	Estimated time for response (hours)	Estimated burden (hour/year)	Rate [1] ($/hour)	Estimated annual respondent cost burden
		(a)	(b)	(a) × (b) = (c)	(d)	(c) × (d) = (e)	(f)	(e) × (f) = (g)
1	Submissions Under CFR 1.55(k)	47	1.5	71	2	142	$400	$56,800
2	Submissions Under 37 CFR 1.78(a)(6).	37	1.5	56	2	112	400	44,800
3	Submissions Under 37 CFR 1.78(d)(6).	9	1.5	14	2	28	400	11,200
Total		96		141		282		112,800

[1] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour.

TABLE 2—TOTAL HOURLY BURDEN FOR INDIVIDUALS OR HOUSEHOLDS RESPONDENTS

Item No.	Item	Estimated annual respondents	Responses per respondent	Estimated annual responses	Estimated time for response (hours)	Estimated burden (hour/year)	Rate [2] ($/hour)	Estimated annual respondent cost burden
		(a)	(b)	(a) × (b) = (c)	(d)	(c) × (d) = (e)	(f)	(e) × (f) = (g)
1	Submissions Under CFR 1.55(k)	1	1	1	2	2	$400	$800
2	Submissions Under 37 CFR 1.78(a)(6)	1	1	1	2	2	400	800
3	Submissions Under 37 CFR 1.78(d)(6)	1	1	1	2	2	400	800
Total		3		3		6		2,400

[2] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour.

Estimated Total Annual Respondent (Non-hourly) Cost Burden: $8. There are no capital start-up, filing fees, recordkeeping, or maintenance costs associated with this information collection. However, the information collection may have annual (non-hour) costs in the form of postage costs.

Although the USPTO prefers that the items in this information collection be submitted electronically, responses may be submitted by mail through the United States Postal Service (USPS). The USPTO estimates that 1% of the items will be submitted in the mail resulting in 1 mailed item. The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail 2-day flat rate legal envelope, will be $8.25. Therefore, the USPTO estimates $8 in postage costs associated with this information collection.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility;

(b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, telephone number, email address, or other personal identifying information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, USPTO cannot guarantee that it will be able to do so.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2021–21724 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–16–P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 21.1]

Notice of Prehearing Conference

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: Notice of prehearing conference for *In the Matter of thyssenkrupp Access Corp., Inc.;* CPSC Docket No. 21–1.

DATES: Wednesday, October 20, 2021 at 11:00 a.m. Eastern Time.

ADDRESSES: This event will be held remotely; Call-in Number: 888–370–8496; Passcode: 69953050

FOR FURTHER INFORMATION CONTACT: Alberta E. Mills, Consumer Product Safety Commission, Office of the General Counsel, Division of the

Secretariat, *cpsc-os@cpsc.gov;* 240–863–8938; 301–504–7479.

SUPPLEMENTARY INFORMATION: Issues to be discussed at the conference are the items numbered (1) through (14) in 16 CFR 1025.21(a). The text of the Presiding Officer's September 29, 2021 Order Scheduling Prehearing Conference appears below.

Authority: Consumer Product Safety Act, 15 U.S.C. 2064.

Dated: September 29, 2021.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

United States of America

Consumer Product Safety Commission

In the Matter of thyssenkrupp Access Corp., CPSC Docket No. 21–1
September 29, 2021

Order Scheduling Prehearing Conference

Pursuant to 16 CFR 1025.21, the undersigned Administrative Law Judge hereby schedules a prehearing conference in the above matter. In view of the social distancing precautions necessitated by the ongoing Covid-19 pandemic, the prehearing conference shall be held by telephone as follows:

Date: Wednesday, October 20, 2021.

Time: 11:00 a.m. Eastern Time.

Call-in Number: 888–370–8496; Passcode: 69953050.

In accordance with 16 CFR 1025.21(b), the issues to be addressed at the conference are the items numbered (1) through (14) in 16 CFR 1025.21(a). If the time of the conference is infeasible for any party, that party should promptly file a motion for a continuance. I direct that notice of this conference and a statement of the issues to be discussed shall be published in the **Federal Register** at least ten days in advance of the scheduled date. 16 CFR 1025.21(b)

A ruling on the parties' Joint Motion to Amend Discovery Schedule and for Protective Order will be forthcoming.

So ordered.

Done and dated September 29, 2021
Arlington, VA

/s/
Mary F. Withum,
Administrative Law Judge.

[FR Doc. 2021–21636 Filed 10–4–21; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2021–HQ–0022]

Proposed Collection; Comment Request

AGENCY: Department of the Army, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* Army Survivor Outreach Services announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by December 6, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to United States Army Installation Management Command Headquarters, 2405 Gun Shed Road, Bldg. 2261 JBSA-Fort Sam Houston, TX 78234, ATTN: Mrs. Kelly Frank, or call 210–466–1200.

SUPPLEMENTARY INFORMATION: *Title; Associated Form; and OMB Number:* Survivor Access Card Application Form; OMB Control Number 0702–SACA.

Needs and Uses: In accordance with AR 190–13, The Army Physical Security Program directed access to Army installations by Family members who are Gold Star and Next of Kin Surviving members to receive services, attend events, view memorials, and similar activities. A Gold Star Family member is a Survivor of a Service member who has lost their life during any armed hostilities in which the United States was engaged and authorized to wear the Gold Star Lapel Button. The Next of Kin Family member is a Survivor of a Service member who lost their life while serving on active duty. Both Gold Star and Gold Star Next of Kin include Survivors of Service members who lose their lives while assigned to a reserve or National Guard unit in drill status. Eligible Survivors to receive the Gold Star Lapel Button or Gold Star Next of Kin (NOK) Lapel Button include the following: Widow or widower, parents, each child, stepchild, child through adoption, brother, half–brother, sister, half–sister or step-siblings. Eligible Survivors must first contact the installation level Survivor Outreach Services (SOS) support coordinator to verify eligibility and coordinate issuance of an installation access credential. Current procedures for obtaining a Survivor Access Card (SAC) direct the Survivor Outreach Service Staff members to assist Survivors in completing the application process for the SAC, verifying the Survivor's eligibility, and coordinating with the installation office responsible for issuing cards. The SAC is issued through the installation's Visitor Control Center. The collection instrument, Survivor Access Card Application Form, is obtained by eligible Surviving Family members from the SOS staff members. The collection instrument is completed electronically and in person by the eligible Surviving Family members, SOS staff members, and Physical Security Personnel. Eligible Surviving Family members are responding to the information collection to obtain the SAC which grants unescorted access onto Army installations to authorized facilities. The SOS staff member forwards the request to the local garrison Physical Security Office to conduct an NCIC–III check. After an applicant is approved, a SAC is issued through the local identification card section or the Automated Installation Entry (AIE) digital SAC is issued through the installation's Visitor Control Center.

Affected public: Individuals or households.

Annual burden hours: 670.

Number of respondents: 670.

Responses per respondent: 1.

Annual responses: 670.

Average burden per response: 1 hour.

Frequency: Once.

Dated: September 28, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–21598 Filed 10–4–21; 8:45 am]

BILLING CODE 2001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

U.S. Strategic Command Strategic Advisory Group; Notice of Federal Advisory Committee Meeting

AGENCY: Office of the Chairman Joint Chiefs of Staff, U.S. Strategic Command Strategic Advisory Group, Department of Defense (DoD).

ACTION: Notice of closed Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the U.S. Strategic Command Strategic Advisory Group (USSTRATCOM SAG) will take place.

DATES:

Day 1—Wednesday, October 27, 2021 from 12:00 p.m. to 5:00 p.m. (Closed)

Day 2—Thursday, October 28, 2021 from 9:00 a.m. to 5:00 p.m. (Closed)

ADDRESSES: 900 SAC Boulevard, Offutt Air Force Base, Nebraska 68113.

FOR FURTHER INFORMATION CONTACT: Mark Olson, (402) 912–0322 (voice), (facsimile), *mark.j.olson.civ@mail.mil* (email). Mailing address is 901 SAC Boulevard, Suite 1F7, Offutt AFB, NE 68113–6030.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to provide independent advice on scientific, technical, intelligence, and policy-related issues to the U.S. Strategic Command, during the development of the Nation's strategic war plans.

Agenda: Topics include: Annual Stockpile Assessment; Nuclear Force Modernization; NC3 Enterprise Center (NEC) status deliverables and timeline; NC3 Joint All Domain Command and Control (JADC2); and Operations in a GPS Denied Environment and Deterring Russian/Chinese Escalation to Nuclear Use.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b, and 41 CFR 102–3.155, the Department of Defense has determined that the meeting shall be closed to the public. Per delegated authority by the Chairman, Joint Chiefs of Staff, Admiral Charles A. Richard, Commander, U.S. Strategic Command, in consultation with his legal advisor, has determined in writing that the public interest requires that all sessions of this meeting be closed to the public because they will be concerned with matters listed in 5 U.S.C. 552b(c)(1).

Written Statements: Pursuant to section 10(a)(3) of the Federal Advisory Committee Act and 41 CFR 102–3.140, interested persons may submit written statements to the Designated Federal Officer for the USSTRATCOM SAG at any time. Written statements should be submitted to the Designated Federal Officer at the email or mailing address listed above in **FOR FURTHER INFORMATION CONTACT**. If statements pertain to a specific topic being discussed at a planned meeting, then these statements must be submitted no later than five (5) business days prior to the meeting in question. Written statements received after this date may not be provided to or considered by the USSTRATCOM SAG until its next meeting. The Designated Federal Officer will review all timely submitted written statements and provide copies to all the committee members before the meeting that is the subject of this notice.

Dated: September 29, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–21601 Filed 10–4–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Administrative Suspension of the Advisory Committee on Industrial Security and Industrial Base Policy

AGENCY: Department of Defense.

ACTION: Notice of administrative suspension of Advisory Committee on Industrial Security and Industrial Base Policy.

SUMMARY: The Department of Defense is publishing this notice to announce it administratively suspended the Advisory Committee on Industrial Security and Industrial Base Policy on September 30, 2021.

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Advisory Committee is being administratively suspended under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix) and 41 CFR 102–3.55, and the Government in the Sunshine Act of 1976 (5 U.S.C. 552b), effective September 30, 2021.

Dated: September 29, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–21592 Filed 10–4–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0145]

Agency Information Collection Activities; Comment Request; District Survey on Use of Funds Under Title II, Part A

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before December 6, 2021.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2021–SCC–0145. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection

activities, please contact Andrew Brake, 202–453–6136.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: District Survey on Use of Funds Under Title II, Part A.

OMB Control Number: 1810–0618.

Type of Review: A revision of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 4,452.

Total Estimated Number of Annual Burden Hours: 8,852.

Abstract: The U.S. Department of Education is requesting clearance for a revision to 1810–0618 in order to continue collecting data annually from school districts about how Title II, Part A funds are used to support authorized activities and improve equitable access to teachers for low-income and minority students; including professional development for teachers, principals, and other school leaders. The reporting requirements are outlined in Section 2104(b) of the Elementary and Secondary Education Act (ESEA), as reauthorized by the Every Student Succeeds Act of 2015 (ESSA). The annual survey will include a state representative sample of traditional school districts, a nationally representative sample of charter school districts, and an annual request for each state to provide a list of districts that receive Title II, Part A funds and each district's allocated Title II, part A amount. The survey will be sent to district Title II, Part A coordinators and administered using an electronic instrument.

Dated: September 30, 2021.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–21650 Filed 10–4–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

List of Borrowers Who Have Defaulted on Their Health Education Assistance Loans

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

SUMMARY: Federal Student Aid (FSA), as required by the Public Health Service Act (the Act), is publishing this list of Health Education Assistance Loan (HEAL) borrowers who have defaulted on their loans as of August 1, 2021. This information is also made available for use by organizations authorized by the Act.

FOR FURTHER INFORMATION CONTACT:

For Defaulted HEAL Borrowers with Account-Related Questions: A borrower who is in default on a HEAL program loan and who has an account-related question should contact: HHS Program Support Center, Debt Collection Center, 7700 Wisconsin Avenue, Suite 8–8310A, Bethesda, MD 20857 (use ZIP code 20814 for overnight mail). Telephone: (301) 492–4664.

For General HEAL Information: For general HEAL program questions, contact the HEAL program team: Telephone: (844) 509–8957. Email: *HEAL@ed.gov.*

For Organizations Requesting HEAL Defaulted Borrower Information or Confirmation under Section 709(c)(2) of the Act (42 U.S.C. 292h(c)(2)): To request information related to a HEAL defaulted borrower or confirmation of the borrower's default status, contact the HEAL program team: Telephone: (844) 509–8957. Email: *HEAL@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: From fiscal year 1978 through fiscal year 1998, the HEAL program insured loans made by participating lenders to eligible graduate students in schools of medicine, osteopathy, dentistry, veterinary medicine, optometry, podiatry, public health, pharmacy, and chiropractic, and in programs in health administration and clinical psychology. Authorization for new HEAL program loans was discontinued on September 30, 1998.

Under division H, title V, section 525 of the Consolidated Appropriations Act, 2014 (Pub. L. 113–76), and title VII, part A, subpart I of the Public Health Service Act (42 U.S.C. chapter 6A), the authority to administer the HEAL program, including servicing, collecting, and enforcing any loans made under the HEAL program that remain outstanding, was transferred from the Secretary of Health and Human Services to the Secretary of Education effective July 1, 2014. Section 709(c)(1) of the Act (42 U.S.C. 292h(c)(1)) requires, and a routine use in a system of records notice published in the **Federal Register** on August 14, 2018 (83 FR 40264) permits, the publishing of the list of HEAL borrowers who have defaulted on their loans.

Information on the HEAL program is available on the Department of Education's FSA Partner Connect Knowledge Center website at: *fsapartners.ed.gov/knowledge-center.*

List of Defaulters

The following list provides the names and other information of borrowers who have defaulted on their HEAL program loans as of August 1, 2021. Specifically, the list includes the borrower's name, last known city and State of residence, area of practice, and the total amount due on the HEAL debt. The Department publishes this information in order to correctly identify the person in default and to provide relevant information to the authorized recipients of this information, such as State licensing boards and hospitals.

In accordance with section 709(c)(2) of the Act (42 U.S.C. 292h(c)(2)), FSA will provide the information included in this **Federal Register** notice and updated information on the borrower's default status to relevant Federal agencies and to schools, school associations, professional and specialty associations, State licensing boards, hospitals with which listed borrowers may be associated, and other relevant organizations, upon written request to the email address listed under **FOR FURTHER INFORMATION CONTACT**. Any written request must be on the

letterhead of the organization making the request.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1071 *et seq.* and 1087a *et seq.;* and 42 U.S.C. 292h(c).

Richard Cordray,

Chief Operating Officer, Federal Student Aid.

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS AS OF AUGUST 1, 2021

Last name	First name	MI	City	State	Discipline	Date reported	Amount due
Abe	Gregory	N	Tujunga	CA	PHA	1/21/1998	$75,209
Ackley	Brainard	L	Kitty Hawk	NC	CHM	1/21/1998	6,715
Acosta-Delgado	Feliberto	D	Bronx	NY	DEN	3/1/1999	96,773
Adams	Stephen	.....	League City	TX	CHM	3/1/1999	91,774
Adeli	Mojgan	E	Los Angeles	CA	DEN	3/1/1999	151,397
Adkins	Margo	M	Austin	TX	MED	1/21/1998	969,306
Aiken	Richard	F	Gardena	CA	CHM	8/21/2015	92,733
Al-Amin	Ihsaan	.....	Ringgold	GA	MED	11/2/2000	103,658
Alana	Manuela	L	Pharr	TX	POD	9/24/2014	244,818
Alden	Thomas	E	Cambridge	MA	CHM	11/2/2000	134,994
Allen	Lawrence	P	Temecula	CA	CHM	7/31/1998	366,716
Alston	Linda	D	Philadelphia	PA	OST	5/21/2019	195,400
Alter	Dale	N	Redding	CA	MED	2/5/2009	447,873
Anaya	Enid	L	Riverhead	NY	MED	5/21/2019	26,963
Anderson	Angela	J	Torrance	CA	MED	1/21/1998	188,572
Anderson	Gwendolyn	.....	Lansdowne	PA	POD	1/21/1998	288,132
Anyaji	George	I	San Diego	CA	MED	4/25/2014	121,825
Aquino	Sayira	I	Homestead	FL	POD	8/15/2019	83,575
Armstrong	Daniel	J	San Francisco	CA	CHM	5/17/1999	167,355
Arnesen	Douglas	W	Atascadero	CA	CHM	5/17/1999	58,329
Azcueta	Justina	Q	San Jose	CA	DEN	5/7/2013	170,277
Bacon	Pamela	M	Hollister	MO	DEN	5/17/1999	260,320
Baez	Ana	V	Somerset	NJ	DEN	5/14/2002	150,312
Bahadue	George	P	Matawan	NJ	OST	3/1/1999	274,455
Bailey	David	W	San Bernadino	CA	MED	3/25/2019	49,126
Baird	Curtis	J	Mount Airy	MD	MED	5/14/2002	113,080
Baker	Walter	A	Mill Valley	CA	DEN	5/11/2005	487,968
Baker	Gale	.....	Olympia Flds	IL	DEN	5/17/2001	80,691
Ball JR	Thomas	.....	Detroit	MI	POD	11/12/2013	111,481
Baranco	Patricia	E	Lake Charles	LA	DEN	3/1/1999	909,409
Baratta	George	.....	Danville	CA	CHM	11/2/2000	31,819
Barber	Mildred	L	Washington	DC	MED	11/14/2007	151,852
Barile	Joseph	V	Valatie	NY	CHM	3/25/2019	12,874
Barnes	De Elward	F	Los Angeles	CA	CHM	11/10/2004	58,170
Barnett	Brian	D	Pearland	TX	CHM	1/21/1998	78,261
Barney	Thomas	W	Sugar Grove	IL	CHM	8/22/2017	48,880
Barrows	Joni	.....	Newmarket	NH	DEN	5/19/2009	714,385
Bayles	Jay	C	Westlake Village	CA	CHM	8/11/2005	109,162
Beckford	Audrey	L	East Orange	NJ	OST	2/15/2002	74,318
Bennett	Kathy	.....	Caldwell	ID	CHM	8/12/2016	83,325
Bentley JR	James	W	Van Nuys	CA	DEN	8/12/2016	26,088
Bergstrom	Eric	R	Anaheim Hills	CA	CHM	5/7/2013	33,412
Bertin	Michael	W	West Bloomfield	MI	DEN	1/21/1998	6,434
Bertsch	Dar	A	Santa Cruz	CA	CHM	4/25/2014	43,535
Bettis	Gail	M	Bellrose	NY	DEN	1/21/1998	99,531
Biosah-Coleman	Ada	N	Houston	TX	PUB	9/24/2014	51,712
Bisbocci	Brady	M	Belmont	OH	CHM	11/14/2019	16,397
Bittenbender	Robert	G	Clarks Summit	PA	CHM	11/7/2001	44,649
Bland JR	Henry	N	Jacksonville	FL	DEN	5/14/2002	250,274
Blase	Richard	M	Worcester	MA	DEN	1/21/1998	501,213
Bolton	Paul	K	Kansas City	MO	CHM	11/2/2000	136,488
Booher	Janette	L	South San Francisco	CA	CHM	2/1/2001	65,972
Boshes	Perri	D	Deerfield Beach	FL	CHM	1/21/1998	84,799
Bowman	Jeffrey	S	Salt Lake City	UT	CHM	1/21/1998	23,903
Boyd	Brian	D	Bellingham	WA	CHM	2/18/2020	4,054
Brandt	Susan	J	Winston Salem	NC	MED	7/6/2012	101,043

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS AS OF AUGUST 1, 2021—Continued

Last name	First name	MI	City	State	Discipline	Date reported	Amount due
Brantley	Carl	E	Houston	TX	DEN	9/24/2014	44,682
Breazeale	Michael	E	Marietta	GA	CHM	1/21/1998	332,016
Brodie	Douglas	K	San Antonio	TX	DEN	1/21/1998	405,665
Brodsky	Barbara	L	San Francisco	CA	CHM	1/21/1998	22,616
Bronk	Brian	R	Santa Monica	CA	CHM	1/21/1998	76,250
Broussard	Charlotte	R	Carrollton	TX	CHM	11/2/2000	17,292
Broussard	Linda	C	Los Angeles	CA	CHM	2/8/2021	3,664
Brown	Darla	J	Highlands	TX	CHM	1/21/1998	497,716
Brown	Jeffrey	T	Gainesville	GA	CHM	11/7/2001	33,172
Brown-Collins	Jannas	E	Columbia	SC	DEN	5/31/2018	596,289
Bruyning	Edwin	F	Miami	FL	DEN	1/21/1998	352,175
Buchta	Joseph	F	Bradenton	FL	DEN	7/26/2018	35,853
Buchwald-Heilig	Bonnie	I	Tucson	AZ	CHM	1/21/1998	40,251
Buford	John	I	Philadelphia	PA	OST	5/17/2001	64,233
Bui	Khai	T	Springfield	MA	DEN	8/16/2006	91,273
Bulen	Jerry	L	Brandon	FL	OST	2/28/2005	187,429
Bunce	Christine	T	Sonoma	CA	CPY	2/1/2001	203,401
Caballero	Jorge	R	Los Angeles	CA	CHM	1/21/1998	294,613
Cabrera	Cecilia	I	Pembroke Pines	FL	OPT	2/5/2009	20,185
Caldwell	William	G	Concord	MA	DEN	5/14/2002	121,857
Calix	Raul	O	Lennox	CA	CHM	5/16/2011	11,673
Campanale	Paul	R	Jacksonville	FL	CHM	1/21/1998	96,130
Canillas	Gregorio	L	Long Beach	CA	CPY	5/16/2011	78,451
Caporaso	Nicholas	G	West Liberty	OH	CHM	2/1/2001	29,723
Caputo	Francesco	J	Plainview	NY	CHM	7/6/2012	271,631
Carlos	Lester	B	San Leandro	CA	CHM	8/5/2004	73,081
Carney	Timothy	M	East Patchogue	NY	CHM	11/26/2012	37,320
Carpenter	Richard	P	Saginaw	MI	CHM	1/21/1998	38,521
Carrie	Thomas	T	Mount Vernon	NY	MED	3/1/1999	374,500
Carthen	Michael	.....	Brooklyn	NY	POD	1/21/1998	401,700
Castaline	Perren	V	Canyon Country	CA	CHM	8/11/2005	143,822
Castellanos	Loretta	M	Key Biscayne	FL	DEN	2/3/2014	285,745
Castro	Henry	G	Corpus Christi	TX	CHM	5/20/2004	59,578
Caulkins	Robert	M	Shrewsbury	MA	MED	8/5/2004	507,575
Cha	Chris	S	Garden Grove	CA	DEN	11/12/1999	358,947
Chalgujian	Hilda	A	Palm Desert	CA	CPY	5/16/2011	153,618
Chen	Syng-Fu	F	Pls Vrds Pnsl	CA	MED	5/20/2004	57,819
Cheney	Julian	L	Reseda	CA	CHM	1/21/1998	9,631
Choi	Seong	Y	Diamond Bar	CA	DEN	3/1/1999	170,092
Christian	Roy	P	Saratoga	CA	DEN	7/6/2012	46,286
Christiansen	John	C	Pleasant Grove	UT	CHM	5/19/2009	82,188
Clark	Garth	A	Humble	TX	MED	8/10/2001	165,063
Cleere	Carrol	E	Cedar Creek	TX	CHM	1/21/1998	235,299
Clifton	Rhea	S	Dallas	TX	CHM	8/5/2004	8,533
Cline	Sherri	L	Sylmar	CA	OST	1/21/1998	9,643
Clouse	William	J	San Antonio	TX	POD	3/1/1999	233,731
Coate	Linda	.....	Reno	NV	CHM	11/9/2010	192,941
Cobrin	Bettina	B	Marina Del Rey	CA	CPY	1/21/1998	284,179
Coleman JR	Harold	J	Tacoma	WA	DEN	5/16/2011	290,952
Collier	George	R	Ponderay	ID	DEN	1/21/1998	269,584
Collins JR	Gail	W	Fullerton	CA	OPT	3/1/1999	33,424
Connaughton	Edward	M	Hermosa Beach	CA	CHM	8/12/2016	39,198
Connor	Kenneth	J	Newport Beach	CA	CHM	11/7/2001	85,776
Cook	Karen	.....	Redwood City	CA	CHM	7/6/2012	519,322
Cook	Ian	K	Christiansted	VI	POD	2/8/2017	196,640
Cooke	Courtney	W	Van Nuys	CA	CHM	5/18/2010	47,354
Coombs	Timothy	R	Anaheim	CA	CHM	5/15/2000	124,230
Cooney	Carey	E	Eugene	OR	DEN	1/21/1998	43,884
Coonts	Terry	A	Eldorado Springs	MO	CHM	2/17/2000	13,564
Cooper	April	D	Hazel Crest	IL	MED	1/21/1998	520,178
Cooper	Carol	A	Keizer	OR	CHM	3/25/2019	216,102
Corcoran	Jamie	M	Bronx	NY	DEN	4/24/1998	568,426
Cothran	Lonnie	A	Shady Point	OK	CHM	11/12/1999	252,359
Cox	Michael	A	Oakland	CA	CHM	11/15/2005	27,842
Coyle	Michele	M	Mission Viejo	CA	CPY	5/12/2020	302,048
Cummins	David	F	St Michael Barbados	FC	DEN	1/21/1998	164,573
Curtin	Michael	M	Fairfax	CA	CHM	1/21/1998	36,549
Cutts	David	P	Temecula	CA	DEN	1/21/1998	173,607
Daniels	Peter	J	San Jose	CA	CHM	2/20/2007	99,539
Darrow	Victoria	L	Boca Raton	FL	CHM	11/26/2012	144,946
Davalos	Steven	M	Carmel Valley	CA	CHM	8/1/2000	52,537
Davidson	Blake	L	Richardson	TX	CHM	8/5/2004	46,952

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS AS OF AUGUST 1, 2021—Continued

Last name	First name	MI	City	State	Discipline	Date reported	Amount due
Davitiashvili	Nodari	.....	Rego Park	NY	DEN	11/12/2013	154,909
Dawe	Michael	E	Fort Worth	TX	OPT	2/18/2020	17,984
De Jesus-Miranda	Luis	A	Fajardo	PR	OPT	5/14/2002	104,003
Deleonardis	Michael	S	Houston	TX	MED	8/10/2001	122,310
Demaria	Lynn	A	Albany	NY	MED	2/2/2018	87,065
Dennis	Gwenda	B	Aliso Viejo	CA	MED	5/14/2016	136,728
Densmore	Robert	D	Tampa	FL	CHM	8/17/2007	51,248
Derbonne	John	R	Lake Jackson	TX	CHM	9/24/2014	43,505
Desai	Nemish	J	Denville	NJ	DEN	5/21/2019	116,285
Dewitt	Eldon	L	Neosho	MO	CHM	2/5/2009	144,565
Dhaliwal	Emaline	K	Riverside	CA	CHM	1/21/1998	12,962
Diesen	James	D	Orange Park	FL	CHM	1/21/1998	454,576
Difiore JR	William	E	Fountain Valley	CA	CHM	1/21/1998	77,138
Dinh	Michael	K	Mcallen	TX	CHM	9/24/2014	11,814
Ditroia	Frederick	.....	Warrington	PA	DEN	1/21/1998	66,874
Divanbeigi	Farah	Z	Las Vegas	NV	DEN	3/25/2019	187,176
Dominic	Anthony	J	Manasquan	NJ	MED	2/15/2002	55,310
Dominicis	Beth	A	Lake Arrowhead	CA	CHM	2/1/2001	28,271
Doom	Randolph	H	Murrells Inlet	SC	CHM	8/17/2012	166,988
Dorian	Saro	S	Glendale	CA	CHM	11/7/2001	35,492
Dructor	James	D	Pittsburgh	PA	MED	8/10/2001	72,275
Duarte	Leonardo	.....	Jackson	NJ	CHM	11/14/2019	40,544
Dudley	Raynold	R	Houston	TX	PHA	1/21/1998	125,811
Dungan	Kim	V	Fort Lauderdale	FL	CHM	11/14/2007	137,275
Dupuis	Kenneth	J	Orono	ME	CHM	5/14/2002	203,102
Durham	Ricky	L	Houston	TX	CHM	1/21/1998	249,338
Dwight	Benton	J	Albuquerque	NM	PHA	7/26/2018	17,381
Dykeman	Peter	J	Hawthorne	CA	CHM	1/21/1998	143,653
Elbayar	Nader	K	Port Washington	NY	POD	1/21/1998	163,422
Elder	Terry	M	Glendale Heights	IL	CHM	8/1/2000	259,024
Eli	Desiree	D	Soquel	CA	CHM	1/21/1998	79,577
Ellis	Mark	S	Miami	FL	POD	2/17/2000	146,088
Emerson	Edwin	A	Selden	NY	CHM	1/21/1998	254,862
Engel	Rob	L	Garden Grove	CA	CHM	2/17/2000	31,869
Ensminger	Aletha	M	Carmichael	CA	DEN	11/9/2010	100,523
Epstein	Judy	J	Carlsbad	CA	CPY	2/17/2000	164,300
Eslao	Caesar	G	Carson	CA	DEN	1/21/1998	161,603
Esmailbeigui	Babak	.....	Pacific Palisades	CA	DEN	9/24/2014	9,910
Etienne	Fernande	.....	West Palm Beach	FL	POD	5/11/2006	189,698
Etumnu	Patrick	C	Houston	TX	CHM	9/24/2014	31,222
Evans	William	L	Spring	TX	CHM	9/24/2014	106,107
Fabricant	Michael	J	Fort Lauderdale	FL	CHM	1/21/1998	269,489
Fair	David	F	Knoxville	TN	CHM	3/1/1999	149,703
Falkinburg	Rory	D	Point Pleasant Boro	NJ	CHM	7/26/2018	94,217
Fallman	James	M	Alhambra	CA	CHM	5/15/2000	50,335
Falth-Vanvollenhoven	Annika	M	San Francisco	CA	MED	3/1/1999	149,119
Fanizzi	Thomas	.....	Brightwaters	NY	POD	4/24/1998	527,752
Farris	Farral	W	Pagosa Springs	CO	CHM	5/15/2000	69,590
Fayazfar	Mitra	.....	Oak Park	CA	CHM	11/7/2001	30,139
Feinman	Brian	M	Tampa	FL	POD	2/20/2007	847,719
Fenton	Mark	A	Van Nuys	CA	CHM	5/11/2006	101,799
Fiore	James	P	Santa Ana	CA	CHM	8/10/2001	70,454
Fletcher	Leonard	G	Corona	CA	MED	8/21/2015	71,148
Flores	Otto	O	Antario	CA	CHM	1/21/1998	187,933
Fluck	Dennis	W	New Tripoli	PA	OST	10/30/2003	317,675
Flunker	Edward	J	Houston	TX	CHM	8/12/2016	13,664
Ford	Leslie	E	Keller	TX	CHM	8/15/2019	15,507
Ford	Thomas	M	Yorba Linda	CA	CHM	2/1/2001	4,877
Formaker	James	W	West Hollywood	CA	DEN	1/21/1998	114,792
Fox	Carl	A	Dana Point	CA	CHM	5/11/2005	115,019
Franco	Michael	G	Glendale	CA	MED	3/3/2015	221,517
Francus	Irwin	N	East Northport	NY	CHM	4/24/1998	497,321
Franks	Michael	A	Wharton	TX	CHM	9/24/2014	29,267
Freeze	Kenneth	J	Amarillo	TX	CHM	8/15/2019	161,373
Fridrick	Tim	P	Las Vegas	NV	CHM	1/21/1998	66,250
Friedman	Marc	H	Huntington Beach	CA	POD	8/12/2016	56,240
Fulton	William	C	Oakland	CA	CPY	11/7/2001	83,021
Funcia	Ana	T	Miami	FL	DEN	2/1/2001	213,417
Gaber	Alan	M	Levittown	PA	DEN	5/14/2002	61,841
Gain	John	J	Wilmington	DE	MED	5/2/2003	375,826
Galliher	Jack	T	Wimberley	TX	OPT	11/7/2001	3,638
Gallucci	Don	A	Dedham	MA	DEN	3/1/1999	159,435

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS AS OF AUGUST 1, 2021—Continued

Last name	First name	MI	City	State	Discipline	Date reported	Amount due
Garner	Jeffrey	L	Cedar Rapids	IA	OPT	3/25/2019	70,242
Gasso	Joaquin	A	Hollywood	FL	CHM	1/21/1998	255,395
Gaydos	Richard	F	Fontana	CA	CHM	11/7/2001	56,506
Gdula	William	J	Brookline	MA	MED	5/16/2011	20,507
Genna	Stephen	A	Bayville	NY	DEN	7/26/2018	43,149
Ghalbi	Abdollnasser	.....	Santa Ana	CA	CHM	5/14/2002	40,649
Gifford	Craig	P	Keller	TX	DEN	2/17/2000	119,614
Giorgio	Stephen	R	Middle Island	NY	CHM	7/26/2018	27,918
Gipson	Bruce	C	Easton	PA	CHM	5/14/2016	17,241
Giventer	Alex	.....	Los Angeles	CA	CHM	5/16/2011	71,650
Gloshinski	Laura	E	Portland	PA	CHM	1/21/1998	148,493
Gloskowski	Aaron	.....	Phoenix	AZ	OST	11/14/2019	10,300
Goins	Rondy	D	Detroit	MI	POD	3/25/2019	335,815
Goldbeck	Donald	E	Woodland Hills	CA	CHM	8/12/2016	105,551
Gomes	Steven	P	Santa Rosa	CA	CHM	4/24/1998	53,774
Gomez	Meneleo	P	Glendale	CA	DEN	5/15/2000	299,060
Gonzalez	Maria	E	East Rockaway	NY	DEN	5/15/2000	73,598
Goodman	William	D	Thorp	WI	DEN	1/21/1998	37,744
Goodwin	Randall	J	Satanta	KS	CHM	7/6/2012	110,884
Gosa-Kersee	Angela	J	Chicago	IL	DEN	3/1/1999	305,609
Gottschling	Carl	F	Cleveland	OH	MED	11/7/2001	163,650
Grant	Terry	E	Hempstead	NY	DEN	2/1/2001	83,374
Gray	David	M	San Francisco	CA	POD	3/2/2004	71,936
Green JR	Edwin	A	Brownwood	TX	MED	12/11/2018	60,585
Greeno	Vincent	A	Bolton	MA	CHM	2/28/2005	63,172
Greeson-Cargioli	Leisa	A	Noblesville	IN	CHM	7/26/2018	40,155
Gregory	Thomas	M	Brentwood	NY	CHM	8/22/2017	337,397
Gregory	Todd	A	Pismo Beach	CA	CHM	1/21/1998	57,119
Gregson	Randall	.....	Kailua	HI	CHM	8/22/2017	104,711
Grenier	Paul	S	Viroqua	WI	CHM	8/9/2010	48,914
Grob-Mick	Renee	J	Dover	DE	MED	5/31/2018	42,570
Grossman	Brian	W	Tulra	CA	CPY	8/12/2016	93,062
Gulas	Carl	M	Los Gatos	CA	CHM	11/18/2011	42,335
Guyer	Larry	G	Santa Rosa	CA	CHM	11/7/2001	43,998
Hahn	Peter	S	Placentia	CA	CHM	1/21/1998	44,313
Haines	Steven	M	Jackson	NJ	CHM	3/1/1999	59,166
Hall	Pamela	A	Miami Gardens	FL	CPY	8/17/2007	211,814
Hamilton	Cynthia	R	Chino Hills	CA	MED	5/16/2011	43,067
Hampton	Jubal	.....	Long Beach	CA	POD	11/12/1999	47,361
Hankins	Dean	G	Anaheim	CA	CHM	8/12/2016	97,827
Hankins	Douglas	A	Anaheim	CA	CHM	8/22/2017	62,511
Hansen	Kristen	T	Washington	UT	CHM	2/6/2003	115,709
Harp	Richard	B	Hacienda Heights	CA	CHM	8/10/2011	25,551
Harris	Conrad	W	Lanham	MD	DEN	1/21/1998	141,977
Harris	Sabrina	D	San Antonio	TX	MED	12/11/2018	168,534
Harris	Darryl	C	Atlanta	GA	MED	11/14/2019	254,879
Harrison	Rodney	B	Claremont	CA	DEN	5/19/2009	469,679
Hasley	Steven	J	Rock Island	IL	CHM	2/28/2005	78,246
Hatfield	Brian	L	Brentwood	CA	CHM	1/21/1998	64,724
Haygood	Regina	J	Brooklyn	NY	POD	4/24/1998	198,722
Hazelwood III	Harry	H	Daytona Beach	NJ	PUB	3/1/1999	314,684
Heckler	Rodney	R	Wheaton	IL	CHM	11/15/2005	25,868
Hempsey	William	C	North Hollywood	CA	CHM	1/21/1998	120,108
Henderson	Charles	A	Baltimore	MD	POD	8/22/2017	46,689
Hennell-Larue	Renata	A	Mapleton	OR	CHM	9/24/2014	44,453
Hernandez	Orestes	M	Los Angeles	CA	CHM	1/21/1998	96,005
Herrera	Diego	F	Long Island City	NY	DEN	8/5/1999	347,175
Hibbert	Harold	H	Mountain View	CA	MED	11/2/2000	30,549
Ho	Wook	.....	Los Angeles	CA	DEN	3/1/1999	61,494
Hoang	Dat	T	Anaheim	CA	MED	8/12/2016	73,422
Hobowsky	Martin	R	South Charleston	OH	OST	11/9/2010	267,265
Hoehn	James	D	Thousand Oaks	CA	DEN	1/21/1998	83,579
Hoffman	Stuart	.....	Venice	CA	CHM	8/12/2016	23,861
Hollingsworth	Derek	J	Kalispell	MT	OST	2/18/2020	60,017
Holt	Kenneth	G	Riverside	CA	CHM	1/21/1998	107,172
Holzer	Richard	M	Glendale	AZ	CHM	8/17/2007	170,722
Horsley	Ronald	G	Yulee	FL	CHM	1/21/1998	91,544
Howell	Ralph	G	Stateline	NV	CHM	11/7/2001	256,036
Hungerford	Richard	D	Portola	CA	CHM	1/21/1998	94,260
Hunt	Richard	D	Pasadena	CA	CHM	2/15/2002	152,882
Hunter	Donald	E	Fairborn	OH	CHM	5/19/2009	77,733
Hush	George	G	Rose City	MI	CHM	1/21/1998	110,643

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Last name	First name	MI	City	State	Discipline	Date reported	Amount due
Ichiuji	Arnold	T	Salinas	CA	DEN	8/10/2001	112,597
Iliou	Claude	B	Punta Gorda	FL	MED	8/16/2006	26,352
Ionova-Zalivchy	Irina	I	Brooklyn	NY	DEN	7/26/2018	68,384
Iqal	Robert	S	Claremont	CA	PHA	1/21/1998	12,224
Ito	Stephen	M	Menifee	CA	CHM	4/24/1998	159,556
Jackson	Harold	O	Atlanta	GA	DEN	5/16/2011	26,115
Jackson	Francesca	A	San Francisco	CA	CHM	4/24/1998	96,780
Jacob-France	Elizabeth	.....	St Petersburg	FL	CHM	2/10/2011	72,974
Jaimes	Laura	.....	Pico Rivera	CA	MED	7/26/2018	9,410
Jansson	Susanne	E	Westhampton Beach	NY	GHA	1/21/1998	127,532
Jeffcoat	Lori	M	Vallejo	CA	CHM	10/30/2003	37,472
Jennifer	Jai	.....	Oakland	CA	MED	7/6/2012	62,263
Jernigan	Sherry	S	Land O Lakes	FL	OST	3/25/2019	167,458
Jewett	Charles	D	Portsmouth	OH	CHM	1/21/1998	110,045
Joergens JR	Donald	W	Staten Island	NY	CHM	1/21/1998	60,946
Johnson	John	B	Pasadena	TX	CHM	8/12/2016	17,342
Johnson	Anthony	.....	Detroit	MI	MED	1/21/1998	11,271
Johnson	Steven	R	Hillsboro	TN	CHM	8/1/2000	163,347
Johnson	Eric	D	Folsom	CA	CHM	1/21/1998	402,509
Johnson	Gary	M	Burbank	CA	CHM	4/24/1998	100,000
Kahan	Robert	M	Mission Viejo	CA	CHM	1/21/1998	80,836
Kamel	Luca	.....	Canyon Country	CA	MED	8/12/2016	248,093
Kantro	Scott	R	New York	NY	POD	8/16/2006	449,219
Katz	Steven	M	Sherman Oaks	CA	CHM	8/10/2001	211,460
Kaufmann	Todd	S	Corte Madera	CA	CHM	8/5/1999	148,434
Kea	Rattana	D	Highland	CA	DEN	11/7/2001	222,855
Keeler-Jones	Dawn	M	Port Saint Lucie	FL	CHM	5/14/2002	120,728
Keenan	John	M	Watertown	NY	CHM	2/5/2009	52,390
Kelly-Soluri	Laura	.....	Farmingdale	NY	POD	5/17/1999	272,003
Kempis	Richard	A	Santa Clara	CA	DEN	2/17/2000	106,833
Khalsa	Har Hari	S	Beverly Hills	CA	CHM	8/10/2011	68,325
Khalsa	Gururakha	S	Springfield	VA	CHM	7/31/1998	151,337
Khan	Tariq	A	San Leandro	CA	DEN	7/6/2012	62,544
Kim	Won Kak	.....	Torrance	CA	CHM	8/12/2016	105,518
King	James	H	Washington	DC	DEN	1/21/1998	50,209
King	Susan	M	Apache Junction	AZ	CHM	9/24/2014	188,383
Kirkpatrick	Ira	P	Hurst	TX	CHM	7/26/2018	215,116
Klapper	Gerald	P	Hollywood	FL	POD	2/11/2008	56,305
Klejnot	Timothy	A	Marietta	GA	CHM	1/21/1998	236,329
Knight	Patricia	A	Bayport	NY	CPY	1/21/1998	99,193
Ko	Joo	H	Marina	CA	CHM	4/25/2014	20,374
Koukeh-Sackett	F	M	San Bernardino	CA	CHM	1/21/1998	160,575
Kowalski	Brian	A	Irvine	CA	CHM	8/21/2015	29,023
Kralj	Mladen	M	Chicago	IL	DEN	4/24/1998	638,350
Krichevsky	Rita	A	Newtown	PA	MED	2/2/2018	149,906
Krystosik	James	D	Streetsboro	OH	CHM	11/9/2006	262,208
Kunen	Frederick	J	Miami	FL	MED	3/1/1999	205,124
Kyprie	Warren	.....	Boca Raton	FL	CPY	2/14/2012	80,955
Lafleur	Allen	R	Hull	MA	CHM	3/1/1999	477,044
Lamb	Robert	D	Portland	OR	CHM	1/21/1998	204,019
Lampley	Joseph	C	Anson	TX	OST	3/25/2019	167,254
Lampman	Chuck	D	Sylmar	CA	CHM	1/21/1998	276,260
Lancaster	Barry	D	Marietta	GA	CHM	1/21/1998	141,015
Landou	Lissa	S	Belleville	NJ	CHM	5/14/2002	221,990
Lane	Craig	R	Baltimore	MD	POD	3/25/2019	333,199
Langham	Mary	L	Talkeetna	AK	OST	5/19/2009	589,068
Lauffer	Mark	A	Mineral Point	PA	CHM	5/16/2011	90,721
Lawton	Michael	D	Riverside	CA	MED	11/12/1999	250,192
Lee	Steve	Y	Livingston	NJ	DEN	8/10/2001	97,748
Lent	Rosella	M	Nahant	MA	CHM	8/11/2005	240,618
Leonor	Lillian	.....	Riverside	CA	DEN	8/10/2011	50,120
Lester	Robert	C	Waxahachie	TX	CHM	2/17/2000	58,260
Leung	Leo	S	Woodside	NY	CHM	1/21/1998	244,156
Levin	Nancy	E	Palm Beach Gardens	FL	CHM	1/21/1998	256,516
Lewis	Richard	C	Colorado Springs	CO	CHM	8/17/2012	22,298
Light	David	N	Winter Garden	FL	DEN	2/28/2005	136,096
Lim	Jong	S	Elmhurst	NY	DEN	11/12/2013	154,915
Lippay	Ronald	W	Fresno	CA	CHM	10/30/2003	78,714
Lipschutz	Robert	B	Philadelphia	PA	POD	2/1/2006	146,656
Little	Carlton	E	Niles	IL	MED	11/12/2013	323,709
Littleton	Charles	R	Edmond	OK	DEN	7/31/1998	1,155
Lodwig	Michael	J	Castro Valley	CA	CHM	1/21/1998	57,289

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Last name	First name	MI	City	State	Discipline	Date reported	Amount due
Lopez	Luis	.....	Cathedral City	CA	CHM	5/7/2013	229,599
Lottie	Mark	E	Covina	CA	CHM	8/21/2015	119,914
Lowry-Brooks	Paulette	M	Summerville	SC	CHM	1/21/1998	231,655
Lucero	Lucky	E	San Bernardino	CA	DEN	4/25/2014	80,827
Lunceford	Glenn	W	Norco	CA	CHM	1/21/1998	61,948
Luta	Patricia	L	Santa Rosa	CA	CHM	2/17/2000	101,422
Maghloubi	Seyed	M	Pacific Palisades	CA	CHM	8/12/2016	44,653
Major	David	C	Whittier	CA	CHM	8/12/2016	10,982
Mannino	Guy	C	North Pole	AK	CHM	3/1/1999	363,958
Manriquez JR	Antonio	M	Coachella	CA	CHM	5/11/2005	99,928
Manvel	Barry	J	Napa	CA	CHM	7/31/1998	40,929
Marcel	Perry	L	Alvarado	TX	DEN	11/12/2013	183,246
Marcus	Alex	.....	Orlando	FL	CHM	2/10/2011	126,522
Marquez	Evelyn	W	Reseda	CA	CPY	2/28/2005	144,902
Martin JR	John	W	Zephyrhills	FL	CHM	1/21/1998	254,991
Marts	Richard	A	Los Angeles	CA	CHM	11/12/1999	102,823
Mattson	James	A	Berkeley	CA	OST	11/7/2001	184,684
Maxfield-Brown	Bobbi	L	Evansville	IN	CHM	1/21/1998	744,333
Mays-Good	Kathryn	M	Reseda	CA	CHM	1/21/1998	369,127
Mazhar	Mark	.....	Los Angeles	CA	CHM	8/11/2005	128,669
McAdams	Glen	R	Spring	TX	CHM	3/1/1999	274,281
McAlees	Raymond	M	North Palm Beach	FL	CHM	11/12/1999	254,333
McCallum III	Ronald	D	Sunnyvale	CA	CHM	5/20/2004	24,007
McClure	Brian	C	Daytona Beach	FL	DEN	1/21/1998	15,960
McCombs	Martin	.....	Long Beach	CA	CPY	11/12/1999	291,515
McConner	Sadie	B	Daytona Beach	FL	POD	1/21/1998	59,113
McElhinney	Thomas	E	Saint Augustine	FL	CHM	1/21/1998	1,314,339
McGee	Billie	J	Simi Valley	CA	CHM	1/21/1998	139,996
McMorris	Bruce	.....	Long Beach	CA	CHM	11/12/1999	180,215
McRoberts	Lynne	S	Ontario Canada	FC	CHM	1/21/1998	107,137
Mcatamney	John	P	Garden City	NY	CHM	11/9/2010	26,988
Mcghee	Stephanie	Y	La Marque	TX	CHM	5/19/2009	40,283
Mckay	Kevin	J	Dallas	TX	CHM	11/10/2004	66,785
Mcmahan	Gregory	E	Fullerton	CA	DEN	11/18/2011	32,026
Meade	Madeline	M	Cleveland	OH	DEN	1/21/1998	75,797
Meggs	Carl	M	Belize	FC	DEN	8/15/2003	114,213
Melendez	Angelina	.....	Bronx	NY	POD	5/19/2009	302,414
Melker	Neil	L	Princeton	NJ	DEN	5/19/2009	239,751
Menezes	Michael	H	Tampa	FL	DEN	2/10/2011	216,799
Mihalakis	Georgia	.....	Bronx	NY	OST	1/21/1998	505,900
Milanes-Scott	Barbara	J	Northridge	CA	MED	1/21/1998	194,645
Milgram	Roman	.....	Brooklyn	NY	DEN	1/19/2017	44,694
Miller	Brad	T	Costa Mesa	CA	CHM	1/21/1998	23,056
Miller	Gaylon	D	Bixby	OK	CHM	2/14/2012	97,460
Miller	Bradley	G	Beverly Hills	CA	MED	1/21/1998	102,590
Millon	Jeffrey	M	Lithonia	GA	MED	1/21/1998	196,075
Mills	Stephen	M	Powell	OH	CHM	3/25/2019	6,122
Mitchell	Warren	A	Yucaipa	CA	DEN	8/1/2000	477,750
Mizell	William	L	Los Lunas	NM	OST	8/12/2016	281,160
Moarefi	Mahmdud	R	Los Angeles	CA	CHM	2/17/2000	74,067
Mohammadkhani	Alireza	D	Chatsworth	CA	CHM	8/11/2005	55,775
Moler	Amy	M	Westerville	OH	MED	8/22/2017	20,067
Moore	Scott	P	Citrus Heights	CA	CHM	2/20/2007	23,364
Morita	Phuong	T	Irvine	CA	CHM	3/1/1999	122,335
Moroney	William	P	Nashville	TN	CHM	4/24/1998	80,072
Morrone	Mark	J	Los Angeles	CA	DEN	7/31/1998	222,053
Moulds JR	Dan	R	Chattanooga	TN	DEN	2/1/2001	210,042
Mouton	Marsha	E	Los Angeles	CA	MED	1/21/1998	106,047
Muecke	Lee	N	Houston	TX	MED	8/12/2016	2,061
Muenker	Mark	E	Hillsboro	OR	CHM	7/31/1998	292,725
Mullinax	Jeffrey	S	Windsor	CA	CHM	5/11/2005	27,832
Munoz	Luis	R	Chicago	IL	MED	11/12/2013	617,903
Murphy	Richard	N	North Bergen	NJ	CHM	1/21/1998	1,484,705
Murphy	John	P	Black Earth	WI	CHM	7/6/2012	35,967
Murphy	Marc	A	Rancho Santa Margar	CA	CHM	1/21/1998	159,861
Myers	Karen	A	Redondo Beach	CA	MED	10/30/2003	237,719
Nagel	Douglas	.....	Herndon	VA	CHM	8/12/2016	48,038
Nappi	Neil	A	West Palm Beach	FL	CHM	3/1/1999	225,368
Nason	Christian	W	Wildomar	CA	CHM	5/18/2010	35,973
Navai	Mehdi	N	Alhambra	CA	CHM	1/21/1998	425,026
New	Richard	A	Conway	SC	CHM	2/14/2013	85,919
Newsome	Raymond	E	Desoto	TX	CHM	11/2/2002	243,268

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Last name	First name	MI	City	State	Discipline	Date reported	Amount due
Newsome	Dorita	.....	Livingston	NJ	DEN	5/19/2009	71,296
Nguyen	Michael	M	Milpitas	CA	MED	11/9/2006	55,331
Nguyen	Ho	H	La Puente	CA	CHM	11/18/2011	147,421
Nguyen	Anh	.....	Sacramento	CA	DEN	11/18/2011	33,669
Nguyen	Charlene	D	La Habra	CA	CHM	5/7/2013	33,786
Nguyen	Tuan	H	Fountain Valley	CA	OST	11/12/2013	158,525
Nichols	Victoria	G	Encinitas	CA	CPY	8/12/2016	12,196
Nieman	Edward	.....	Riverside	CA	CHM	2/1/2001	116,972
Ninomiya	Jesse	K	Honolulu	HI	DEN	5/17/2001	165,462
Nipper-Collins	Kristie	L	Lutz	FL	OST	2/10/2011	42,876
Nkuku	Christopher	N	Berkeley	IL	MED	5/17/2001	72,221
Nnokam	Kennedy	I	Jasper	TX	PUB	9/24/2014	64,501
Nolasco	Elizabeth	R	Brooklyn	NY	MED	11/12/2013	18,258
Norville	Michael	T	Costa Mesa	CA	CHM	1/21/1998	217,393
Ocon	Luis	E	Salinas	CA	CHM	10/30/2003	11,137
Olajide	Gbolahan	A	Corona	CA	CHM	5/19/2009	349,634
Olberg	Gregory	S	Hayward	CA	CHM	3/1/1999	119,556
Owens	James	R	Evans	GA	CHM	1/21/1998	14,603
Owens	Gregory	A	Claremore	OK	CHM	1/21/1998	52,448
Pacheco	Carlos	A	Mcallen	TX	MED	9/24/2014	33,062
Padilla-Torres	Carlos	.....	Ponce	PR	OPT	5/31/2018	21,654
Palmer	Becky	A	Fallbrook	CA	CHM	1/21/1998	193,936
Palmer	Richard	M	Thousand Oaks	CA	CHM	3/1/1999	264,347
Palmer-Mitchell	Donna	C	Phoenix	AZ	POD	1/21/1998	137,282
Pankey	John	.....	Oakland	CA	CHM	8/5/2004	149,617
Parkin	Dianne	E	Houston	TX	MED	9/24/2014	21,440
Parsa-Forspte	Sepideh	.....	San Clemente	CA	CHM	11/18/2011	49,579
Patterson JR	Arthur	E	Holmdel	NJ	CHM	9/24/2014	62,183
Paunovic	Susan	J	Hopewell Jct	NY	DEN	11/2/2000	14,606
Payne	Patricia	D	Long Beach	CA	OPT	11/14/2019	126,105
Peerenboom-Grenier	Paula	J	Viroqua	WI	CHM	11/7/2001	46,660
Pehush	Marie	L	Florida	NY	CHM	3/25/2019	103,633
Pellegrini	John	H	Huntington	WV	OST	3/25/2019	182,098
Pennington	Bradley	R	Denver	CO	CHM	5/31/2018	34,893
Perez	Daysi	E	New York	NY	CHM	4/24/1998	160,784
Perkins	Daniel	R	Colorado Springs	CO	CHM	2/18/2020	126,466
Perlmutter	Mark	A	Ann Arbor	MI	CHM	2/23/2010	75,617
Perrault	Mark	D	Culver City	CA	MED	5/19/2009	145,841
Perry	John	E	Houston	TX	MED	9/24/2014	57,728
Petrosky	Michael	J	Mandeville	LA	CHM	4/24/1998	297,837
Pham	Nghi	D	Fountain Valley	CA	CHM	1/21/1998	121,589
Pham	Vinh	H	Fountain Valley	CA	DEN	5/17/2001	261,559
Philipson	David	.....	Huntington Beach	CA	CHM	11/12/1999	162,193
Pierson	Steven	R	Minneapolis	MN	CHM	8/17/2007	96,094
Pigott	Abu	G	Alameda	CA	CHM	11/12/2013	81,055
Pinson	Jeffrey	R	El Paso	TX	CHM	11/12/1999	119,880
Podry	Robert	J	Simi Valley	CA	CHM	1/21/1998	143,407
Ponder III	Alvin	F	Brooklyn	NY	MED	1/21/1998	222,633
Porter	Jacqueline	R	Washington	DC	POD	1/21/1998	160,053
Potok	Leonard	A	Brooklyn	NY	DEN	3/1/1999	105,181
Potts	David	A	Pasadena	TX	CHM	9/24/2014	28,963
Powell	Carlton	F	Elkins Park	PA	DEN	1/21/1998	145,803
Powers	Thomas	P	Oklahoma City	OK	CHM	2/15/2002	3,725
Pratt	Kerrie	G	Los Angeles	CA	CHM	7/6/2012	55,002
Price	Steven	V	Los Angeles	CA	DEN	1/21/1998	3,931
Pritchard	Doyle	P	El Centro	CA	CHM	11/7/2001	33,054
Prom	Van	S	Modesto	CA	CHM	8/22/2017	73,621
Pulli	Louise	A	Green Lane	PA	CHM	8/22/2017	6,042
Puryear	Cheryll	D	Houston	TX	CHM	2/17/2000	207,427
Pust	Keith	W	Lake Elsinore	CA	CPY	1/21/1998	127,685
Radetic	Peter	M	Eagle	ID	CHM	11/17/2009	98,328
Radtke	Joseph	D	Pueblo	CO	OST	9/24/2014	75,960
Ramirez	Richard	R	Houston	TX	CHM	2/28/2005	35,756
Ramu	Nalaya	.....	Beaumont	CA	DEN	5/14/2002	100,696
Rappa	Richard	J	North Haven	CT	CHM	5/11/2005	69,785
Rashti	Kouros	.....	Encino	CA	DEN	5/14/2002	308,772
Ratliff	Cynthia	.....	Aptos	CA	CHM	2/1/2006	292,160
Ravinski	Deborah	G	Plymouth	MA	CHM	8/12/2016	6,715
Rayas-Felix	Magdalena	.....	Los Angeles	CA	CHM	1/21/1998	74,196
Reddick	David	J	Miami	FL	MED	11/14/2007	163,075
Reese-Thurmond	Elaine	M	Chicago	IL	MED	1/21/1998	171,395
Renz	Howard	W	Astoria	NY	CHM	1/21/1998	96,022

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS AS OF AUGUST 1, 2021—Continued

Last name	First name	MI	City	State	Discipline	Date reported	Amount due
Rey	Jorge	E	Chino	CA	CHM	2/1/2001	34,486
Reyes	Danniell	J	Bethlehem	PA	CHM	7/6/2012	146,609
Rhine	Cecil	T	Lawrenceville	GA	CHM	1/21/1998	99,178
Ribera	Alfred	R	Miami	FL	CHM	3/1/1999	243,981
Rice	William	M	Malden	MA	CHM	8/5/1999	188,566
Richardson	Katherine	J	Oakland	CA	CPY	7/6/2012	449,026
Richardson	Joseph	M	Fayetteville	NC	DEN	1/21/1998	793,443
Richichi	Mark	S	Center Moriches	NY	CHM	2/15/2002	181,448
Richmond	Katherine	L	Cleveland	OH	OST	2/18/2020	182,084
Ringstad	Celia	F	Cameron Park	CA	CHM	12/2/2020	16,058
Ritto	Sharlene	M	Corona	CA	POD	11/12/2013	263,990
Robinson	Glenn	R	Dallas	TX	CHM	3/3/2015	127,772
Robinson	Bruce	K	Jupiter	FL	CHM	1/21/1998	422,950
Rogers	Thomas	C	Santa Ana	CA	CHM	3/1/1999	233,334
Romero	Gloriana	M	Guaynabo	PR	MED	2/8/2017	133,085
Rosenfeld	Jeffre	B	Los Angeles	CA	CHM	1/21/1998	124,614
Roshy	Gary	L	Lake City	FL	CHM	1/21/1998	505,534
Ross	Roger	A	Coraopolis	PA	CHM	1/21/1998	49,070
Rostami	Helena	.....	Calabasas	CA	CHM	5/16/2011	31,041
Rothman	Laura	L	Arroyo Grande	CA	CHM	11/7/2001	10,734
Rubinstein	David	M	Fort Lauderdale	FL	CHM	2/15/2002	68,973
Rushing	Gary	W	Matawan	NJ	CHM	2/15/2002	162,951
Russell	Robert	J	Hollywood	FL	CHM	1/21/1998	10,538
Ryan	Kathleen	.....	West Springfield	MA	POD	5/19/2009	126,838
Saadia	David	M	Brooklyn	NY	DEN	12/2/2020	7,694
Saadia	Sammy	.....	Brooklyn	NY	DEN	7/30/2013	185,309
Sainez	Juana	A	Maryland	NY	MED	2/2/2018	85,920
Sainten	Adrienne	C	San Leandro	CA	CHM	8/26/2009	18,950
Saldana-Quinonez	Salvador	S	La Puente	CA	CHM	7/6/2012	39,908
Sambor	David	H	Lockport	NY	DEN	11/12/1999	10,535
Santa Cruz	Matthew	E	Tampa	FL	CHM	5/19/2009	46,252
Sargent	John	F	Lawndale	CA	CHM	1/21/1998	231,139
Sastre	Armando	A	Cortez	CO	DEN	11/9/2010	107,262
Saunders	Ronald	W	San Antonio	TX	CHM	3/25/2019	34,127
Savage	Robert	L	Harrisburg	PA	DEN	5/31/2018	128,262
Schalk	Ronald	R	Corpus Christi	TX	CHM	5/14/2016	68,612
Schiff	Barbara	S	Woodland Hills	CA	CHM	2/17/2000	137,583
Schow	Kenneth	M	Glendale	CA	CHM	1/21/1998	169,732
Schroder	Anthony	M	Middletown	NY	DEN	1/21/1998	91,207
Schulten	Eric	A	Sarasota	FL	MED	11/2/2000	219,991
Schwartz	Eric	G	Atlantic Beach	NY	DEN	1/21/1998	250,250
Scruggs	Virginia	M	Seneca	SC	OST	11/26/2012	71,356
Scully	Stephen	M	Redondo Beach	CA	CHM	3/1/1999	52,841
Sek	Amaramony	B	Houston	TX	CHM	8/12/2016	23,873
Selko	Robert	L	Morro Bay	CA	CHM	3/1/1999	174,733
Sellitto	Rocco	V	Brooklyn	NY	POD	8/1/2000	263,983
Senatore	Salvatore	.....	Kenilworth	NJ	CHM	11/9/2010	152,354
Sepahbody	Cyrus	J	Asbury Park	NJ	DEN	5/21/2019	69,903
Serratos	Ernesto	.....	Crestline	CA	CHM	1/21/1998	134,890
Shahrestani	Shahriar	.....	Anaheim	CA	CHM	3/1/1999	58,190
Shanefelter III	Charles	D	San Francisco	CA	CHM	1/21/1998	41,928
Shapiro	Michael	S	Newhall	CA	CHM	1/21/1998	129,774
Shapley	Kevin	N	Concord	CA	CHM	3/2/2004	46,084
Shaw	Michael	G	Inglewood	CA	MED	1/21/1998	115,574
Shaw	Linda	J	Gladwyne	PA	DEN	1/21/1998	32,687
Shear	David	S	Staten Island	NY	CHM	1/21/1998	220,815
Sheehan	Alex	J	West Palm Beach	FL	CHM	9/24/2014	46,255
Sheehy	Daniel	J	Middletown	CA	CHM	2/28/2005	66,825
Shin	Hui-Yong	.....	Los Angeles	CA	DEN	1/21/1998	100,412
Shoeleh	Hossien	M	Irvine	CA	DEN	1/21/1998	248,979
Siguenza	Francisco	A	Maspeth	NY	OST	8/12/2016	156,147
Simon	Greg	L	Murrieta	CA	CHM	1/21/1998	234,190
Simpson	Ashley	L	Allston	MA	MED	2/10/2011	343,627
Slusher-Maroudas	Patricia	L	Gilroy	CA	CHM	11/12/2013	11,552
Smith	Stacey	D	Malibu	CA	CHM	8/1/2000	171,955
Smith	Jessica	.....	Downey	CA	CHM	1/21/1998	167,365
Smith	Michael	P	Encinitas	CA	MED	5/21/2019	74,744
Smith	Lee	A	Sterling	VA	CHM	5/31/2018	55,737
Smith	Rusty	A	Santa Barbara	CA	CHM	3/1/1999	10,083
Smith	Michael	D	Bethel Park	PA	DEN	8/5/2004	414,010
Smith	George	.....	Philadelphia	PA	MED	1/19/2017	611,048
Smukler	Evie	L	Los Angeles	CA	CPY	1/21/1998	39,520

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS AS OF AUGUST 1, 2021—Continued

Last name	First name	MI	City	State	Discipline	Date reported	Amount due
Snavely	Danny	H	San Juan Capistrano	CA	CHM	8/21/2015	324,001
Snyder	Mark	S	Roslyn	NY	CHM	12/11/2018	17,306
Sokol	Louis	J	Stuart	FL	CHM	11/12/1999	61,319
Sosa	Richard	.....	Colton	CA	CHM	3/1/1999	97,326
Soto	Vera	A	Fort Lauderdale	FL	OPT	5/7/2008	20,883
Sparks	Stacey	L	Houston	TX	CHM	11/26/2012	80,889
Spears	Timothy	P	Arlington	TX	CHM	3/25/2019	45,258
Spicer	Mary	C	Essex Junction	VT	CHM	7/26/2018	16,616
St Juste	Dominique	.....	Brooklyn	NY	DEN	8/1/2000	113,441
Staley	Judith	M	Annapolis	MD	CPY	4/25/2014	113,566
Stalker	James	W	Castro Valley	CA	CHM	2/10/2011	15,550
Stanbridge	Gary	R	Whittier	CA	CHM	2/28/2005	44,121
Steder	Sandra	.....	San Rafael	CA	CPY	8/5/2004	82,621
Steiner	Jean Marie	.....	Sunnyvale	CA	CHM	5/15/2000	22,460
Steinfeld	Audrey	G	Tarzana	CA	CHM	2/17/2000	267,064
Stephens	Charles	N	Milledgeville	GA	CHM	5/19/2009	58,651
Stevenson	Teresa	M	Los Angeles	CA	CPY	1/21/1998	150,851
Stoltz	William	D	Grants Pass	OR	CHM	5/19/2009	331,617
Stone	Steven	D	San Leandro	CA	CHM	1/21/1998	63,787
Street	James	F	Gainesville	GA	CHM	11/12/2013	84,639
Stricklan	David	K	Haverton	PA	MED	7/26/2018	204,036
Strus	Deborah	A	San Antonio	TX	MED	11/12/2013	129,549
Sturgeon	David	E	Malibu	CA	DEN	11/14/2019	194,991
Sullivan	Daniel	B	Fruita	CO	DEN	5/31/2018	5,244
Sullivan	John	M	Corpus Christi	TX	CHM	8/22/2017	124,090
Sullivan	Joseph	C	Burbank	CA	CHM	1/21/1998	129,405
Sullivan	John	K	Eugene	OR	DEN	8/15/2019	52,504
Taylor	Scott	M	Thousand Oaks	CA	DEN	7/6/2012	179,117
Tchakalian	Leon	J	Van Nuys	CA	CHM	11/7/2001	20,109
Teague	Jenette	.....	Los Angeles	CA	DEN	11/7/2001	151,928
Tennant	Michael	D	Wheat Ridge	CO	CHM	11/12/1999	98,332
Thomas	Randy	L	Fairbanks	AK	DEN	4/24/1998	236,784
Thomas	Gordon	A	Atlanta	GA	CHM	1/21/1998	225,298
Thomas Sr	Robert	B	Stone Mountain	GA	DEN	1/21/1998	475,572
Thompson	Emma	R	Grenada West Indies	FC	MED	2/15/2002	90,259
Tierney	Richard	W	Atlanta	GA	POD	8/5/1999	431,248
Tolbert JR	William	.....	Los Angeles	CA	MED	11/12/2013	79,172
Tomlin-Knight	Teresa	L	Manahawkin	NJ	POD	2/11/2008	83,064
Toporovsky	Nathan	A	White Plains	NY	DEN	2/8/2017	23,139
Townsend	Thomas	E	Fortmill	SC	CHM	4/24/1998	9,498
Tramontana	Raul	E	Cincinnati	OH	OPT	5/14/2002	229,941
Tran	Ngoc	H	Simi Valley	CA	CHM	3/1/1999	109,096
Tran	Huong	N	Carpinteria	CA	CHM	8/12/2016	65,282
Tran	Thuan	K	Henderson	NV	DEN	8/12/2016	103,601
Trumbo	Traig	T	Sunland	CA	CHM	3/1/1999	96,506
Tschabrun	Kevin	L	Holdrege	NE	DEN	3/1/1999	119,800
Tumas	Mary	D	Brielle	NJ	CHM	3/11/2015	90,256
Turner	Nancy	A	San Francisco	CA	CHM	1/21/1998	25,503
Urquhart	Charles	N	Reading	PA	DEN	11/14/2019	71,481
Ussery	Marvin	.....	Los Angeles	CA	DEN	8/12/2016	58,126
Vacula	Nicole	A	Tonawanda	NY	CPY	8/12/2016	58,662
Vafaee	Mohammadali	.....	Santa Monica	CA	CHM	2/28/2005	24,855
Vaishvila	Gail	A	Santa Monica	CA	CHM	8/1/2000	237,141
Valicenti	Patrick	J	Wallkill	NY	DEN	8/5/2004	146,858
Vanrensselaer	Jeffrey	A	Lake Forest	CA	CHM	4/24/1998	101,229
Vardanian	Michael	A	Fullerton	CA	CHM	1/21/1998	118,149
Vega	Javier	J	Rancho Cucamonga	CA	CHM	8/12/2016	53,568
Vernon	Earl	M	Davenport	IA	CHM	1/21/1998	1,794
Vessels	Steven	L	Redlands	CA	CHM	1/21/1998	214,219
Vessey	Ned	.....	Arcadia	CA	CHM	8/1/2000	69,014
Villaverde	John	J	Vestavia	AL	MED	8/22/2017	76,266
Villegas	Isreal	.....	Goddard	KS	CHM	3/25/2019	45,503
Villeta	Javier	G	Kissimmee	FL	MED	3/1/1999	341,503
Viloria-Else	Jenifer	A	North Hollywood	CA	CHM	1/21/1998	187,838
Voboril JR	William	R	Carlisle	IA	POD	8/5/1999	27,277
Vosburgh	Stephen	E	Lutz	FL	CHM	1/21/1998	164,740
Wada	Isao	N	Oakland	CA	CHM	7/6/2012	25,308
Wade	Michael	J	La Quinta	CA	OST	5/19/2009	304,309
Wahdan	Buthayna	W	Jordan	FC	DEN	3/1/1999	170,430
Wainwright	Mark	.....	Oakland	CA	DEN	7/6/2012	32,072
Walcher	Kevin	R	Booker	TX	CHM	5/14/2002	107,718
Walker	Joel	W	Annapolis	MD	MED	8/12/2016	57,343

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS AS OF AUGUST 1, 2021—Continued

Last name	First name	MI	City	State	Discipline	Date reported	Amount due
Wall	Michael	J	Sandy	UT	MED	3/3/2015	142,094
Wallace	Owen	.....	Tonkawa	OK	CHM	1/21/1998	53,743
Walsh	Richard	J	Ventura	CA	CHM	1/21/1998	41,976
Walton	Teri	R	Pasadena	CA	CPY	8/5/1999	175,864
Ward	Fairfield	A	Hampton	VA	DEN	8/12/2016	36,946
Warner	Arthur	.....	San Ramon	CA	DEN	5/20/2004	132,648
Warner	Rick	A	Aurora	CO	CHM	11/7/2001	110,908
Washington	George	L	Baldwyn	MS	DEN	5/7/2013	589,338
Washington	Arthur	C	Houston	TX	MED	9/24/2014	24,213
Washington-Houzell	Patricia	L	Lakewood	CA	POD	8/10/2001	561,151
Weatherly	Darrel	F	Jacksonville	FL	OST	5/16/2011	605,593
Weil	Mitchell	A	San Clemente	CA	MED	1/21/1998	68,299
Weisheit-Dasylva	Lyn	D	Marietta	GA	CHM	3/1/1999	59,956
Welch	Ronald	B	Sandpoint	ID	CHM	3/1/1999	102,173
Westing	Denise	D	Alameda	CA	CHM	1/21/1998	121,583
Whedbee	Joseph	I	Redlands	CA	DEN	5/14/2002	144,015
Whigham	Gwendolyn	E	Houston	TX	CHM	3/1/1999	69,018
Whipkey	Douglas	G	Jensen Beach	FL	CHM	1/21/1998	139,400
Whitaker	Aaron	T	Washington	DC	DEN	5/19/2009	215,511
White	Judith	U	Huntington Beach	CA	CHM	1/21/1998	39,062
Whittlesey	James	B	Novato	CA	CHM	1/21/1998	58,546
Williams	Pamela	A	Buena Park	CA	PUB	1/21/1998	41,437
Williams	Simeon	J	Washington	DC	MED	3/1/1999	114,885
Williams	Johnnie	.....	Hayward	CA	MED	3/25/2019	501,103
Williams	Brett	S	Los Angeles	CA	MED	5/14/2016	189,694
Williams	Duane	A	Livermore	CA	CHM	1/21/1998	129,743
Williams	David	L	Pasadena	CA	POD	1/21/1998	96,143
Winston	Gregg	O	Pompano Beach	FL	CHM	3/1/1999	208,726
Wong	Wan Sing	V	South San Francisco	CA	POD	10/30/2003	207,439
Wong	Matt	S	Mountain View	CA	CHM	11/9/2010	49,047
Wright-Benford	Sheila	A	Southfield	MI	POD	2/8/2017	63,078
Yeates	Terrance	C	Brooklyn	NY	DEN	1/21/1998	231,444
Yniguez	Alma	B	Newark	CA	CHM	2/20/2007	253,942
Yoste	Joseph	.....	Brownsville	TX	DEN	8/12/2016	105,079
Yurick	Richard	.....	Bay St Louis	MS	CHM	11/12/2013	62,939
Yurkovich	Mark	R	Bentleyville	PA	CPY	8/12/2016	59,379
Zaun	Timothy	M	Lakewood	OH	DEN	1/21/1998	202,026
Zeitsoff-Mahar	Deborah	L	Aptos	CA	CHM	1/21/1998	140,936
Zucker	Ronald	G	Long Beach	NY	CHM	4/24/1998	229,163
Totals	671	.....	.....		.....	.....	98,275,936

[FR Doc. 2021–21648 Filed 10–4–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Renewal of a Currently Approved Information Collection for the Energy Efficiency and Conservation Block Grant Financing Programs

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years a currently approved collection of information with the Office of Management and Budget (OMB). The information collection request, Energy Efficiency and Conservation Block Grant Program, was previously approved under OMB Control No. 1910–5150 and its current expiration date is September 30, 2021. The proposed collection will collect information on the status of Grantee activities, expenditures, and results, to ensure that program funds are being used appropriately, effectively, and expeditiously.

DATES: Comments regarding this collection must be received on or before November 4, 2021. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at (202) 395–4650.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function, or to: James Carlisle, EE–5W, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585, Email: *james.carlisle@ee.doe.gov*.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to: James Carlisle, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585, Phone: (202) 287–1724, Fax: (412) 386–5835, Email: *james.carlisle@ee.doe.gov*.

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) *OMB No.:* 1910–5150; (2) *Information Collection Request Title:* Energy Efficiency and Conservation Block Grant Program Financing Programs; (3) *Type of Review:* Renewal

of a Currently Approved Information Collection; (4) *Purpose:* To collect information on the status of Financing Program activities, expenditures, and results, to ensure that program funds are being used appropriately, effectively and expeditiously; (5) *Annual Estimated Number of Respondents:* 54; (6) *Annual Estimated Number of Total Responses:* 101; (7) *Annual Estimated Number of Burden Hours:* 303; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $12,120. Respondents, total responses, burden hours and the annual cost burden have all been reduced over time because of the retirement of grants, fewer programs and a lessened burden on reporting and recordkeeping costs.

Statutory Authority: Title V, Subtitle E of the Energy Independence and Security Act (EISA), Public Law 110–140 as amended (42 U.S.C. 17151 *et seq.*).

Signing Authority

This document of the Department of Energy was signed on September 27, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary and Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on September 29, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–21573 Filed 10–4–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Supply of Molybdenum-99 (Mo-99) Produced Without the Use of Highly Enriched Uranium (HEU)

AGENCY: National Nuclear Security Administration (NNSA), Department of Energy (DOE).

ACTION: Request for information (RFI).

SUMMARY: DOE, in accordance with Section 3174 of the American Medical Isotopes Production Act of 2012 (AMIPA), is preparing for a Secretarial certification regarding the sufficiency of supply of non-HEU based Mo-99. DOE is seeking public input as part of its certification development process and analysis to determine the sufficiency of Mo-99 supply to meet U.S. patient needs.

DATES: DOE will accept comments, data, and information in response to this RFI on or before November 4, 2021.

ADDRESSES: Interested persons may submit comments via email to the Office of Conversion at *OfficeofConversion@nnsa.doe.gov.*

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing coronavirus (COVID–19) pandemic. DOE is currently accepting only electronic submissions at this time.

If a commenter finds that this change poses an undue hardship, please contact the Office of Conversion at *OfficeofConversion@nnsa.doe.gov* to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier. No facsimiles (faxes) will be accepted.

Instructions: All submissions received must include the agency name and title for this RFI in Microsoft Word or PDF file format and avoid the use of special characters or any form of encryption.

FOR FURTHER INFORMATION CONTACT: Requests for additional information may be sent to Max Postman in the Office of Conversion at 240–246–5564, *Max.Postman@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Authority and Background

The U.S. medical community depends on a reliable supply of the radioisotope Mo-99 for nuclear medical diagnostic procedures. Approximately 80 percent of these procedures depend on the use of technetium-99m (Tc-99m), a decay product of Mo-99. Tc-99m is used in over 40,000 medical procedures every day in the United States. Its primary uses include diagnosing heart disease and cancer, as well as studying organ structure and function. Historically, the United States has not had the capability to produce Mo-99 domestically and, until 2018, imported 100 percent of its supply from international producers, some of which supply was produced using targets fabricated with proliferation-sensitive HEU.

AMIPA (Subtitle F, Title XXXI of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–139)), enacted on January 2, 2013, amended Section 134 of the Atomic Energy Act of 1954 (42 U.S.C. 2160d) by striking subsection c. and inserting language that prohibits the Nuclear Regulatory Commission (NRC) from issuing a license for the export of HEU from the United States for the purposes of medical isotope production, effective seven years after enactment of AMIPA, subject to a certification regarding the sufficiency of Mo-99 supply in the United States.

Section 3174 of AMIPA requires the Secretary of Energy to either jointly certify, with the Secretary of Health and Human Services, that there is a sufficient supply of Mo-99 produced without the use of HEU available to meet U.S. patient needs, and that it is not necessary to export U.S.-origin HEU for the purposes of medical isotope production in order to meet U.S. patient needs, or, to unilaterally certify that there is insufficient global supply of Mo-99 produced without the use of HEU available to satisfy the domestic market, and that the export of U.S.-origin HEU for the purposes of medical isotope production is the most effective temporary means to increase the supply of Mo-99 to the domestic U.S. market, thereby delaying the effective date of the export license ban for up to six years.

DOE published a **Federal Register** notice (84 FR 65378) on November 27, 2019 requesting public comment on the status of Mo-99 supplies for U.S. patients in preparation for a Secretarial certification regarding the sufficiency of supply of non-HEU based Mo-99. The Secretary of Energy certified on January 2, 2020, that, at the time, there was an insufficient global supply of Mo-99 produced without the use of HEU and that the export of U.S.-origin HEU for the purposes of medical isotope production was the most effective temporary means to increase the supply of Mo-99 to the domestic U.S. market. This certification was published in the **Federal Register** on January 21, 2020 (85 FR 3362). This certification was effective for no more than two years from the effective date of January 2, 2020. The **Federal Register** notice stated that DOE would conduct periodic reviews of the domestic U.S. and global Mo-99 markets and would work toward a certification to Congress regarding the

sufficiency of supply as soon as the statutory conditions are satisfied.

DOE must issue a new certification on or before January 2, 2022. In accordance with AMIPA and to ensure public review and comments, the development of the certification is being announced in the **Federal Register**.

II. Issues on Which DOE Seeks Comment and Information

DOE is seeking information from interested parties on the status of Mo-99 supplies for U.S. patients. DOE requests that commenters fully explain any assumptions that underlie their reasoning. DOE also requests that commenters provide underlying data or other information sufficient to allow DOE to review and verify any of the assumptions, calculations, or views expressed by the commenters. DOE specifically invites responses to the following questions:

(1) Do current supplies of Mo-99 meet U.S. patient demand?

(2) Do current supplies of non-HEU based Mo-99 meet U.S. patient demand?

(3) Since the publication of DOE's November 27, 2019 **Federal Register** notice requesting public comment on the status of Mo-99 supplies for U.S. patients (84 FR 65378) have there been shortages of Mo-99 in the United States? If so, how severe, how often, and how did shortages impact patient care? What caused such shortages?

(4) How would extending the period that the NRC may issue HEU export licenses for medical isotope production impact the supply of Mo-99 in the United States?

(5) How would enacting a ban on the export of HEU for medical isotope production impact the supply of Mo-99 in the United States?

In addition, DOE welcomes information on other topics that interested parties consider significant in preparing for the Secretarial certification.

Confidential Business Information: According to 10 CFR 1004.11, any person submitting information he or she believes to be confidential and exempt from public disclosure should submit via email two well-marked copies: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Signing Authority

This document of the Department of Energy was signed on September 29, 2021, by Kasia Mendelsohn, Acting Deputy Administrator for Defense Nuclear Nonproliferation, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on September 30, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–21634 Filed 10–4–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21–259–000.
Applicants: Mililani I Solar, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Mililani I Solar, LLC.
Filed Date: 9/29/21.
Accession Number: 20210929–5010.
Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: EG21–260–000.
Applicants: Lanikuhana Solar, LLC.
Description: Self-Certification of Exempt Wholesale Generator Status of Lanikuhana Solar, LLC.
Filed Date: 9/29/21.
Accession Number: 20210929–5018.
Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: EG21–261–000.
Applicants: Ventress Solar Farm 1, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Ventress Solar Farm 1, LLC.
Filed Date: 9/29/21.
Accession Number: 20210929–5053.
Comment Date: 5 p.m. ET 10/20/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2034–008.
Applicants: Duke Energy Indiana, Inc.
Description: Notice of Change in Status of Duke Energy Indiana, LLC.
Filed Date: 9/28/21.
Accession Number: 20210928–5155.
Comment Date: 5 p.m. ET 10/19/21.

Docket Numbers: ER21–2952–000.
Applicants: Public Service Company of New Mexico.
Description: § 205(d) Rate Filing: PNM, Pattern NM Wind, Red Cloud Wind, Clines Corners Wind to be effective 11/29/2021.
Filed Date: 9/28/21.
Accession Number: 20210928–5149.
Comment Date: 5 p.m. ET 10/19/21.

Docket Numbers: ER21–2953–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: UMPA Agmt Re SS of Ancillary Serv Sched 5 and/or 6 to be effective 9/27/2021.
Filed Date: 9/28/21.
Accession Number: 20210928–5152.
Comment Date: 5 p.m. ET 10/19/21.

Docket Numbers: ER21–2954–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2021–09–29_SA 3700 MEC-Heartland Divide Wind II FSA (J583) to be effective 11/29/2021.
Filed Date: 9/29/21.
Accession Number: 20210929–5028.
Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2955–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2021–09–29_SA 3701 MEC-Walleye Wind FSA (J569) to be effective 11/29/2021.
Filed Date: 9/29/21.
Accession Number: 20210929–5030.
Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2956–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2021–09–29_SA 3702 MEC-Emmons-Logan Wind FSA (J302 J503) to be effective 11/29/2021.
Filed Date: 9/29/21.
Accession Number: 20210929–5039.
Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2957–000.
Applicants: Avista Corporation.
Description: § 205(d) Rate Filing: Avista Corp RS T1188, Interim Interconnected Systems Agmt BPA to be effective 10/1/2021.
Filed Date: 9/29/21.
Accession Number: 20210929–5052.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2958–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to OA and RAA re: Quarterly Membership Lists to be effective 6/22/2021.

Filed Date: 9/29/21.

Accession Number: 20210929–5065.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2959–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 3395; Queue No. R33 to be effective 9/6/2012.

Filed Date: 9/29/21.

Accession Number: 20210929–5072.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2960–000.

Applicants: Avista Corporation.

Description: Tariff Amendment: Avista Corp Cancellation of RS 184 BPA Exchange Agreement to be effective 10/1/2021.

Filed Date: 9/29/21.

Accession Number: 20210929–5075.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2961–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2021–09–29 LPL Hold Harmless to be effective 10/1/2021.

Filed Date: 9/29/21.

Accession Number: 20210929–5080.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2962–000.

Applicants: PacifiCorp.

Description: Notice of Cancellation of Service Agreement Nos. 307 and 436 with Arizona Public Service Company of PacifiCorp.

Filed Date: 9/29/21.

Accession Number: 20210929–5086.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2963–000.

Applicants: CLN Energy LLC.

Description: Baseline eTariff Filing: Market-Based Rate Tariff Application to be effective 10/1/2021.

Filed Date: 9/29/21.

Accession Number: 20210929–5092.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2964–000.

Applicants: Sterlington Power LLC.

Description: Tariff Amendment: Notice of Cancellation of Market Based Rate Tariff to be effective 9/30/2021.

Filed Date: 9/29/21.

Accession Number: 20210929–5093.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2965–000.

Applicants: Atlantic City Electric Company, Delmarva Power & Light Company, PECO Energy Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Atlantic City Electric Company submits tariff filing per 35.13(a)(2)(iii: ACE, Delmarva and PECO Revisions to OATT, Atts. H–1A, H–3D, and H–7A to be effective 1/1/2022.

Filed Date: 9/29/21.

Accession Number: 20210929–5096.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2965–001.

Applicants: Atlantic City Electric Company, Delmarva Power & Light Company, PECO Energy Company, PJM Interconnection, L.L.C.

Description: Tariff Amendment: Atlantic City Electric Company submits tariff filing per 35.17(b): Amendment to ACE, Delmarva and PECO Revisions to Atts. H–1A, H–3D, and H–7A to be effective 1/1/2022.

Filed Date: 9/29/21.

Accession Number: 20210929–5103.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2966–000.

Applicants: Illinois Power Generating Company, Bracewell LLP.

Description: Baseline eTariff Filing: Illinois Power Generating Company submits tariff filing per 35.1: Filing of Limited Use Agreement to be effective 11/29/2021.

Filed Date: 9/29/21.

Accession Number: 20210929–5100.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2967–000.

Applicants: Strategic Energy Capital Fund, LP.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization.

Filed Date: 9/29/21.

Accession Number: 20210929–5111.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2968–000.

Applicants: Upper Michigan Energy Resources Corporation.

Description: § 205(d) Rate Filing: Filing of Reactive Supply Service Rate Schedule FERC No. 1 to be effective 9/30/2021.

Filed Date: 9/29/21.

Accession Number: 20210929–5115.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2969–000.

Applicants: Avista Corporation.

Description: § 205(d) Rate Filing: Avista Corp LTF PTP Agreement T–1189 to be effective 10/1/2021.

Filed Date: 9/29/21.

Accession Number: 20210929–5122.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21–2970–000.

Applicants: Peninsula Power, LLC.

Description: Tariff Amendment: Notice of Cancellation of Market Based Rate Tariff to be effective 9/30/2021.

Filed Date: 9/29/21.

Accession Number: 20210929–5136.

Comment Date: 5 p.m. ET 10/20/21.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR21–9–000.

Applicants: North American Electric Reliability Corporation.

Description: Amendment to August 24, 2021 request of NERC for acceptance of 2022 Business Plans and Budgets of NERC and Regional Entities and for Approval of Proposed Assessments to Fund Budgets under RR21–9.

Filed Date: 9/29/21.

Accession Number: 20210929–5105.

Comment Date: 5 p.m. ET 10/13/21.

Docket Numbers: RR21–10–000.

Applicants: North American Electric Reliability Corporation.

Description: Petition of the North American Electric Reliability Corporation and the Regional Entities for Approval of Revisions to the NERC Rules of Procedure.

Filed Date: 9/29/21.

Accession Number: 20210929–5133.

Comment Date: 5 p.m. ET 10/20/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–21702 Filed 10–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR21–12–000]

Tesoro Logistics Northwest Pipeline LLC; Notice of Petition for Declaratory Order

Take notice that on September 24, 2021, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2019) and section 284.502(b)(1) of the Commission's regulations,[1] Tesoro Logistics Northwest Pipeline LLC (TLNP), a subsidiary of MPLX LP, hereby requests (Petition) that the Commission issue a declaratory order approving various requested rulings related to a proposed expansion (Expansion) of its SLC Core Pipeline system that, following the Expansion, will be capable of transporting crude oil from Fort Laramie Station, Wyoming to Wahsatch Station, Utah. TLNP respectfully requests that the Commission act on this Petition no later than December 23, 2021 so that TLNP and its shippers may receive the certainty necessary for TLNP to move forward with the development of the Expansion and place it into service.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene, or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on October 25, 2021.

Dated: September 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–21700 Filed 10–4–21; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 284.502(b)(1) (2020).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: CP21–502–000.
Applicants: Midcontinent Express and Enable Oklahoma.
Description: Joint Abbreviated Application of Midcontinent Express Pipeline LLC and Enable Oklahoma Intrastate Transmission, LLC for Partial Lease Capacity Abandonment Authorization.
Filed Date: 09/28/21.
Accession Number: 20210928–5083.
Comments Due: 5 p.m. ET 10/19/21.

Docket Numbers: RP21–1151–000.
Applicants: Young Gas Storage Company, Ltd.
Description: Compliance filing: Operational Purchase and Sale Report 2021 to be effective N/A.
Filed Date: 9/28/21.
Accession Number: 20210928–5042.
Comments Due: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1152–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—ESS—Six One Commodities to be effective 10/1/2021.
Filed Date: 9/28/21.
Accession Number: 20210928–5063.
Comments Due: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1153–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (APS Oct 2021) to be effective 10/1/2021.
Filed Date: 9/28/21.
Accession Number: 20210928–5075.
Comments Due: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1154–000.
Applicants: Enable Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Enable Gas Transmission, LLC submits tariff filing per 154.403(d)(2): Fuel Tracker Filing—Effective November 1 2021 to be effective 11/1/2021.
Filed Date: 9/28/21.
Accession Number: 20210928–5081.
Comments Due: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1155–000.
Applicants: Enable Mississippi River Transmission, LLC.
Description: § 4(d) Rate Filing: 2021 MRT Annual Fuel Filing to be effective 11/1/2021.
Filed Date: 9/28/21.
Accession Number: 20210928–5082.
Comments Due: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1156–000.
Applicants: Texas Eastern Transmission, LP.
Description: Compliance filing: Appalachia to Market Project (CP20–436) In-Service Compliance Filing to be effective 11/1/2021.
Filed Date: 9/28/21.
Accession Number: 20210928–5098.
Comments Due: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1157–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Pipeline Safety and Greenhouse Gas Cost Adjustment Mechanism—2021 to be effective 11/1/2021.
Filed Date: 9/28/21.
Accession Number: 20210928–5120.
Comments Due: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1158–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Volume No. 2—ConEd SP367660 & NextEra SP370331 to be effective 11/1/2021.
Filed Date: 9/28/21.
Accession Number: 20210928–5125.
Comments Due: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1159–000.
Applicants: Eastern Gas Transmission and Storage, Inc.
Description: § 4(d) Rate Filing: EGTS—2021 Annual EPCA to be effective 11/1/2021.

Filed Date: 9/29/21.
Accession Number: 20210929–5016.
Comments Due: 5 p.m. ET 10/12/21.
Docket Numbers: RP21–1160–000.
Applicants: Eastern Gas Transmission and Storage, Inc.
Description: § 4(d) Rate Filing: EGTS—2021 Annual TCRA to be effective 11/1/2021.
Filed Date: 9/29/21.
Accession Number: 20210929–5020.
Comments Due: 5 p.m. ET 10/12/21.
Docket Numbers: RP21–1161–000.
Applicants: Stagecoach Pipeline & Storage Company LLC.
Description: § 4(d) Rate Filing: Re-collation Filing to be effective 11/1/2021.
Filed Date: 9/29/21.
Accession Number: 20210929–5024.
Comments Due: 5 p.m. ET 10/12/21.
Docket Numbers: RP21–1162–000.
Applicants: Arlington Storage Company, LLC.
Description: § 4(d) Rate Filing: Re-Collation Filing to be effective 11/1/2021.
Filed Date: 9/29/21.
Accession Number: 20210929–5031.
Comments Due: 5 p.m. ET 10/12/21.
Docket Numbers: RP21–1163–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Compliance filing: AGT 2021 OFO Penalty Disbursement Report to be effective N/A.
Filed Date: 9/29/21.
Accession Number: 20210929–5032.
Comments Due: 5 p.m. ET 10/12/21.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–21703 Filed 10–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11834–080]

Brookfield White Pine Hydro, LLC; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Application for Temporary Variance of Minimum Flow Requirements.

b. *Project No:* 11834–080.

c. *Date Filed:* September 21, 2021.

d. *Applicant:* Brookfield White Pine Hydro, LLC (licensee).

e. *Name of Project:* Upper and Middle Dams Storage Hydroelectric Project.

f. *Location:* The project is located on Rapid River in Oxford and Franklin counties, Maine.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Kelley Maloney, Manager, Licensing and Compliance, Brookfield White Pine Hydro, LLC, 150 Main Street, Lewiston, ME 04240, Phone: (207) 755–5605.

i. *FERC Contact:* Jonathan Schram, (202) 502–8264, *jonathan.schram@ferc.gov*.

j. *Deadline for filing comments, motions to intervene, and protests:* October 29, 2021.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docsfiling/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P–11834–080. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee requests a temporary variance of the minimum flow requirements in the Rapid River below the Middle Dam development due to drought conditions. License Article 402, in part, requires the licensee to release a minimum flow of 472 cubic feet per second (cfs) from September 16 through the start of the spring refill of Richardson Lake. The licensee explains that due to ongoing drought conditions, it is concerned that there might not be enough water storage to sustain brook trout through their fall spawning season under the current license-required minimum flows. Therefore, in order to conserve as much water as possible, the licensee is requesting Commission approval to reduce the minimum flow below Middle Dam to 310 cfs until April 23, 2022, at which time a minimum flow of 472 cfs would be released in accordance with its license requirements. Should the 2022 spring refill of Richardson Lake start, or have already started by April 23, 2022, then the licensee would instead release a minimum flow of 382 cfs as required by license Article 402.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit

comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: September 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–21699 Filed 10–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP21–1146–000]

Southwest Gas Storage Company; Notice of Petition for Declaratory Order

Take notice that on September 22, 2021, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2019) and section 284.502(b)(1) of the Commission's regulations,[1] Southwest Gas Storage Company (Southwest Gas Storage or Petitioner) filed a petition for declaratory order (petition) requesting that the Commission issue a declaratory order granting Southwest Gas Storage authorization to charge market-based rates for proposed no-notice storage, firm parking, firm loan and interruptible gas balancing services, all as more fully explained in its petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene, or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on October 22, 2021.

Dated: September 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–21701 Filed 10–4–21; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 284.502(b)(1) (2020).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–496–000]

NFEnergía LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on September 15, 2021, NFEnergía LLC (NFEnergía), 111 W 19th Street, New York, New York 10011, filed in Docket No. CP21–496–000 an abbreviated application under Section 3(a) of the Natural Gas Act (NGA), Parts 153 and 380 of the Commission's regulations, and the Order issued by the Commission on March 19, 2021 in Docket No. CP20–466–000 (Order on Show Cause),[1] requesting authorization to operate the San Juan Micro-Fuel Handling Facility (MFH Facility), a liquefied natural gas (LNG) import and regasification facility, located at the Port of San Juan in Puerto Rico, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this filing may be directed to Cameron MacDougall, General Counsel, NFEnergía LLC, 111 W 19th Street, New York, New York, 10011, by phone at (202) 479–1522, or by email at *cmacdougall@fortress.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[2] within 90 days of this Notice the Commission staff will either:

[1] New Fortress Energy LLC, 174 FERC ¶ 61,207 (2021) (Order on Show Cause), notice of reh'g denial, 175 FERC ¶ 62,108 (2021), reh'g denial confirmed, 176 FERC ¶ 61,031 (2021) (Rehearing Order).

[2] 18 CFR (Code of Federal Regulations) § 157.9.

Complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are two ways to become involved in the Commission's review of this project: You can file comments on the project, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on October 20, 2021.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please submit your comments on or before October 20, 2021.

There are three methods you can use to submit your comments to the Commission. In all instances, please reference the project docket number CP21–496–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov)* under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You may file a paper copy of your comments by mailing them to the address below.[3] Your written comments must reference the project docket number (CP21–496–000).

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.* Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[4] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is October 20, 2021. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as the your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP21–496–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov)* under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf.;* or

(2) You may file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below.[7] Your motion to intervene must reference the project docket number CP21–496–000.

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Motions to intervene must be served on the applicant either by mail at: Cameron MacDougall, General Counsel, NFEnergía LLC, 111 W 19th Street, New York, New York, 10011, or by email at *cmacdougall@fortress.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [8] motions to intervene are automatically granted by

[3] Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

[4] 18 CFR 385.102(d).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

[7] Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

[8] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

operation of Rule 214(c)(1).[9] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[10] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on Wednesday, October 20, 2021.

Dated: September 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–21704 Filed 10–4–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2021–0637; FRL–9089–01–OGC]

Proposed Consent Decree; Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with the Clean Air Act, as amended (CAA or the Act), notice is given of a proposed consent decree in *Center for Biological Diversity, et al.* v. *Regan,* No. 4–21–cv–02498–JST (N.D. CA.). On April 7, 2021 and May 26, 2021, the Center for Biological Diversity and the Center for Environmental Health (collectively, Plaintiffs) filed a complaint and a first amended complaint, respectively, in the United States District Court for the Northern District of California, alleging that the Administrator of the United States Environmental Protection Agency (EPA) failed to perform certain nondiscretionary duties.

DATES: Written comments on the proposed consent decree must be received by *November 4, 2021.*

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2021–0637, online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Additional Information about Commenting on the Proposed Consent Decree'' heading under the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov,* as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID–19.

FOR FURTHER INFORMATION CONTACT: Derek Mills, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone (202) 564–3341; email address *mills.derek@epa.gov.*

SUPPLEMENTARY INFORMATION: First, Plaintiffs allege that EPA failed to issue a finding of failure to submit for state implementation plans (SIPs) addressing reasonably available control technology (RACT) for volatile organic compounds (VOC) from sources covered by the 2016 Oil and Gas control techniques guideline (CTG) for the 2015 ozone National Ambient Air Quality Standards (NAAQS) for states and areas listed in the First Amended Complaint within six months after the SIP due date. Second, Plaintiffs allege that EPA failed to take final action to approve or disapprove, in whole or in part, Oil and Gas CTG SIPs for the 2008 NAAQS submitted by various states for the nonattainment areas listed in the First Amended Complaint. The proposed consent decree would establish deadlines for EPA to take specified actions.

I. Obtaining a Copy of the Proposed Consent Decree

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2021–0637) contains a copy of the proposed consent decree.

The electronic version of the public docket for this action contains a copy of the proposed consent decree and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About the Proposed Consent Decree

The proposed consent decree, which would fully resolve the current lawsuit cited above filed by the Center for Biological Diversity and the Center for Environmental Health, would require the EPA to take action under the CAA to make a finding of failure to submit for SIPs addressing RACT for VOC from sources covered by the 2016 Oil and Gas CTG pursuant to 42 U.S.C. 7410(k)(1)(B) for the 2015 ozone NAAQS for certain states and areas as listed in the proposed consent decree (Pennsylvania and New York), unless the state provides the SIP submission and it is deemed complete prior to EPA issuing the finding. The proposed consent decree would also require the EPA, pursuant to CAA sections 110(k)(2)–(4), 42 U.S.C. 7410(k)(2)–(4), to take final

[9] 18 CFR 385.214(c)(1).

[10] 18 CFR 385.214(b)(3) and (d).

action to approve or disapprove, in whole or in part a SIP submission addressing the 2016 Oil and Gas CTG submitted by California to address various areas as listed in the proposed consent decree.

Under the terms of the proposed consent decree, EPA shall sign a notice or notices finding that the states identified as such in the consent decree have failed to submit a SIP or SIP revision addressing RACT for VOC sources covered by the Oil and Gas RACT CTG for the 2015 ozone NAAQS for the nonattainment area or state listed in the proposed consent decree by the established deadline, unless the state provides the SIP submission and it is deemed complete prior to EPA issuing the finding. In addition, under the proposed consent decree, EPA shall sign a notice or notices of final rulemaking to approve, disapprove, conditionally approve, or approve in part and conditionally approve or disapprove in part, the Oil and Gas RACT CTG SIP submission for the areas as listed and identified as such in the proposed consent decree by the established deadline.

In accordance with section 113(g) of the CAA, for a period of thirty (30) days following the date of publication of this document, the Agency will accept written comments relating to the proposed consent decree. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

III. Additional Information About Commenting on the Proposed Consent Decree

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2021–0637, via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Gautam Srinivasan,

Associate General Counsel.

[FR Doc. 2021–21564 Filed 10–4–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9107–01–OA]

Local Government Advisory Committee (LGAC) and Small Communities Advisory Subcommittee (SCAS) Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), EPA herby provides notice of a meeting for the Local Government Advisory Committee (LGAC) and the Small Communities Advisory Subcommittee (SCAS) on the date and time described below. This meeting will be open to the public. For information on public attendance and participation, please see the registration information under **SUPPLEMENTARY INFORMATION**. Due to unforeseen administrative circumstances, EPA is announcing this meeting with less than 15 calendar days' notice.

DATES: The LGAC and the SCAS will meet virtually October 15th, 2021 starting at 12:00 p.m. through 4:30 p.m. Eastern Time.

FOR FURTHER INFORMATION CONTACT: Paige Lieberman, Designated Federal Officer (DFO), at *LGAC@epa.gov* or 202–564–3115.

Information on Accessibility: For information on access or services for individuals requiring accessibility accommodations, please contact Paige Lieberman by email at *LGAC@epa.gov.* To request accommodation, please do so five (5) business days prior to the meeting, to give EPA as much time as possible to process your request.

SUPPLEMENTARY INFORMATION: This will convene the first LGAC and SCAS meeting since EPA's August 2021 appointment of new and returning members. During the meeting, EPA will share its vision for the agency over the next several years, including providing clean and safe water to all, safeguarding and revitalizing communities, addressing climate change, advancing environmental justice, and ensuring the safety of chemicals for people and the environment. LGAC and SCAS members will discuss workgroups and future plans to address EPA's priorities.

All interested persons are invited to attend and participate. The LGAC and SCAS will hear comments from the public from 3:45–4:15 p.m. (EDT). Individuals or organizations wishing to address the Committee or Subcommittee will be allowed a maximum of five (5)

minutes to present their point of view. Also, written comments should be submitted electronically to *LGAC@epa.gov* for the LGAC and SCAS. Please contact the DFO at the email listed under **FOR FURTHER INFORMATION CONTACT** to schedule a time on the agenda by October 12, 2021. Time will be allotted on a first-come first-served basis, and the total period for comments may be extended if the number of requests for appearances requires it.

Registration: The meeting will be held virtually through an online audio and video platform. Members of the public who wish to participate should register through the LGAC website at *https://www.epa.gov/ocir/local-government-advisory-committee-lgac* or by contacting the Designated Federal Officer (DFO) at *LGAC@epa.gov* by October 12, 2021. The agenda and other supportive meeting materials will be available online at *https://www.epa.gov/ocir/local-government-advisory-committee-lgac* and can be obtained by written request to the DFO. In the event of cancellation for unforeseen circumstances, please contact the DFO or check the website above for reschedule information.

Dated: September 29, 2021.

Julian Bowles,

Director, State and Local Relations, Office of Congressional and Intergovernmental Relations.

[FR Doc. 2021–21566 Filed 10–4–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX; FR ID 51257]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before December 6, 2021. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Inmate Calling Services, 2021 One-Time Data Collection.

Form Number(s): FCC Form 2302(a) and FCC Form 2302(b).

Type of Review: New collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 20 respondents; 20 responses.

Estimated Time per Response: 245 hours on average.

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in sections 1, 4(i)-4(j), 201(b), 218, 220, 225, 255, 276, 403, and 617 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i)-(j), 201(b), 218, 220, 225, 255, 276, 403 and 617.

Total Annual Burden: 4,900 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Protective Order in the Commission's inmate calling services (ICS) proceeding, WC Docket 12–375, 28 FCC Rcd 16954 (WCB 2013), provides confidential treatment for the proprietary information submitted by (ICS providers in response to the Commission's directives. The Commission will treat as presumptively confidential any particular information identified as confidential by the provider in accordance with the Freedom of Information Act and Commission rules. Each confidential document should be stamped and submitted to the Secretary's Office with an accompanying cover letter, as specified by the Protective Order.

Needs and Uses: In the 2021 ICS Order, WC Docket No. 12–375, FCC 21–60, 86 FR 40682, the Commission continued its reform of the ICS industry by, among other things, directing the Commission's Wireline Competition Bureau (WCB) and Office of Economics and Analytics (OEA) (collectively, WCB/OEA) to collect data and other information regarding ICS providers' operations, costs, demands, and revenues. The Commission explained that it would use this Third Mandatory Data Collection to set permanent interstate and international ICS provider-related rate caps that more closely reflect providers' costs of serving correctional facilities. The Commission also emphasized that those data would enable it to evaluate and, if warranted, revise the current ancillary service charge caps.

The Commission delegated authority to WCB/OEA to implement the Third Mandatory Data Collection—including determining and describing the types of information to require providers to submit regarding their operations, costs, demand, and revenues—and directed WCB/OEA to develop a template and instructions for the collection.

Pursuant to their delegated authority, WCB/OEA drafted proposed instructions, a template, and a certification form for the Third Mandatory Data Collection. *See* Third Mandatory Data Collection Instructions, available for download at *http://www.fcc.gov/sites/default/files/third_mandatory_data_collection_instructions.docx*. Under WCB/OEA's proposals, ICS providers would be required to submit the required data using a reporting template, to be filed through the Commission's electronic comment filing system (ECFS). The proposed template consists of a Word document (Appendix A to the instructions) for responses requiring narrative information and Excel spreadsheets (Appendix B to the instructions) for responses that require specific numbers or information. ICS

providers must also submit an audited financial statement or report for each Year from 2019 through 2021, and a signed certification of truthfulness, accuracy, and completeness. The instructions, template, and certification form will simplify compliance with, and reduce the burden of, this data collection. These proposed documents will be submitted for approval by the Office of Management and Budget as FCC Form 2302(a) and FCC Form 2302(b).

On September 22, 2021, WCB/OEA issued a Public Notice seeking comment on all aspects of the proposed collection, including the draft instructions, template, and certification form. Notice of this document is being published elsewhere in this issue of the **Federal Register**. WCB/OEA will consider comments submitted in response to both of these **Federal Register** documents in finalizing this information collection prior to submitting the documents to the Office of Management and Budget.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–21782 Filed 10–4–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

FDIC Advisory Committee on Community Banking; Notice of Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Advisory Committee on Community Banking. The Advisory Committee will provide advice and recommendations on a broad range of policy issues that have particular impact on small community banks throughout the United States and the local communities they serve. The meeting is open to the public. Out of an abundance of caution related to current and potential coronavirus developments, the public's means to observe this meeting of the Advisory Committee on Community Banking will be via a Webcast live on the internet. In addition, the meeting will be recorded and subsequently made available on-demand approximately two weeks after the event. The web addresses for viewing the live event and the recording are provided below in the **ADDRESSES** paragraph.

DATES: Wednesday, November 3, 2021, from 1:00 p.m. to 5:00 p.m.

ADDRESSES: To view the live event, visit *http://fdic.windrosemedia.com.* To view the recording, visit *http://fdic.windrosemedia.com/index.php?category=Community+Banking+Advisory+Committee.* If you require a reasonable accommodation to participate, please contact *DisabilityProgram@fdic.gov* or call 703–562–2096 to make necessary arrangements.

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Debra A. Decker, Committee Management Officer of the FDIC, at (202) 898–8748.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include a discussion of current issues affecting community banking. The agenda is subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: This meeting of the Advisory Committee on Community Banking will be Webcast live via the internet *http://fdic.windrosemedia.com.* For optimal viewing, a high-speed internet connection is recommended.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 30, 2021.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2021–21673 Filed 10–4–21; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL HOUSING FINANCE AGENCY

[No. 2021–N–10]

Proposed Collection; Comment Request

AGENCY: Federal Housing Finance Agency.

ACTION: 30-Day notice of submission of information collection for approval from Office of Management and Budget.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Housing Finance Agency (FHFA or the Agency) is seeking public comments concerning an information collection known as ''Minority and Women Inclusion,'' which has been assigned control number 2590–0014 by the Office of Management and Budget (OMB). FHFA intends to submit the information collection to OMB for review and approval of a three-year extension of the control number, which is due to expire on October 31, 2021.

DATES: Interested persons may submit comments on or before November 4, 2021.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs of the Office of Management and Budget, Attention: Desk Officer for the Federal Housing Finance Agency, Washington, DC 20503, Fax: (202) 395–3047, Email: *OIRA_submission@omb.eop.gov.* Please also submit comments to FHFA, identified by ''Proposed Collection; Comment Request: ''Minority and Women Inclusion, (No. 2021–N–10)'' by any of the following methods:

- *Agency Website: www.fhfa.gov/open-for-comment-or-input.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the *Federal eRulemaking Portal,* please also send it by *email* to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by the Agency.
- *Mail/Hand Delivery:* Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219, ATTENTION: Proposed Collection; Comment Request: ''Minority and Women Inclusion, (No. 2021–N–10)''.

We will post all public comments we receive without change, including any personal information you provide, such as your name and address, email address, and telephone number, on the FHFA website at *http://www.fhfa.gov.* In addition, copies of all comments received will be available for examination by the public through the electronic comment docket for this PRA Notice also located on the FHFA website.

FOR FURTHER INFORMATION CONTACT: Felicia Bland, Supervisory Examination Specialist, Office of Minority and Women Inclusion, by email at *Felicia.Bland@fhfa.gov* or by telephone at (202) 365–7471; or Angela Supervielle, Counsel, *Angela.Supervielle@fhfa.gov,* (202) 649–3973 (these are not toll-free numbers); Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. The Telecommunications Device for the Deaf is (800) 877–8339.

SUPPLEMENTARY INFORMATION: FHFA is seeking comments on its collection of information regarding the minority and gender classification of individuals serving on the boards of directors of the Federal Home Loan Banks (Banks) and of the Office of Finance under FHFA's regulations on Minority and Women

Inclusion (MWI), codified at 12 CFR part 1223, which it will be submitting for renewal of the OMB control number under the PRA.

A. Need for and Use of the Information Collection

The Federal Home Loan Bank System consists of eleven regional Banks and the Office of Finance, which issues and services the Banks' debt securities. The Banks are wholesale financial institutions, organized under authority of the Federal Home Loan Bank Act (Bank Act) to serve the public interest by enhancing the availability of residential housing finance and community lending credit through their member institutions and, to a limited extent, through certain eligible non-member entities. Each Bank is structured as a regional cooperative that is owned and controlled by member financial institutions located within its district, which are also its primary customers. The Bank Act vests the management of each Bank in a board of directors that consists of two types of directors: (1) Member directors, who are drawn from the officers and directors of member institutions located in the Bank's district and who are elected to represent members in a particular state in that district; and (2) independent directors, who are unaffiliated with any of the Bank's member institutions, but who reside in the Bank's district and are elected on an at-large basis.[1] The Office of Finance is also governed by a board of directors, which consists of the presidents of the eleven Banks and five independent directors.[2]

Section 1319A of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act) requires that each of the Banks establish an Office of Minority and Women Inclusion (OMWI) to be responsible for all matters relating to diversity in its management, employment, and business activities, in accordance with requirements established by FHFA.[3] Section 1319A also requires that each Bank implement standards and procedures to ensure, to the maximum extent possible, the inclusion and utilization of women and minorities ''at all levels'' of its business and activities, and submit an annual report to FHFA detailing actions taken to achieve those goals.[4]

FHFA's MWI regulations implement those statutory requirements and also extend the requirements to the Office of Finance. The MWI regulations require generally that each Bank and the Office of Finance ''develop, implement, and maintain policies and procedures to ensure, to the maximum extent possible in balance with financially safe and sound business practices, the inclusion and utilization of minorities, women, individuals with disabilities, and minority-, women-, and disabled-owned businesses in all business and activities and at all levels of the regulated entity, including in management, employment, procurement, insurance, and all types of contracts.'' [5] In recognition of the fact that each Bank is required by statute to promote diversity and inclusion ''at all levels'' of its business and activities, the MWI regulations further require that the Banks' policies and procedures (as well as those of the Office of Finance) ''[e]ncourage the consideration of diversity in nominating or soliciting nominees for positions on boards of directors and engage in recruiting and outreach directed at encouraging individuals who are minorities, women and individuals with disabilities to seek or apply for employment with the regulated entity.'' [6]

In conformity with the statutory requirements, FHFA's MWI regulations require that each Bank and the Office of Finance submit to FHFA an annual report describing, among other things, its efforts to promote diversity at all levels of management and employment, and the results of those efforts.[7] In order to provide a quantitative basis upon which to assess the results of those efforts, FHFA's MWI regulations require that each Bank and the Office of Finance set forth in their respective annual reports the demographic data reported on the EEO–1 form, which they are required to file annually with the Equal Employment Opportunity Commission (EEOC).[8] The EEO–1 form requires that each respondent provide race, ethnicity and gender information for its employees, broken down into various job categories. Because the EEO–1 form does not require that a respondent provide information on board directors, FHFA cannot use the EEO–1 data to assess the effectiveness of the Federal Home Loan Bank System's efforts to ''encourage the consideration of diversity in nominating or soliciting nominees for positions on boards of directors.''

Therefore, in order to enable FHFA to assess those efforts, the MWI regulations separately require that the annual reports set forth ''[d]ata showing for the reporting year by minority and gender classification, the number of individuals on the board of directors of each Bank and the Office of Finance,'' using the same racial and ethnic classifications that are used on the EEO–1 form (which comply with OMB's ''Statistical Policy Directive No. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting'').[9] The MWI regulations require that each Bank and the Office of Finance collect that data ''through an information collection requesting each director's voluntary self-identification of his or her minority and gender classification without personally identifiable information.''

FHFA uses the information collected under this control number to assess the effectiveness of the policies and procedures that each Bank and the Office of Finance is required to implement to promote diversity in all of its business and activities ''at all levels'' and, specifically, to encourage diversity in the nomination and solicitation of nominees for members of its boards of directors. FHFA also uses the information to establish a baseline to analyze future trends related to the diversity of the boards of directors of the Banks and the Office of Finance and to assess the effectiveness of the strategies developed by the Banks and the Office of Finance for promoting, developing, and retaining diverse board talent.

B. Burden Estimate

FHFA estimates the total annual hour burden imposed upon respondents by this information collection to be 20.5 hours. This is based on estimates that 205 Bank and Office of Finance Directors will respond annually, with each response taking an average of 0.1 hours (6 minutes) (205 respondents × 0.1 hours = 20.5 hours).

C. Comments Request

In accordance with the requirements of 5 CFR 1320.8(d), FHFA published an initial notice and request for public comments regarding this information collection in the **Federal Register** on July 17, 2021.[10] The 60-day comment period closed on July 16, 2018. FHFA received no comments.

FHFA requests written comments on the following: (1) Whether the collection of information is necessary for the proper performance of FHFA functions, including whether the information has

[1] *See* 12 U.S.C. 1427(a)(1), (b), (d).

[2] *See* 12 CFR 1273.7(a).

[3] *See* 12 U.S.C. 4520(a).

[4] *See* 12 U.S.C. 4520(b), (d).

[5] *See* 12 CFR 1223.21(b).

[6] *See* 12 CFR 1223.21(b)(7).

[7] *See* 12 CFR 1223.22(a).

[8] *See* 12 CFR 1223.23(b)(1). As required by 29 CFR 1602.7, each Bank and the Office of Finance annually files an EEO–1 form with the EEOC.

[9] *See* 12 CFR 1223.23(b)(10)(i).

[10] *See* 86 FR 37330 (July 15, 2021).

practical utility; (2) the accuracy of FHFA's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Kevin Smith,

Chief Information Officer, Federal Housing Finance Agency.

[FR Doc. 2021–21733 Filed 10–4–21; 8:45 am]

BILLING CODE 8070–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Policy Impact Survey (FR 3075; OMB No. 7100–0362).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Policy Impact Survey.

Agency form number: FR 3075.

OMB control number: 7100–0362.

Frequency: On occasion.

Respondents: Bank holding companies, savings and loan holding companies, any nonbank financial company that the Financial Stability Oversight Council has determined should be supervised by the Board, and the combined domestic operations of foreign banking organizations.

Estimated number of respondents: 14.

Estimated average hours per response: 700.

Estimated annual burden hours: 68,600.

General description of report: This survey collects information from certain types of institutions regulated by the Board in order to assess the effects of proposed, pending, or recently adopted policy changes at the domestic and international levels. The Board uses the survey to collect information used for certain quantitative impact studies (QISs) [1] sponsored by financial stability bodies such as the Basel Committee on Banking Supervision (BCBS) and the Financial Stability Board. Recent collections have included the Basel III monitoring exercise, which monitors the global impact of the Basel III framework,[2] the global systemically important bank (G–SIB) exercise, which assesses firms' systemic risk profiles,[3] and a survey of the domestic systemic risk footprint of large foreign banking organizations. Since the collected data may change from survey to survey, there is no fixed reporting form.

Legal authorization and confidentiality: Information collected under the FR 3075 is authorized by the Board's reporting authorities, which are located in section 5(c) of the Bank Holding Company Act [4] for bank holding companies and their subsidiaries, section 10(b)(2) of the Home Owners' Loan Act [5] for savings and loan holding companies and their subsidiaries, section 161(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act [6] for nonbank financial companies supervised by the Board, section 8(a) of the International Banking Act and section 5(c) of the Bank Holding Company Act [7] for the combined domestic operations of certain foreign banking organizations, section 9 of the Federal Reserve Act [8] for state member banks, sections 25 and 25A of the Federal Reserve Act [9] for Edge and agreement corporations, and section 7(c)(2) of the International Banking Act and section 7(a) of the Federal Deposit Insurance Act [10] for U.S. branches and agencies of foreign banks. Response to the FR 3075 is voluntary.

The questions asked on each survey will vary. The Board's ability to keep confidential responses to the FR 3075 must therefore be determined on a case-by-case basis. To the extent responses include nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent, such information may be kept confidential pursuant to exemption 4 of the Freedom of Information Act (FOIA).[11] Some survey responses may also contain information contained in or related to an examination of a financial institution, which may be kept confidential under exemption 8 of the FOIA.[12] To the extent a respondent submits personal, medical, or similar files, the disclosure of which would constitute an unwarranted invasion of privacy, the respondent may request confidential treatment pursuant to exemption 6 of the FOIA.[13]

Aggregate survey information from the FR 3075 is not considered confidential and may be cited in published material such as Board studies or working papers, proposed or final rules, professional journals, the *Federal Reserve Bulletin,* testimony and reports to the Congress, or other vehicles.

Current actions: On May 26, 2021, the Board published a notice in the **Federal Register** (86 FR 28345) requesting public comment for 60 days on the extension, without revision, of the Policy Impact Survey, FR 3075. The comment period for this notice expired on July 26, 2021. The Board did not receive any comments.

[1] A QIS is a survey of financial institutions that allows supervisors to assess the quantitative impact of policy changes.

[2] For more information on the Basel III monitoring exercise, including recent examples of QISs sponsored by BCBS and conducted by the Board, see *www.bis.org/bcbs/qis/.*

[3] For more information on the G–SIB exercise, see *www.bis.org/bcbs/gsib/.*

[4] 12 U.S.C. 1844(c).

[5] 12 U.S.C. 1467a(b)(2).

[6] 12 U.S.C. 5361(a).

[7] 12 U.S.C. 3106(a) and 1844(c).

[8] 12 U.S.C. 324.

[9] 12 U.S.C. 602 and 625.

[10] 12 U.S.C. 3105(c)(2) and 1817(a).

[11] 5 U.S.C. 552(b)(4).

[12] 5 U.S.C. 552(b)(8).

[13] 5 U.S.C. 552(b)(6).

Board of Governors of the Federal Reserve System, September 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–21596 Filed 10–4–21; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Supervisory and Regulatory Survey (FR 3052; OMB No. 7100–0322).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: The Supervisory and Regulatory Survey.

Agency form number: FR 3052.

OMB control number: 7100–0322.

Frequency: On occasion.

Respondents: May include bank holding companies, state member banks, savings and loan holding companies, intermediate holding companies, U.S. branches and agencies of foreign banking organizations (FBOs), Edge Act and agreement corporations, nonbank financial companies that the Financial Stability Oversight Council has determined should be supervised by the Board, and the combined domestic operations of FBOs.

Estimated number of respondents: 5,000.

Estimated average hours per response: 0.5.

Estimated annual burden hours: 60,000.

General description of report: The FR 3052 collects information from financial institutions specifically tailored to the Federal Reserve's supervisory, regulatory, and operational responsibilities. The Board utilizes the survey process, as needed, to collect information on specific issues that affect its decision making. The principal value of the FR 3052 is the flexibility it provides the Federal Reserve to respond quickly to the need for data due to unanticipated economic, financial, supervisory, or regulatory developments. The Board cannot predict what specific information will be needed, but such needs are generally very time-sensitive. Because the relevant questions may change with each survey, there is no fixed reporting form. Past surveys have collected information related to energy lending exposure, cloud-based data exchange services, regulatory capital, Comprehensive Capital Analysis and Review, operational risk loss event history, transactions by government securities dealers, and small debit card issuers.

Written qualitative questions or questionnaires may include categorical questions, yes-no questions, ordinal questions, and open-ended questions. Written quantitative surveys may include dollar amounts, percentages, numbers of items, interest rates, and other such information. Institutions might also be asked to provide copies of existing documents (for example, pertaining to practices and performances for a particular business activity). Before conducting a survey, the Board reviews any information to be collected to determine if the information is available by other means.

Legal authorization and confidentiality: The FR 3052 is authorized by a number of statutes authorizing the Board to require reports of condition from institutions subject to its supervision. These include section 9 of the Federal Reserve Act (FRA),[1] section 5 of the Bank Holding Company Act,[2] section 10 of the Home Owners' Loan Act,[3] section 7 of the International Banking Act (IBA),[4] section 8 of the IBA,[5] sections 25 and 25A of the FRA,[6] and section 161 of the Dodd-Frank Wall Street Reform and Consumer Protection Act.[7] Survey submissions under the FR 3052 are voluntary.

The questions asked on each survey will vary. The Board's ability to keep confidential responses to the FR 3052 must therefore be determined on a case-by-case basis. Much of the information collected is likely to constitute nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent, and may be kept confidential by the Board pursuant to exemption 4 of the Freedom of Information Act (FOIA).[8] Some survey responses may also contain information contained in or related to an examination of a financial institution, which may be kept confidential under exemption 8 of the FOIA.[9] Responses to the FR 3052 are tabulated and summarized at the Board. This aggregate information is not considered confidential, and aggregate survey information may be cited in published material such as Board studies or working papers, professional journals, the Federal Reserve Bulletin, testimony and reports to the Congress, or other vehicles.

[1] 12 U.S.C. 324 (requiring state member banks to make reports of condition ''in such form and [containing] such information as the Board of Governors of the Federal Reserve System may require'').

[2] 12 U.S.C. 1844(c)(1)(A) (authorizing the Board to require a bank holding company and any subsidiary thereof to submit reports regarding financial condition and compliance).

[3] 12 U.S.C. 1467a(b)(2) (authorizing the Board to require a savings and loan holding company and any subsidiary thereof to submit reports containing such information concerning the operation of the company or its subsidiaries as the Board may require).

[4] 12 U.S.C. 3105(c)(2) (subjecting each branch or agency of a foreign bank to the provisions of 12 U.S.C. 324 requiring reports of financial condition as if it were a state member bank).

[5] 12 U.S.C. 3106(a) (generally subjecting foreign banking organizations to the Bank Holding Company Act).

[6] 12 U.S.C. 602 and 625 (requiring Edge and agreement corporations to ''make reports to the Board of Governors of the Federal Reserve System at such times and in such form as it may require'').

[7] 12 U.S.C. 5361 (authorizing the Board to require reports of financial condition and compliance from nonbank financial companies subject to the Board's supervision).

[8] 5 U.S.C. 552(b)(4).

[9] 5 U.S.C. 552(b)(8).

Current actions: On May 26, 2021, the Board published a notice in the **Federal Register** (86 FR 28344) requesting public comment for 60 days on the extension, without revision, of the Supervisory and Regulatory Survey (FR 3052). The comment period for this notice expired on July 26, 2021. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, September 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–21597 Filed 10–4–21; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the Weekly Report of Selected Assets and Liabilities of Domestically Chartered Commercial Banks and U.S. Branches and Agencies of Foreign Banks (FR 2644; OMB No. 7100–0075).

DATES: Comments must be submitted on or before December 6, 2021.

ADDRESSES: You may submit comments, identified by FR 2644, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number or FR number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection

Report title: Weekly Report of Selected Assets and Liabilities of Domestically Chartered Commercial Banks and U.S. Branches and Agencies of Foreign Banks.

Agency form number: FR 2644.

OMB control number: 7100–0075.

Frequency: Weekly.

Respondents: Domestically chartered commercial banks and U.S. branches and agencies of foreign banks.

Estimated number of respondents: 850.

Estimated average hours per response: 2.19.

Estimated annual burden hours: 96,798.

General description of report: The FR 2644 is a balance sheet report that is collected as of each Wednesday from an authorized stratified sample of 875 domestically chartered commercial banks and U.S. branches and agencies of foreign banks. The FR 2644 is the only source of high-frequency data used in the analysis of current banking developments. The FR 2644 collects sample data that are used to estimate universe levels for the entire commercial banking sector in conjunction with data from the quarterly commercial bank Consolidated Reports of Condition and Income (FFIEC 031, FFIEC 041, and FFIEC 051; OMB No. 7100–0036) and the Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks (FFIEC 002;

OMB No. 7100–0032) (Call Reports). Data from the FR 2644 and the Call Reports are utilized in construction of weekly estimates of U.S. bank credit, balance sheet data for the U.S. commercial banking sector, and sources and uses of banks' funds, and to analyze current banking developments, including the monitoring of broad credit and funding conditions. The Board publishes the data in aggregate form in the weekly H.8 statistical release, *Assets and Liabilities of Commercial Banks in the United States,* which is followed closely by other government agencies, the banking industry, financial press, and other users.[1] The H.8 release provides a balance sheet for the commercial banking industry as a whole as well as data disaggregated by its large domestic, small domestic and foreign-related bank components.

Proposed revisions: The Board proposes four revisions to simplify and reduce the overall reporting burden associated with the FR 2644 report. The proposed FR 2644 reporting form would consist of 29 balance-sheet items and no memoranda items, an overall reduction of two data items, and be collected from fewer respondents.

Proposed Elimination of Two Data Items

Data item M.1, Net unrealized gains (losses) on available-for-sale securities, has been included on the FR 2644 reporting form since July 1, 2009, when this report was first used to collect data for all bank groups (large, small, and foreign-related). Before that, this item appeared on the FR 2416 reporting form (Weekly Report of Assets and Liabilities for Large Banks) beginning October 2, 1996. Data item M.1 was added to the FR2416 form, and included in the subsequent single FR2644 form, to better understand how changing interest rates and market valuations affect the fair value of banks' available-for-sale securities.

Data item M.1.a, Net unrealized gains (losses) on available-for-sale securities, U.S. Treasury and U.S. government agency obligations, mortgage-backed securities, was added to the FR2644 as of January 7, 2015. Since M.1.a was the largest component of M.1, its addition enabled staff to split the residual (M.1 less M.1.a) into estimates of the effects on the fair value of the remaining two categories of securities included on the FR2644 reporting form.

The recommendation to discontinue the collection of these two data items is based on the following two factors:

(1) There is insufficient additional information available from the weekly data relative to the corresponding Call Report data. The reporting instructions for these items state that banks that do not revalue daily or weekly should report the most recent value available. In reviewing the weekly data, the Board's experience has been that many banks, including some large banks, revalue only quarterly, when filing Call Reports. For these banks, the weekly data add no more value than the corresponding Call Report data.

(2) Banks that do not report item M.1 on the Call Report are being asked to report the item weekly on the FR 2644. Beginning March 31, 2015, only banks that use the accumulated other comprehensive income (AOCI) opt-out election on Call Report Schedule RC–R, Regulatory Capital Components and Ratios, report net unrealized gains (losses) on the Call Reports. (Banks that do not report these values on the Call Reports, which includes all advanced approaches institutions, include net unrealized gains (losses) in the AOCI component.) In addition, item M.1.a, net unrealized gains (losses) related to mortgage-backed securities, was never included on the Call Reports. The Board generally seeks to collect data items on the FR 2644 that are comparable, if not identical, to items appearing on the Call Reports. This standard simplifies reporting for weekly respondents, allows the Board to perform interseries edits of the FR 2644 data with corresponding Call Report data, and enables estimation, based on Call Report data, of the universe of banks. Currently, data items M.1 and M.1.a do not meet this standard.

Proposed Definitional Changes for FFIEC 002 Filers

Currently, all respondents on the FR 2644 panel are instructed to include loans to individuals in one of the three consumer loan categories on the reporting form. However, for FFIEC 002 filers (U.S. agencies and branches of foreign banks), this instruction does not match the reporting of these data on their Call Report. U.S. branches and agencies of foreign banks are instructed to combine any consumer loans they might hold with other, non-segregated loans on the FFIEC 002,[2] unlike their domestically chartered counterparts who have comparable consumer loan items on their Call Reports. Thus, these FFIEC 002 reporters have been asked to report weekly data on the FR 2644 that are not required on their quarterly Call Reports. For respondents to the FR 2644 that file the FFIEC 002, the Board proposes to revise the instructions for the FR 2644 to match those of the FFIEC 002—to instruct FFIEC 002 filers to include consumer loans in all other loans and leases on the FR 2644.

Likewise, all respondents to the FR 2644 panel report loans and leases gross of any allowances for loan and lease losses, with a separate entry for these allowances. However, the FFIEC 002 instructs U.S. agencies and branches of foreign banks to net loans and leases of any specific reserves. The Board recommends amending the FR 2644 instructions for these reporters to match those for the FFIEC 002. Thus, U.S. agencies and branches of foreign banks would net any specific reserves from the loan items and leave the allowance for loan and lease losses (item 4.g) blank.

The reasons for these proposed changes are the same as those listed in bullet item 2 above: Simplification of reporting, performance of interseries edits, and ability to create universe estimates. Both changes in reporting instruction will only affect a handful of U.S. branches and agencies of foreign banks, as most of these institutions do not issue consumer loans or establish accounts for loan and lease losses.

Proposed Definitional Change for Small Domestically Chartered Commercial Banks

The FR 2644 reporting form captures loans to, and acceptances of, commercial banks in the U.S. (item 4.b) to isolate interbank lending which is not considered a true measure of bank credit and their willingness to lend. However, the smallest respondents (those FFIEC 041 filers with less than $300 million in assets and all FFIEC 051 filers) only report loans to depository institutions and acceptances of other banks on their respective Call Reports and therefore, their data for this item frequently fails comparisons to Call Report data (interseries edits). Therefore, the Board proposes to revise the reporting instructions for these two bank groups—FFIEC 041 filers with less than $300 million in assets and FFIEC 051 filers would report loans to depository institutions—to minimize reporting discrepancies and to align reporting with the Call Reports.

Reduce the Authorized Sample

The FR 2644 panel has an authorized maximum respondent panel size of 875 domestically chartered commercial banks and U.S. branches and agencies of foreign banks. Currently, the panel

[1] The H.8 release is available on the Board's website, *http://www.federalreserve.gov/releases/h8/current/default.htm.*

[2] Prior to July 2009, foreign-related institutions filed the FR 2069 report, which was tailored to that bank group and did not include consumer loan items; on that report, consumer loans were included in ''all other loans.''

consists of 792 total reporters—727 domestically chartered banks and 65 foreign-related institutions [3]—covering all 12 Federal Reserve Districts. The panel accounts for about 89 percent of the total assets of U.S. commercial banks, as well as a high level of coverage for most reported items. While the number of panel respondents tends to run below the authorized size due to mergers among reporters and loss of respondents due to the voluntary nature of the collection, the current number of respondents is unusually low relative to the authorized size because the recruitment of new respondents was temporarily paused with the onset of the COVID–19 pandemic in 2020.

Quarterly Call Reports are used to benchmark the universe estimates of small domestically chartered banks [4] and foreign-related institutions. Average revisions to the estimates of small banks over the last 16 benchmarks—from March 2017 to December 2020—were somewhat larger than those over the previous renewal cycle, while those for the foreign-related institutions shrank considerably. While the average revisions are not overly large, they are still significant. Even so, the Board proposes reducing the authorized panel size from 875 to 850 in light of the continuing consolidation in the commercial bank universe as well as the ongoing difficulty in attracting and maintaining respondents due to the voluntary nature of this collection.

Legal authorization and confidentiality: The FR 2644 is authorized by section 2A of the Federal Reserve Act (FRA), which states that the Board ''shall maintain long run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates'' (12 U.S.C. 225a.) and by section 11(a)(2) of the FRA, which authorizes the Board to require a depository institution to provide ''reports of its liabilities and assets as the Board may determine to be necessary or desirable to enable the Board to discharge its responsibility to monitor and control monetary and credit aggregates'' (12 U.S.C. 248(a)(2)). Section 7(c)(2) of the International Banking Act of 1978 makes U.S. branches and agencies of foreign banks subject to the reporting requirements of section 11(a)(2) of the FRA (12 U.S.C. 3105(c)(2)). The FR 2644 is voluntary, although the Board would have the authority to require depository institutions to file these reports.

Although the Board releases aggregate data derived from the FR 2644 in the weekly H.8 Statistical Release, individual bank information provided by each respondent is treated as confidential because that information constitutes nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent, and thus may be kept confidential by the Board pursuant to exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Board of Governors of the Federal Reserve System, September 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–21595 Filed 10–4–21; 8:45 am]

BILLING CODE 6210–01–P

[3] As of March 31, 2021. Two branches in the Second District file combined reports on the FR 2644.

[4] Small domestic banks are those not in the top 25 in asset size as of each quarterly Call Report.

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Application Form for Membership on the Community Advisory Committee Council (FR 1401; OMB No. 7100–0371).

DATES: Comments must be submitted on or before December 6, 2021.

ADDRESSES: You may submit comments, identified by FR 1401, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be available at *https://www.reginfo.gov/public/do/PRAMain,* if approved. These documents will also be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under

the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Report title: Application Form for Membership on the Community Advisory Committee Council.

Agency form number: FR 1401.

OMB control number: 7100–0371.

Frequency: Annually.

Respondents: Any person seeking to be considered for membership on the Community Advisory Committee (CAC) Council.

Estimated number of respondents: 300.

Estimated average hours per response: 1.

Estimated annual burden hours: 300.

General description of report: The CAC Application (Application) is used to obtain information about the experience and qualification of persons seeking to be considered for membership on the CAC of the Board. The Application collects an applicant's contact information; details regarding current employment and areas of expertise; a resume, which typically includes information about employment history, education, and training; and a cover letter explaining why the applicant is interested in serving on the CAC and what he or she believes are their primary qualifications. Applicants can voluntarily elect to provide additional information to support their application.

Legal authorization and confidentiality: The Application is authorized pursuant to sections 2A and 10 of the Federal Reserve Act (FRA).[1] Section 2A of the FRA requires the Board and Federal Open Market Committee to maintain long run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates.[2] Section 10 of the FRA authorizes the Board to ''determine and prescribe the manner in which its obligations shall be incurred and its disbursements and expenses allowed and paid.'' [3]

Providing information collected as part of the Application is required to obtain a benefit.

Generally, information provided on the Application may be kept confidential from the public under exemption 6 of the Freedom of Information Act (FOIA) to the extent that the disclosure of the information ''would constitute a clearly unwarranted invasion of personal privacy.'' For example, the release of information such as the applicant's address, home telephone number, or personal email address to the public would likely constitute a clearly unwarranted invasion of personal privacy and be kept confidential. However, the release of information such as the educational and professional qualifications of successful applicants would not likely constitute a clearly unwarranted invasion of personal privacy and may be disclosed under the FOIA. In addition, once a person becomes a member of the CAC, their name, and the name and location of the organization where they are employed, would generally be listed on the Board's public website.

Board of Governors of the Federal Reserve System, September 29, 2021.

Michele Taylor Fennell, Deputy Associate Secretary of the Board.

[FR Doc. 2021–21594 Filed 10–4–21; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the Disclosure Requirements of Subpart H of Regulation H (Consumer Protection in Sales of Insurance) (FR H–7; OMB No. 7100–0298).

DATES: Comments must be submitted on or before December 6, 2021.

ADDRESSES: You may submit comments, identified by *FR H–7,* by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

[1] 12 U.S.C. 225a and 244.

[2] 12 U.S.C. 225a.

[3] 12 U.S.C. 244. This authority permits the Board to collect personal information (*e.g.,* bank account routing numbers) needed to disburse travel funds to CAC members.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be available at *https://www.reginfo.gov/public/do/PRAMain,* if approved. These documents will also be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection

Report title: Disclosure Requirements of Subpart H of Regulation H (Consumer Protection in Sales of Insurance).

Agency form number: FR H–7.

OMB control number: 7100–0298.

Frequency: On occasion.

Respondents: State member banks or any other person at an office of a bank or on behalf of a bank (collectively, Covered Persons).

Estimated number of respondents: Insurance and extension of credit, 341; advertisements, 341.

Estimated average hours per response: Insurance and extension of credit, 1.5 minutes; advertisements, 25 minutes.

Estimated annual burden hours: Insurance and extension of credit, 5,371; advertisements, 142.

General description of report: The insurance consumer protection rules in Regulation H require depository institutions to prepare and provide certain disclosures to consumers. The disclosure requirements are codified at 12 CFR 208.81 *et seq.* and require Covered Persons to make certain disclosures: Before the completion of the initial purchase of an insurance product or annuity by a consumer; at the time a consumer applies for an extension of credit in connection with which an insurance product or annuity is solicited, offered, or sold; and in advertisements and promotional materials for insurance products or annuities.

Proposed revisions: The Board proposes to revise the FR H–7 information collection to account for the advertisements and promotional materials disclosure requirement in Regulation H, Subpart H, that has not been previously cleared by the Board under the PRA. The Board is not proposing to create any forms associated with the FR H–7 to address this requirement.

Legal authorization and confidentiality: The Disclosure Requirements of Subpart H of Regulation H are authorized by section 305 of the Gramm-Leach-Bliley Act of 1999 (GLBA), which requires that the Board issue regulations, including disclosure requirements, applicable to retail sales practices, solicitations, advertising, or offers of insurance by depository institutions.[1] The disclosures required under Subpart H of Regulation H are mandatory.

Because the FR H–7 disclosures are provided by state member banks to customers, confidentiality issues should generally not arise. In the event the records are obtained by the Board as part of the examination or supervision of a financial institution, this information may be considered confidential pursuant to exemption 8 of the Freedom of Information Act, which protects information contained in ''examination, operating, or condition reports'' obtained in the bank supervisory process.[2]

Consultation outside the agency: The Board consulted with the other federal banking agencies with similar regulations pursuant to section 305 of the GLBA.

Board of Governors of the Federal Reserve System, September 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–21593 Filed 10–4–21; 8:45 am]

BILLING CODE 6210–01–P

[1] 12 U.S.C. 1831x. The Board also has the authority to require reports from state member banks. 12 U.S.C. 248(a) and 324.

[2] 5 U.S.C. 552(b)(8).

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW,

Washington, DC 20551–0001, not later than October 20, 2021.

A. Federal Reserve Bank of Dallas (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Rita Hancock, individually, and as trustee of the John W. Hancock, Jr. SB Trust, both of El Campo, Texas;* to acquire voting shares of Louise Bancshares, Inc., and thereby indirectly acquire voting shares of The First State Bank, both of Louise, Texas and Dilley State Bank, Dilley, Texas.

Board of Governors of the Federal Reserve System, September 30, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–21637 Filed 10–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10417, CMS–10768 and CMS–R–43]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *November 4, 2021.*

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Title of Information Collection:* Medicare Fee-for-Service Prepayment Review of Medical Records; *Type of Information Collection Request:* Revision; *Use:* The Medical Review program is designed to prevent improper payments in the Medicare FFS program. Whenever possible, Medicare Administrative Contractors (MACs) are encouraged to automate this process; however, it may require the evaluation of medical records and related documents to determine whether Medicare claims are billed in compliance with coverage, coding, payment, and billing policies. Addressing improper payments in the Medicare fee-for-service (FFS) program and promoting compliance with Medicare coverage and coding rules is a top priority for the CMS. Preventing Medicare improper payments requires the active involvement of every component of CMS and effective coordination with its partners including various Medicare contractors and providers. The information required under this collection is requested by Medicare contractors to determine proper payment, or if there is a suspicion of fraud. Medicare contractors request the information from providers/suppliers submitting claims for payment when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program. *Form Number:* CMS–10417 (OMB control number: 0938–0969); *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 485,632; *Number of Responses:* 485,632; *Total Annual Hours:* 242,816. (For questions regarding this collection, contact Christine Grose at (410–786–1362).)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* The ESRD Network Peer Mentoring Program; *Use:* The End Stage Renal Disease (ESRD) Network Peer Mentoring Program is a voluntary program designed to provide patient peer support to people with kidney disease. In part, the peer support is beneficial because patients can give each other something most practitioners do not have: Lived experience with kidney disease. The support and perspective of someone who has ''been there'' can help people better cope with their circumstances.

The ESRD Network Peer Mentoring Program is a partnership between dialysis facilities, ESRD Networks, and patient peer mentors and mentees that wish to engage in the program. The peer mentoring program is organized and published with educational opportunities for peer mentors and mentees, provides resources, and includes a complementary toolkit for ESRD Networks and dialysis facilities to promote and operationalize the program.

Program applicants are people with ESRD who: (1) Are adults over the age of 18; have been receiving in-center or home dialysis or have been transplanted for at least six months; actively engage in the care plan; consistently demonstrate leadership qualities at facility Quality Assurance & Performance Improvement (QAPI) meetings, Lobby Days, and other facility

activities; and wish to be a peer mentor; or (2) are over 18 years of age; are newly diagnosed patients but have been on in-center dialysis for at least six months; are looking for peer support to help them transition to their new reality; and are known as a peer mentee.

To participate in the ESRD Network Peer Mentoring Program, peer mentors and mentees will complete an online application form stored in Confluence. The application serves to validate the peer mentor or peer mentee interest in the ESRD Network Peer Mentoring Program. Information collection is important to the process of pairing peer mentors and mentees with similarly lived experience and interests with their kidney disease. In addition, the application collects information about the peers' interest in kidney disease, treatment modality, age range, preferred gender recognition, and attitudes toward their kidney disease diagnosis. It also supports aligning hobbies, and genders to support best matched peers with each other. *Form Number:* CMS–10768 (OMB control number: 0938–NEW); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 19. (For policy questions regarding this collection, contact Lisa Rees at 816–426–6353.)

3. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Conditions of Coverage for Portable X-ray Suppliers and Supporting Regulations; *Use:* The requirements contained in this information collection request are classified as conditions of participation or conditions for coverage. Portable X-rays are basic radiology studies (predominately chest and extremity X-rays) performed on patients in skilled nursing facilities, residents of long-term care facilities and homebound patients. The CoPs are based on criteria described in the law, and are designed to ensure that each portable X-ray supplier has properly trained staff and provides the appropriate type and level of care for patients. The information collection requirements described below are necessary to certify portable X-ray suppliers wishing to participate in the Medicare program. There are currently 506 portable X-ray suppliers participating in the Medicare program.

On September 30, 2019 (84 FR 51732), CMS updated the personnel requirements for portable X-ray technicians at 42 CFR 486.104(a), to focus on the qualifications of the individual performing services removing school accreditation requirements and simplifying the structure of the requirements. Additionally, CMS also revised the requirements for referral of service at 42 CFR 486.106(a) for portable X-ray requirements for orders. This change removed the requirement that physician or non-physician practitioner's orders for portable X-ray services must be written and signed and replacing the specific requirements related to the content of each portable X-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable X-ray services. *Form Number:* CMS–R–43 (OMB Control number: 0938–0338); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 506; *Total Annual Responses:* 1,012; *Total Annual Hours:* 324. (For policy questions regarding this collection contact James Cowher at 410–786–1948.)

Dated: September 29, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–21580 Filed 10–4–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0031]

Best Practices for Development and Application of Disease Progression Models; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research, and Center for Biologics Evaluation and Research, are announcing a public workshop entitled ''Best Practices for Development and Application of Disease Progression Models.'' The purpose of this public workshop is to discuss the best practices for developing disease progression models and their application to support drug development decisions, share experiences and case studies that highlight the opportunities and limitations in the development and application of disease progression models including models for natural history of disease and clinical trial simulations, and discuss the knowledge gaps and research needed to advance the development and use of disease progression models.

DATES: The public workshop will be held on November 19, 2021, from 9:30 a.m. to 2:30 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: This workshop will be virtual only.

FOR FURTHER INFORMATION CONTACT: Maryanne Dingman, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8777; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Under the FDA Reauthorization Act of 2017 (Pub. L. 115–52), FDA agreed, in accordance with section I of the Prescription Drug User Fee Act (PDUFA) VI Performance Goals, ''Ensuring the Effectiveness of the Human Drug Review, part J, Enhancing Regulatory Decision Tools to Support Drug Development and Review,'' to hold several workshops to identify best practices for model-informed drug development. This workshop, ''Best Practices for Development and Application of Disease Progression Models,'' fulfills FDA's performance commitment under PDUFA VI.

II. Topics for Discussion at the Public Workshop

The following topics will be discussed at the public workshop:

- Role of disease models in drug development and regulatory review;
- Lessons learned from past experiences of applying disease models in drug development;
- Best practice considerations for disease modeling to support drug development and regulatory decisions; and
- Best practice considerations for clinical trial simulations based on disease progression/natural history models to support drug development and regulatory decisions.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register by November 9, 2021, at *https://go.usa.gov/xMxPZ.*

If you need special accommodations due to a disability, please contact

Maryanne Dingman (see **FOR FURTHER INFORMATION CONTACT**) no later than November 9, 2021.

Streaming Webcast of the Public Workshop: This public workshop will be webcast. A live webcast of this workshop will be available at *https://go.usa.gov/xMxPZ* on the day of the workshop.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It will also be accessible at *https://go.usa.gov/xMxPZ.*

Dated: September 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21758 Filed 10–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0669]

S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals; International Council for Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals''. The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance expands the testing scheme for assessing human carcinogenic risk of small molecule pharmaceuticals by introducing an additional approach that is not described in the original S1B Guideline. The draft guidance is intended to offer an integrative approach that provides specific weight of evidence (WoE) criteria that inform whether or not a 2-year rat study adds value in completing a human carcinogenicity risk assessment. The Addendum also adds a plasma exposure ratio-based approach for setting the high dose in the rasH2-Tg mouse model, while all other aspects of the recommendations for high dose selection in S1C(R2) Guideline would still apply.

DATES: Submit either electronic or written comments on the draft guidance by December 6, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0669 for ''S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food

and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Timothy McGovern, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6426, Silver Spring, MD 20993–0002, 240–402–0477, *Timothy.McGovern@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals''. The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In May 2021, the ICH Assembly endorsed the draft guideline entitled ''S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft guidance provides guidance on expanding the testing scheme for assessing human carcinogenic risk of small molecule pharmaceuticals by introducing an additional approach that is not described in the original S1B Guideline and also adds a plasma exposure ratio-based approach for setting the high dose in the rasH2-Tg mouse model.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals''. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: September 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21692 Filed 10–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Committee on Rural Health and Human Services

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces the Secretary's National Advisory Committee on Rural Health and Human Services (NACRHHS) has scheduled a public meeting. Information about NACRHHS

and the agenda for this meeting can be found on the NACRHHS website at *https://www.hrsa.gov/advisory-committees/rural-health/index.html.*

DATES:

- Monday, October 25, 2021, 12:00 p.m.–5:30 p.m. Eastern Time (ET);
- Tuesday, October 26, 2021, 12:30 p.m.–4:15 p.m. ET; and
- Wednesday, October 27, 2021, 12:30 p.m.–4:30 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required. Please register online at *https://www.surveymonkey.com/r/WLSYQS5* by the deadline of 12:00 p.m. ET on October, 24, 2021. Instructions on how to access the meeting via Zoom will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Steven Hirsch, Administrative Coordinator at the Federal Office of Rural Health Policy, HRSA, 5600 Fishers Lane, 17W59D, Rockville, Maryland 20857; (301) 443–7322; or *shirsch@hrsa.gov.*

SUPPLEMENTARY INFORMATION: NACRHHS provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning both rural health and rural human services.

At this meeting, NACRHHS will discuss Behavioral Health and Primary Care Integration in Rural America and recommendations to the Secretary on designation of a new type of provider, the Rural Emergency Hospital.

Members of the public will have the opportunity to provide comments. Public participants wishing to provide oral comments must submit a written version of their statement at least three business days in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time permits. Public participants wishing to offer a written statement should send it to Steven Hirsch, using the contact information above, at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Steven Hirsch at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–21581 Filed 10–4–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting. Information about ACHDNC and the agenda for this meeting can be found on ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: Tuesday, November 9, 2021, from 10:00 a.m. to 3:00 p.m. Eastern Time (ET) and Wednesday, November 10, 2021, from 10:00 a.m. to 3:00 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required.

Please register online at *https://www.achdncmeetings.org/registration/* by 12:00 p.m. ET on November 8, 2021. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; (301) 443–0721; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

During the November 9–10, 2021, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

(1) The Committee will vote on whether or not to approve the following updates to the Committee's evidence-based review and decision-making process: The condition nomination form, methods for assessing published and unpublished evidence, and additional guidance for the Committee's decision matrix.

(2) A presentation on phase two of the Mucopolysaccharidosis type II evidence review;

(3) A presentation on phase one of the Guanidinoacetate methyltransferase deficiency evidence review;

(4) A Krabbe disease nomination overview;

(5) A possible Committee vote on whether to move Krabbe disease forward to a full evidence review; and

(6) Workgroup updates.

The agenda for this meeting does not include any vote or decision to recommend a condition for inclusion in the Recommended Uniform Screening Panel. As noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (Krabbe disease) to full evidence review, and will hear presentations on evidence review of Mucopolysaccharidosis type II and Guanidinoacetate methyltransferase deficiency, any of which may lead to such a recommendation at a future time. Agenda items are subject to change as priorities dictate. Information about ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website.

Members of the public also will have the opportunity to provide comments. Public participants providing general oral comments may submit written statements in advance of the scheduled meeting. Oral comments will be

honored in the order they are requested and may be limited as time allows. Requests to provide a written statement or make oral comments to ACHDNC must be submitted via the registration website by 12:00 p.m. ET on Thursday, November 4, 2021. Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–21582 Filed 10–4–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Visual and Perception Processes.

Date: October 28, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karen Elizabeth Seymour, Ph.D., Scientific Review Officer, Center for Scientific Review National Institute of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (240) 762–2729, *karen.seymour@nih.gov*.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.

Date: October 28–29, 2021.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maribeth Champoux, Ph.D., BA, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892 (301) 594–3163, *champoum@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics: Noninvasive Neuromodulation and Neuroimaging Technologies.

Date: November 3, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pablo M. Blazquez Gamez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (301) 435–1042, *pablo.blazquezgamez@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Endocrinology, Metabolism, Nutrition and Reproductive Sciences.

Date: November 3, 2021.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jonathan Michael Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *jonathan.peterson@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Therapeutics and Drug Development.

Date: November 4–5, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maureen Shuh, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892 (301) 480–4097, *maureen.shuh@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Mechanisms of Memory and Sound Processing.

Date: November 5, 2021.

Time: 10:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sepandarmaz Aschrafi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040D, Bethesda, MD 20892 (301) 451–4251, *Armaz.aschrafi@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Motivated Behavior and Alcohol.

Date: November 9, 2021.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892 (301) 435–1119, *selmanom@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–21–230: Chronic, Non-Communicable Diseases and Disorders Across the Lifespan: Fogarty International Research Training Award.

Date: November 10, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892 (301) 237–9838, *bhagavas@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; R15 AREA and REAP: Musculoskeletal, Oral, Skin, Rheumatology and Rehabilitation Sciences.

Date: November 10, 2021.

Time: 2:00 p.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Chi-Wing Chow, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4110, Bethesda, MD 20892 (301) 402–3912, *chowc2@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 30, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21726 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; NIGMS Review of K99/R00 MOSAIC Applications.

Date: October 29, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of General Medical Sciences, Building 45 Natcher, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18C, Bethesda, MD 20892, 301–594–2771, *johnsonrh@nigms.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 30, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21731 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group; Cancer Centers Study Section (A).

Date: December 3, 2021.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W530, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Shamala K. Srinivas, Ph.D., Associate Director, Office of Referral, Review, and Program Coordination, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W530, Rockville, Maryland 20850, 240–276–6442, *ss537t@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 29, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21600 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Multi-site Clinical Trial Special Emphasis Panel.

Date: November 16, 2021.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Keary A. Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209–A, Bethesda, MD 20892–7924, (301) 827–7912, *copeka@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 29, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21602 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; NIH Pathway to Independence Award (K99/R00).

Date: December 3, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of General Medical Sciences, Building 45 Natcher, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lisa A. Dunbar, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301–594–2849, *dunbarl@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical

Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 30, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21728 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; NIGMS Review of Research Training Modules and Conference Grant Applications.

Date: November 18, 2021.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of General Medical Sciences, Building 45 Natcher, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18C, Bethesda, MD 20892, 301–594–2771, *johnsonrh@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 30, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21730 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; Biofabricated 3-D Disease Tissue Models Review.

Date: November 10, 2021.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jing Chen, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892, *chenjing@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 29, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21603 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Study Sections Member Conflict Applications Review Panel.

Date: October 22, 2021.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700 B Rockledge Drive, Room 2114, Bethesda, MD 20892, (301) 451–2067, *srinivar@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: September 29, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21606 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Research on Current Topics in Alzheimer's Disease and Its Related Dementias.

Date: November 4–5, 2021.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, *bhagavas@csr.nih.gov*.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Therapeutic Approaches to Genetic Diseases Study Section.

Date: November 8–9, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karobi Moitra, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–480–6893, *karobi.moitra@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular Sciences Activities.

Date: November 11–12, 2021.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301–435–0912, *katherine.malinda@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 30, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21665 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; NIGMS Review of Centers of Biomedical Research Excellence (COBRE) Phase 3 Applications.

Date: November 4–5, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of General Medical Sciences, Building 45 Natcher, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nina Sidorova, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.22, Bethesda, MD 20892–6200, 301–594–3663, *sidorova@nigms.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 30, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21729 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; ALACRITY Research Centers P50.

Date: November 1, 2021.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Serena Chu, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6000, MSC 9606, Bethesda, MD 20852, 301–500–5829, *serena.chu@nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Research Education Applications (R25).

Date: November 4, 2021.

Time: 11:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892–9608, 301–443–4525, *steinerr@mail.nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Post-Acute Interventions for the Treatment of Anorexia Nervosa (R34).

Date: November 4, 2021.
Time: 12:00 p.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).
Contact Person: Serena Chu, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6000, MSC 9606, Bethesda, MD 20852, 301–500–5829, *serena.chu@nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative: Tools to Facilitate High-Throughput Microconnectivity Analysis (R01).
Date: November 4, 2021.
Time: 12:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).
Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: September 29, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21605 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIGMS Initial Review Group; Training and Workforce Development Study Section—B.
Date: October 20–21, 2021.
Time: 10:00 a.m. to 6:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute of General Medical Sciences, Building 45/Natcher, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–3907, *pikebr@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 30, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21727 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; Addressing Social Determinants of Health to Eliminate Oral Health Disparities.
Date: November 3, 2021.
Time: 1:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Yun Mei, MD, Scientific Review Officer, Scientific Review Branch, Natl Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite #670, Bethesda, MD 20892, (301) 827–4639, *yun.mei@nih.gov*.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; Review of Data Analysis R03 Applications.
Date: November 16, 2021.
Time: 11:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Scientific Review Branch, NIDCR, NIH, 6701 Democracy Boulevard, Suite 664, Bethesda, MD 20892, 301–402–8559, *jimok.kim@nih.gov*.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; DSR Member Conflict.
Date: November 18, 2021.
Time: 3:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Yun Mei, MD, Scientific Review Officer, Scientific Review Branch, Natl Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite #670, Bethesda, MD 20892, (301) 827–4639, *yun.mei@nih.gov*.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis; Panel Review of R35 SOAR Award.
Date: November 19, 2021.
Time: 11:00 a.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Scientific Review Branch, NIDCR, NIH, 6701 Democracy Boulevard, Suite 664, Bethesda, MD 20892, 301–402–8559, *jimok.kim@nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: September 29, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21604 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors.

The meeting will be held as a virtual meeting and is open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of the National Cancer Advisory Board meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended. The intramural programs and projects and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the intramural programs and projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board and NCI Board of Scientific Advisors.

Date: December 7, 2021.

Closed: 12:00 p.m. to 1:00 p.m.

Agenda: Review of intramural program site visit outcomes and the discussion of confidential personnel issues.

Open: 1:15 p.m. to 4:45 p.m.

Agenda: NCAB Subcommittee Meetings—Subcommittee on Planning and Budget; *Ad Hoc* Subcommittee on Experimental Therapeutics; and *Ad Hoc* Subcommittee on Population Science, Epidemiology and Disparities.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

Name of Committee: National Cancer Advisory Board and NCI Board of Scientific Advisors.

Date: December 8, 2021.

Open: 1:00 p.m. to 5:00 p.m.

Agenda: Joint meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors, NCI Director's report and presentations, NCI Board of Scientific Advisors Concepts Review.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

Name of Committee: National Cancer Advisory Board and NCI Board of Scientific Advisors.

Date: December 9, 2021.

Open: 1:00 p.m. to 5:00 p.m.

Agenda: Joint meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors, NCI Board of Scientific Advisors Concepts Review and presentations.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

Contact Person: Paulette S. Gray, Ph.D., Director, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, 7th Floor, Room 7W444, Bethesda, MD 20892, 240–276–6340, *grayp@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: NCAB: *https://deainfo.nci.nih.gov/advisory/ncab/ncabmeetings.htm,* BSA: *https://deainfo.nci.nih.gov/advisory/bsa/bsameetings.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 30, 2021.

Melanie Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21666 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Center for Scientific Review Special Emphasis Panel: Mechanisms of Emotion, Stress and Health, October 25, 2021, 5:00 p.m. to October 25, 2021, 5:30 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on September 28, 2021, FR Doc 2021–21035, 86 FR 53665.

This notice is being amended to announce that the meeting is cancelled.

Dated: September 30, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21723 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Silvio O. Conte Centers for Basic Neuroscience or Translational Mental Health Research (P50).

Date: November 5, 2021.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Erin E. Gray, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, NSC 6152B, Bethesda, MD 20892, 301–402–8152, *erin.gray@nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Systems-Level Risk Detection and Interventions to Reduce Suicide, Ideation, and Behaviors.

Date: November 17, 2021.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of

Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, *aschulte@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Invasive Recording and Stimulating in Humans to Advance Neural Circuitry Understanding of Mental Health Disorders (R01, R21).

Date: November 23, 2021.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Erin E. Gray, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, NSC 6152B, Bethesda, MD 20892, 301–402–8152, *erin.gray@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: September 30, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21664 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Clinical Trials Monitoring Support TEP.

Date: November 2, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W102, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Shakeel Ahmad, Ph.D., Branch Chief, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, Maryland 20850, 240–276–6442, *ahmads@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 29, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21599 Filed 10–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

Docket No. USCG–2021–0740]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0032

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0032, Vessel Inspection Related Forms and Reporting Requirements Under Title 46 U.S. Code; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before December 6, 2021.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2021–0740] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov*. See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov*. Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2021–0740], and must be received by December 6, 2021.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov*. If your material cannot be submitted using *https://*

www.regulations.gov, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Vessel Inspection Related Forms and Reporting Requirements Under Title 46 U.S. Code.

OMB Control Number: 1625–0032.

Summary: This collection of information requires owners, operators, agents or masters of certain inspected vessels to obtain and/or post various forms as part of the Coast Guard's Commercial Vessel Safety Program.

Need: The Coast Guard's Commercial Vessel Safety Program regulations are found in 46 CFR, including parts 2, 26, 31, 71, 91, 107, 115, 126, 169, 176 and 189, as authorized in Title 46 U.S. Code. A number of reporting and recordkeeping requirements are contained therein.

Forms:

- CG–841, Certificate of Inspection
- CG–854, Temporary Certificate of Inspection
- CG–948, Permit to Proceed to Another Port for Repairs
- CG–949, Permit to Carry Excursion Party
- CG–950, Application for Permit to Carry Excursion Party
- CG–950A, Application for Special Permit
- CG–2832, Vessel Inspection Record

Respondents: Owners, operators, agents and masters of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 1,705 hours to 735 hours a year, due to change in the estimated time for respondents to complete certain recordkeeping tasks.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: September 29, 2021.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2021–21639 Filed 10–4–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2021–0735]

Policy Letter: Change 1 to CG–MMC Policy Letter 01–21, Guidelines for Qualifying for STCW Endorsements for Basic and Advanced IGF Code Operations

AGENCY: Coast Guard, Homeland Security (DHS).

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of Change 1 to CG–MMC Policy Letter 01–21, Guidelines for Qualifying for STCW Endorsements for Basic and Advanced IGF Code Operations. The Coast Guard will use applicable regulations and this policy to evaluate whether mariners may be issued endorsements for Basic and Advanced IGF Code Operations.

DATES: The policies announced in Change 1 to CG–MMC Policy Letter 01–21 are effective as of September 20, 2021.

ADDRESSES: To view the policy letter mentioned in this notice, search the docket number USCG–2021–0735 using the Federal eRulemaking Portal at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For information about this document, contact James Cavo, Mariner Credentialing Program Policy Division (CG–MMC–2), Coast Guard; telephone 202–372–1205; email *MMCPolicy@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard is revising CG–MMC Policy Letter 01–21 to reduce the amount of seagoing service required to renew an endorsement for Basic or Advanced IGF Code Operations and to add an additional method to renew the endorsement by providing evidence of being a qualified instructor of a relevant course.

The seagoing service option to renew a Basic or Advanced IGF Code Operations endorsement in the original policy letter exceeds the seagoing service requirement to initially qualify for an STCW endorsement in Basic IGF Code Operations. Holding an STCW endorsement for Advanced Liquefied Gas Tanker Cargo Operations or Basic Liquefied Gas Tanker Cargo Operations is a method to qualify for the Basic IGF Code endorsement. The seagoing service requirement to qualify for either an Advanced Liquefied Gas Tanker Cargo Operations endorsement or an Basic Liquefied Gas Tanker Cargo Operations endorsement is 90 days. This change reduces the seagoing service required as an option to renew an STCW endorsement for Basic IGF Code Operations to 90 days. In addition, this change notice reduces the seagoing service required as an option to renew an STCW for Advanced IGF Code Operations to 90 days.

Methods to qualify for renewal of an STCW endorsement in IGF Code Operations include completion of refresher training, evidence of being a qualified instructor of a relevant course, or seagoing service. Mariners will also need to meet the applicable requirements in 46 CFR 10.227 for the renewal of their MMC.

This notice is issued under authority of 5 U.S.C. 552(a).

Dated: September 20, 2021.

J.G. Lantz,

U.S. Coast Guard, Director of Commercial Regulations and Standards.

[FR Doc. 2021–21635 Filed 10–4–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2021–0734]

Policy Letter: Change 1 to CG–MMC Policy Letter 02–18, Guidelines for Qualifications of Personnel for Issuing STCW Endorsements for Basic and Advanced Polar Code Operations

AGENCY: Coast Guard, Homeland Security (DHS).

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of Change 1 to CG–MMC Policy Letter 02–18, Guidelines for Qualifications of Personnel for Issuing STCW Endorsements for Basic and Advanced Polar Code Operations. The Coast Guard will use applicable regulations and this policy to evaluate whether mariners may be issued endorsements for Basic and Advanced Polar Code Operations.

DATES: The policies announced in Change 1 to CG–MMC Policy Letter 02–18 are effective as of September 20, 2021.

ADDRESSES: To view the policy letter mentioned in this notice, search the docket number USCG–2021–0734 using the Federal eRulemaking Portal at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For information about this document, contact James Cavo, Mariner Credentialing Program Policy Division (CG–MMC–2), Coast Guard; telephone 202–372–1205; email *MMCPolicy@uscg.mil.*

SUPPLEMENTARY INFORMATION: This change revises CG-Policy Letter 02–18 to include the requirements for renewal of Basic and Advanced Polar Code Operations endorsements. Renewal requirements for these endorsements were not included in the original policy letter. Methods to qualify for renewal of an STCW endorsement in Polar Code Operations will include completion of refresher training, evidence of being a qualified instructor of a Basic or Advanced Polar Code Operations course at least twice within the past five years, or sea service.

The professional requirements to renew a merchant mariner credential (MMC) in 46 CFR 10.227 include the option to present evidence of at least 1 year of sea service during the past 5 years. However, Section A–I/11 paragraph 4.1 of the STCW Code only requires 2 months of seagoing service within the previous 5 years for renewal of Basic and Advanced Polar Code endorsements. To align with the STCW requirements and to ensure the seagoing service requirement for the renewal of a Polar Code Operations endorsement does not exceed the seagoing service requirement to initially qualify for Polar Code Operations endorsement, the seagoing service requirement for renewal of Polar Code Operations endorsements will be 2 months of seagoing service in the previous 5 years. Mariners will also need to meet the applicable requirements in 46 CFR 10.227 for the renewal of their MMC.

This change also removes transitional provisions that expired on July 1, 2020.

This notice is issued under authority of 5 U.S.C. 552(a).

Dated: September 20, 2021.

J.G. Lantz,

U.S. Coast Guard, Director of Commercial Regulations and Standards.

[FR Doc. 2021–21633 Filed 10–4–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2021–0741]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0036

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0036, Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before December 6, 2021.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2021–0741] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov*. See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov*. Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2021–0741], and must be received by December 6, 2021.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov*. If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk.

OMB Control Number: 1625–0036.

Summary: This information collection aids the Coast Guard in determining if a vessel complies with certain safety and environmental protection standards. Plans, to include records, for construction or modification of U.S. or foreign vessels submitted and maintained on board are required for compliance with these standards.

Need: Title 46 U.S. Code 3703 provides the Coast Guard with the authority to regulate design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels carrying oil in bulk. See *e.g.,* 33 CFR part 157, Rules for the Protection of the Marine Environment Relating to Tank Vessels Carrying Oil in Bulk, and 46 CFR Subchapter D, Tank Vessels.

Forms: None.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 2,109 hours to 2,497 hours a year, due to an increase in the estimated number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: September 29, 2021.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2021–21638 Filed 10–4–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6222–N–02]

Appointments to the Housing Counseling Federal Advisory Committee; Solicitation of Nominations

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Announcement of new members of the Housing Counseling Federal Advisory Committee and notice of the solicitation of nominations for appointment to the Housing Counseling Federal Advisory Committee.

SUMMARY: This notice announces the members of the Housing Counseling Federal Advisory Committee (HCFAC) that were appointed or reappointed by the Secretary on September 14, 2021. This notice also invites nominations for appointments to fill four additional vacancies on the HCFAC.

DATES: All Nominations must be received no later than November 4, 2021.

ADDRESSES: Nominations must be in writing using form HUD–90005 (Application for Membership on the HCFAC, OMB Approval Number: 2502–0606) and submitted via electronically to *HCFAC.application@hud.gov.* Individuals who do not have internet access may submit nominations to the Office of the Deputy Assistant Secretary for Housing Counseling, HUD, 451 7th Street SW, Room 9224, Washington DC 20410.

FOR FURTHER INFORMATION CONTACT: Virginia F. Holman, Housing Program Specialist, U.S. Department of Housing and Urban Development, Office of Housing Counseling, Office of Outreach and Capacity Building, *Virginia.F.Holman@hud.gov,* telephone number 540–894–7790. (This is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877–8339 (This is a toll-free number). Individuals with questions may also email *HCFAC.application@hud.gov* and in the subject line write ''HCFAC application question.''

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The HCFAC is congressionally mandated to provide advice to the Office of Housing Counseling (OHC) (42 U.S.C. 3533(g)(4)). The HCFAC provides the OHC valuable advice regarding its mission to provide individuals and families with the knowledge they need to obtain, sustain, and improve their housing through a strong national network of HUD-approved housing counseling agencies and HUD-certified counselors. The HCFAC, however, does not have any role in reviewing or awarding of OHC housing counseling grants and procurement contracts. The HCFAC is subject to the requirements of the Federal Advisory Committee Act, and the Presidential Memorandum ''Final Guidance on Appointments of Lobbyists to Federal Boards and Commissions,'' dated June 18, 2010, along with any relevant guidance published in the **Federal Register** or otherwise issued by the Office of Management and Budget (OMB).[1]

Pursuant to section 3533(g)(4)(B), the HCFAC shall consist of not more than 12 individuals appointed by the Secretary. The membership will equally represent the mortgage industry, the real estate industry, consumers and HUD-approved housing counseling agencies. Each member shall be appointed in his or her individual capacity for a term of up to 3 years.

II. HCFAC Members

On September 14, 2021, the following members were appointed to the HCFAC for a 3-year term:

Ibijoke Akinbowale, Director, National Community Reinvestment Coalition Housing Counseling Network

Lawrence Batiste, President, Batiste Premier Realty

Carol Ann Dujanovich, Vice President and Director of Operations, 1st Nations Reverse Mortgage

Marcia Lewis, Deputy Executive Director—Change Management, Indianapolis Housing Authority

Bill Sevilla, Director, Community Development and Asset Building, Centro Campesino; and

Tony Walters, Executive Director, National American Indian Housing Council

On September 14, 2021, the following members were reappointed to the HCFAC for a 3-year term:

Patricia Arvielo, President and Co-Founder, New American Funding; and Paul Yorkis, President, Patriot Real Estate

III. Nominations for the Housing Counseling Federal Advisory Committee

HUD is seeking additional nominations for membership on the HCFAC. Nominees shall have experience representative of at least one of the 4 categories—the mortgage industry, real estate industry, consumers, and HUD-approved housing counseling agencies. Nominations may be made by agency officials, members of Congress, the general public, professional organizations, and self-nominations. Nominees must be U.S. citizens and cannot be U.S. Government employees.

All appointed nominees will be serving on the HCFAC in their individual capacity and not in a representative capacity, therefore, no Federally-registered lobbyists may serve on the HCFAC.[2] Individual capacity, as clarified by OMB, refers to individuals

[1] *See* 5 U.S.C. appendix; 79 FR 47482.

[2] *See* 79 FR 4782 (''Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards, and Commissions'') (clarifying that federally registered lobbyists may not serve on advisory committee, board, or Commission in an ''individual capacity.'')

who are appointed to committees to exercise their own individual best judgment on behalf of the government, such as when they are designated as Special Government Employees as defined in 18 U.S.C. 202.

Nominations to the HCFAC must be submitted via Form HUD–90005, which is available here: *https://files.hudexchange.info/resources/documents/HCFAC-Application-HUD-Form-90005.pdf.* Each nominee will be required to provide all the information on Form HUD–90005.

Nominations should be submitted electronically to *HCFAC.application@hud.gov.* Individuals that do not have internet access may submit nominations to the Office of the Deputy Assistant Secretary for Housing Counseling, HUD, 451 7th Street SW, Washington DC 20410. Those who submitted applications previously, and those who have been appointed previously, must reapply if they wish to be considered for an appointment.

HCFAC members will be required to adhere to the conflict-of-interest rules applicable to Special Government Employees as such employees are defined in 18 U.S.C. 202(a). The rules include relevant provisions in 18 U.S.C. related to criminal activity, Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635) and Executive Order 12674 (as modified by Executive Order 12731). Therefore, applicants will be required to submit to pre-appointment screenings relating to identity of interest and financial interests that HUD might require. If selected, HCFAC members will also be asked to complete OGE Form-450 (Confidential Financial Disclosure Report).

Members of the HCFAC shall serve without pay but shall receive travel expenses including per diem in lieu of subsistence as authorized by 5 U.S.C. 5703. Regular attendance is essential to the effective operation of the HCFAC.

This Notice is not intended to be the exclusive method by which HUD will solicit nominations and expressions of interest to identify qualified candidates; however, all nominees for membership on the HCFAC will be subject to the same application process and evaluation criteria.

IV. Selection and Meetings

Member selections will be made by the Secretary and will be based on the Nominee's qualifications to contribute to the accomplishment of the HCFAC's objectives. Membership on the Committee is personal to the appointee and committee members serve at the discretion of the Secretary.

The estimated number of meetings (in-person or virtual) anticipated within a fiscal year is two (2). Additional meetings may be held as needed to render advice to the Deputy Assistant Secretary for the Office of Housing Counseling. The meetings may use electronic communication technologies for attendance.

All meetings will be announced by notice in the **Federal Register**. Announcements of the meetings may be made using other methods as well.

Janet Golrick,

Acting Chief of Staff, Office of Housing—Federal Housing Administration.

[FR Doc. 2021–21678 Filed 10–4–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7035–N–02]

60-Day Notice of Proposed Information Collection: Coronavirus Aid, Relief, and Economic Security (CARES) Act Reporting Information Collection Request; OMB Control No: 2535–0123

AGENCY: Office of the Chief Financial Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the revision of existing information collection requests, as well as a new information request, described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* December 6, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna Guido, Management Analyst, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–5535 (this is not a toll-free number) or email at *Anna.P.Guido@HUD.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through Teletype (TTY) by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Dustin Hogenson, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; telephone 202–402–6554, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Dustin Hogenson.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: CARES Act Reporting Information Collection Request.

OMB Approval Numbers:

2535–0123 Collection of required information for CARES Act Quarterly Reporting

Type of Request: Revisions of existing collections 2506–0133 (Housing Opportunities for Persons with AIDS (HOPWA) Program) 2506–0089 (Emergency Solutions Grant Data Collection), and 2506–0077 (Community Development Block Grant (CDBG) Entitlement Program) and a new collection activity under 2535–0123 (Collection of Required Information for CARES Act Quarterly Reporting).

Form Number(s)

OMB Control Numbers

- 2506–0133
- 2506–0089
- 2506–0077

Other affected forms and systems

- HUD–40110–C
- HUD–40110–D
- Integrated Disbursement and Information System (IDIS)
- Sage HMIS Reporting Repository

Description of the need for the information and proposed use: The change to the existing ICRs and renewal of the CARES Act Reporting ICR will enable HUD to collect from recipients of large covered funds, which are defined as CARES Act grants that exceed $150,000 in the aggregate, the quarterly information required to be in compliance with the requirements outlined in Section 15011 of the CARES Act.

This will revise and renew existing OMB control numbers 2506–0133, 2506–0089, and 2506–0077, to help improve compliance with CARES Act requirements. This information will be reported by the grant recipients to the program offices within HUD, then aggregated with the related information

already approved. This aggregated information will form the required quarterly reporting for CARES Act funds that HUD submits to the Pandemic Response Accountability Committee (PRAC).

A new information collection request under OMB control number 2353–0123 is also being submitted that will allow the collection of grant recipient reporting information through a reporting portal. This portal is in development, and upon completion will enable certain HUD programs to collect and report information in line with CARES Act requirements.

BURDEN ESTIMATES

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
CDBG	1,209	4	4,836	78.5	379,626	35.16	13,347,650.16
ESG	2,360	4	9,440	12.75	120,360	39.96	4,809,585.60
HOPWA (HUD–40110–C)	128	4	512	41	20,992	25.35	532,147.20
HOPWA (HUD–40110–D)	116	4	464	55	25,520	25.35	646,932.00
IHBG	792	4	3,168	1	3,168	25	79,200.00
TBRA/Op Fund	1,230	4	4,920	2	9,840	35.16	345,974.40
Total	5,835	4	23,340		559,506		19,761,489.36

**Please note:* The CPD programs (CDBG, ESG, and HOPWA) in the table above reference existing ICRs under control numbers 2506–0113, 2506–0089, and 2506–0077. The PIH programs (IHBG, TBRA, Op Fund) will leverage the existing ICR under control number 2535–0123 to implement a new reporting portal.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Sairah R Ijaz,

Assistant Chief Financial Officer for Systems. The Office of the Chief Financial Officer.

[FR Doc. 2021–21669 Filed 10–4–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R7–ES–2021–0075; FXFR133707PB000–212–FF07CAMM00]

Endangered and Threatened Wildlife and Plants; Initiation of a 5-Year Status Review of the Polar Bear (Ursus maritimus)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce our intention to conduct a 5-year status review under the Endangered Species Act of 1973, as amended, for the polar bear (*Ursus maritimus*). The polar bear was listed as threatened in 2008. A 5-year status review is based on the best scientific and commercial data available at the time of the review. We are requesting submission of information that has become available since the last review of the species in 2017.

DATES: To ensure consideration of your comments in our preparation of this 5-year status review, we must receive your comments and information by December 6, 2021. However, we will accept information about any species at any time.

ADDRESSES: Please submit your information on the current status of the polar bear by one of the following methods:

- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–R7–ES–2021–0075, U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, Virginia 22041–3803; or
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting information to Docket No. FWS–R7–ES–2021–0075. For more about submitting information, see Request for Information in the **SUPPLEMENTARY INFORMATION** section, below.

FOR FURTHER INFORMATION CONTACT: David Gustine, Polar Bear Lead, Marine Mammals Management, by telephone at 907–786–3800. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We are initiating a 5-year status review under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), for the polar bear (*Ursus maritimus*). A 5-year status review is based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any new information on this species that has become available since the last 5-year review was conducted in 2017.

Why do we conduct a 5-year review?

Under the ESA, we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2)(A) of the ESA requires us to review each listed species' status at least once every 5 years. Further, our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species

under active review. For additional information about 5-year reviews, go to *http://www.fws.gov/endangered/what-we-do/recovery-overview.html.*

What information do we consider in our review?

In conducting these reviews, we consider the best scientific and commercial data that have become available since the listing determination or most recent status review, such as:

(1) The biology of the species, including, but not limited to, population trends, distribution, abundance, demographics, and genetics;

(2) Habitat conditions, including, but not limited to, amount, distribution, and suitability;

(3) Conservation measures that have been implemented that benefit the species;

(4) Threat status and trends in relation to the five listing factors (as defined in section 4(a)(1) of the ESA); and

(5) Other new information, data, or corrections, including, but not limited to, taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

Any new information will be considered during the 5-year review and will also be useful in evaluating the ongoing recovery programs for the species.

Species Under Review

Entity listed: Polar bear (*Ursus maritimus*).

- *Where listed:* wherever found.
- *Classification:* Threatened.
- *Date listed (publication date for final listing rule):* May 15, 2008.
- ***Federal Register*** *citation for final listing rule:* 73 FR 28212.

Request for Information

To ensure that a 5-year review is complete and based on the best available scientific and commercial information, we request new information from all sources. See What Information Do We Consider in Our Review? for specific criteria. If you submit information, please support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Completed and Active Reviews

A list of all completed and currently active 5-year reviews addressing species for which the Alaskan Region of the Service has lead responsibility is available at *https://www.fws.gov/alaska/pages/endangered-species-program/recovery-endangered-species.*

Authority

This document is published under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Peter Fasbender,

Assistant Regional Director, Fisheries and Ecological Service, Alaska Region.

[FR Doc. 2021–21713 Filed 10–4–21; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–670 and 731–TA–1570 (Preliminary)]

Freight Rail Coupler Systems and Components From China; Institution of Anti-Dumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–670 and 731–TA–1570 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of freight rail coupler systems and components thereof from China, provided for in subheading 8607.30.10 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Subject merchandise attached to finished rail cars may also enter under HTSUS heading 8606 or under subheading 980300 if imported as an Instrument of International Traffic. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by November 15, 2021. The Commission's views must be transmitted to Commerce within five business days thereafter, or by November 22, 2021.

DATES: September 29, 2021.

FOR FURTHER INFORMATION CONTACT: Stamen Borisson, (202) 205–3125, Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to petitions filed on September 29, 2021, by the Coalition of Freight Coupler Producers, consisting of Amsted Rail Company, Inc., Chicago, IL and McConway & Torley LLC, Pittsburgh, PA.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The

Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission is conducting the staff conference through video conferencing on October 20, 2021. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before October 18, 2021. Please provide an email address for each conference participant in the email. Information on conference procedures will be provided separately and guidance on joining the video conference will be available on the Commission's Daily Calendar. A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before October 25, 2021, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than noon on October 19, 2021. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Dated: September 30, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–21725 Filed 10–4–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1199]

Certain Tobacco Heating Articles and Components Thereof; Commission's Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and Cease and Desist Orders; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has found a violation of section 337 of the Tariff Act of 1930, as amended, in this investigation and has issued a limited exclusion order prohibiting the importation of infringing tobacco heating articles and components thereof and cease and desist orders directed against respondents Philip Morris USA, Inc. (''PM USA'') and Altria Client Services LLC (''ACS''). The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On May 15, 2020, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by RAI Strategic Holdings, Inc., R.J. Reynolds Vapor Company, and R.J. Reynolds Tobacco Company, all of Winston-Salem, North Carolina (collectively, ''Complainants''). *See* 85 FR 29482–83. The complaint, as supplemented, alleges a violation of section 337 based upon the importation of certain tobacco heating articles and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 9,839,238 (''the '238 patent''); 9,930,915 (''the '915 patent'');

9,901,123 (''the '123 patent) (collectively, ''the Asserted Patents''). The complaint also alleges the existence of a domestic industry. The notice of investigation names five respondents: ACS Altria Group, Inc. (''AGI''), and PM USA, all of Richmond, Virginia; Philip Morris International Inc. (''PMI'') of New York, New York; and Philip Morris Products S.A. of Neuchatel, Switzerland (collectively, ''Respondents''). *See id.* The Office of Unfair Import Investigations (''OUII'') is also a party to the investigation. *See id.*

The Commission previously terminated respondents AGI and PMI from the investigation based on Complainants' partial withdrawal of the complaint. *See* Order No. 24 (Dec. 14, 2020), *unreviewed by* Comm'n Notice (Jan. 5, 2021).

The Commission previously affirmed that the economic prong of the domestic industry requirement is satisfied under 19 U.S.C. 1337(a)(3)(A) with respect to the '238 and '915 patents and provided supplemental analysis. Order No. 35 (Jan. 19, 2021), *affirmed in part by* Notice (Feb. 18, 2021).

On May 14, 2021, the presiding ALJ issued the final initial determination on violation (''FID''), which finds a violation of section 337 based on infringement of the '123 patent and the '915 patent and finds no violation as to the '238 patent.

On June 15, 2021, both Complainants and Respondents filed submissions on the public interest pursuant to Commission Rule 210.50(a)(4). OUII did not file a statement on the public interest. The Commission also received seven filings in response to its **Federal Register** notice calling for public interest comments. *See* 86 FR 28382 (May 16, 2021).

On July 27, 2021, the Commission determined to review the FID in part. 86 FR 41509–11 (Aug. 2, 2021). Specifically, the Commission determined to review: (1) As to the '915 patent, the ALJ's construction of the limitation ''electrical energy source'' recited in asserted claims 1 and 3 and the FID's infringement, technical prong, and invalidity findings to the extent they may be affected by a modified claim construction; (2) as to the '123 patent, the FID's obviousness and domestic industry findings; and (3) as to the '238 patent, the FID's infringement finding. *Id.* The Commission also asked the parties to address a question related to the issues under review regarding the '915 patent. *Id.* The Commission further requested briefing on remedy, bonding, and the public interest. *Id.*

On August 10, 2021, Complainants, Respondents, and OUII each filed an initial written response to the Commission's request for briefing. On August 17, 2021, Complainants and Respondents each filed a reply submission. On August 20, 2021, OUII filed its reply submission.

On August 5, 6, 9, and 10, 2021, twenty-nine members of the public submitted public interest submissions. On August 9, 2021, the Hispanic Leadership Fund and the National Minority Quality Form filed public interest submissions. On August 10, 2021, Nextera Healthcare filed a public interest submission. On August 11, 2021, Tom Miller, the Attorney General of Iowa, filed a public interest submission.

On September 13, 2021, Respondents filed Respondents' Motion to Take Judicial Notice of Recent Regulatory Determinations and District Court Opinion. On September 15, 2021, Complainants filed Complainants' Opposition to Respondents' Motion to Take Judicial Notice of Recent Regulatory Determinations and District Court Opinion. The Commission has determined to deny the motion, but has considered the parties' submissions in its consideration of the public interest factors.

Having reviewed the record of the investigation, including the FID and the parties' submissions, the Commission has found a violation of section 337 as to claims 1–3, and 5 of the '915 patent and claims 27–30 of the '123 patent. Specifically, with respect to the '915 patent, the Commission has determined to: (1) Modify the construction of the limitation ''electrical energy source'' recited in asserted claims 1 and 3 to mean ''receptacle that provides for transmission of electrical current from the power source to the heating member, where the receptacle is not limited to a structure that requires wiring or insertion''; and (2) affirm the FID's findings as to infringement, technical prong, and invalidity findings under the modified claim construction. With respect to the '123 patent, the Commission has determined to: (1) Affirm, with supplemental analysis, the FID's finding that Respondents failed to prove claims 27–30 of the '123 patent are invalid for obviousness under 35 U.S.C. 103; and (2) take no position as to the FID's findings with respect to the economic prong of the domestic industry requirement under subsection 337(a)(3)(A). The Commission has further determined to affirm the FID's non-infringement finding for the '238 patent.

The Commission has determined that the appropriate remedy is: (1) A limited exclusion order prohibiting the importation of tobacco heating articles and components thereof that infringe claims 1–3, and 5 of the '915 patent and claims 27–30 of the '123 patent; and (2) cease and desist orders directed to respondents PM USA and ACS. The Commission has determined that the public interest factors do not preclude issuance of the limited exclusion order or the cease and desist orders. The Commission has further determined that no bond is required during the period of Presidential review. *See* 19 U.S.C. 1337(j)(3).

The investigation is terminated. The Commission's reasoning in support of its determinations is set forth more fully in its opinion. The Commission's orders and opinion were delivered to the President and the United States Trade Representative on the day of their issuance.

The Commission vote for this determination took place on September 29, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: September 29, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–21626 Filed 10–4–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Barcode Scanners, Mobile Computers with Barcode Scanning Capabilities, Scan Engines, and Components Thereof, DN 3570;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be

accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Honeywell International Inc.; Hand Held Products, Inc.; and Metrologic Instruments, Inc. on September 29, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain barcode scanners, mobile computers with barcode scanning capabilities, scan engines, and components thereof. The complainant names as respondents: Zebra Technologies Corporation of Lincolnshire, IL; and Symbol Technologies, Inc. of Holtsville, NY. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3570'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures.[1]) Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: September 30, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–21720 Filed 10–4–21; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

JOINT BOARD FOR THE ENROLLMENT OF ACTUARIES

Meeting of the Advisory Committee; Meeting

AGENCY: Joint Board for the Enrollment of Actuaries.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Joint Board for the Enrollment of Actuaries gives notice of a closed teleconference meeting of the

Advisory Committee on Actuarial Examinations.

DATES: The meeting will be held on October 29, 2021, from 9:00 a.m. to 5:30 p.m. (EDT).

FOR FURTHER INFORMATION CONTACT: Elizabeth Van Osten, Designated Federal Officer, Advisory Committee on Actuarial Examinations, at (202) 317–3648 or *elizabeth.j.vanosten@irs.gov.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Advisory Committee on Actuarial Examinations will hold a teleconference meeting on October 29, 2021, from 9:00 a.m. to 5:30 p.m. (EDT). The meeting will be closed to the public.

The purpose of the meeting is to discuss topics and questions that may be recommended for inclusion on future Joint Board examinations in actuarial mathematics, pension law and methodology referred to in 29 U.S.C. 1242(a)(1)(B).

A determination has been made as required by section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. App., that the subject of the meeting falls within the exception to the open meeting requirement set forth in Title 5 U.S.C. 552b(c)(9)(B), and that the public interest requires that such meeting be closed to public participation.

Dated: September 29, 2021.

Thomas V. Curtin, Jr.,

Executive Director, Joint Board for the Enrollment of Actuaries.

[FR Doc. 2021–21574 Filed 10–4–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to The National Cooperative Research and Production Act Of 1993—Cooperative Research Group On CHEDE–8

Notice is hereby given that, on August 31, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Cooperative Research Group on CHEDE–8 (''CHEDE–8'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Borgwarner Inc., Auburn Hills, MI, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and CHEDE–8 intends to file additional written notifications disclosing all changes in membership.

On December 4, 2019, CHEDE–8 filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on December 30, 2019 (84 FR 71977).

The last notification was filed with the Department on June 2, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 26, 2021 (86 FR 40079).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–21695 Filed 10–4–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—The Integrated Photonics Institute for Manufacturing Innovation Operating Under the Name of the American Institute for Manufacturing Integrated Photonics

Notice is hereby given that, on August 19, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the Integrated Photonics Institute for Manufacturing Innovation operating under the name of the American Institute for Manufacturing Integrated Photonics (''AIM Photonics'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Seagate Technology LLC, Fremont, CA; Texas A&M Engineering Experiment Station, College Station, TX; and SiPhox Inc., Burlington, MA, have been added as parties to this venture.

Also, Baker College of Flint, Flint, MI; Bridgewater State University, Bridgewater, MA; The Cornell Center for Materials Research of Cornell University, Ithaca, NY; Eastman Kodak Company, Rochester, NY; and Viewpoint Systems, Inc., Rochester, NY, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and AIM Photonics intends to file additional written notifications disclosing all changes in membership.

On June 16, 2016, AIM Photonics filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 25, 2016 (81 FR 48450).

The last notification was filed with the Department on May 10, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on June 10, 2021 (86 FR 30981).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–21685 Filed 10–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Advanced Fluids Ffr Electrified Vehicles

Notice is hereby given that, on August 18, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Cooperative Research Group on Advanced Fluids for Electrified Vehicles (''AFEV'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Aisin Corporation, Kariya, Aichi, JAPAN; Hyundai Motor Company, Seoul, KOREA; Petro-Canada Lubricants Inc, Ontario, CANADA; Shell Global Solutions (US), Inc., Houston, TX; and Volvo Group, Greensboro, NC, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and AFEV intends to file additional written notifications disclosing all changes in membership.

On June 16, 2021, AFEV filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on August 16, 2021 (86 FR 45751).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–21693 Filed 10–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Pistoia Alliance, Inc.

Notice is hereby given that, on September 12, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. Section 4301 *et seq.* (the ''Act''), Pistoia Alliance, Inc. filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Qubit Pharmaceuticals, Paris, FRANCE; Molecular Quantum Solutions, Søborg, DENMARK; LifeArc, London, UNITED KINGDOM; JSR North America Holdings, Inc., Sunnyvale, CA; Gilead Sciences, Foster City, CA; and Dante Labs, New York, NY have been added as parties to this venture. Also, Scinapsis Analytics Inc. DBA BenchSci, Toronto, CANADA; and PERCAYAI LLC, St. Louis, MO have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Pistoia Alliance, Inc. intends to file additional written notifications disclosing all changes in membership.

On May 28, 2009, Pistoia Alliance, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 15, 2009 (74 FR 34364).

The last notification was filed with the Department on June 23, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 16, 2021 (86 FR 45750).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–21698 Filed 10–4–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Southwest Research Institute—Cooperative Research Group on ROS-Industrial Consortium-Americas

Notice is hereby given that, on August 23, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on ROS-Industrial Consortium-Americas (''RIC-Americas'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, GM–IT Innovation Center North, Austin, TX, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and RIC-Americas intends to file additional written notifications disclosing all changes in membership.

On April 30, 2014, RIC-Americas filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 9, 2014 (79 FR 32999).

The last notification was filed with the Department on April 29, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on May 25, 2021 (86 FR 28149).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–21694 Filed 10–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—UHD Alliance, Inc.

Notice is hereby given that, on August 18, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), UHD Alliance, Inc. (''UHD Alliance'') filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Vestel Elektronik Sanayi ve Ticaret A.S., Yunusemre, TURKEY; and Vu Technologies Pvt. Ltd., Mumbai, INDIA have been added as parties to this venture.

Also, TCL North America, Corona, CA has been dropped as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and UHD Alliance intends to file additional written notifications disclosing all changes in membership.

On June 17, 2015, UHD Alliance filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 17, 2015 (80 FR 42537).

The last notification was filed with the Department on June 10, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 23, 2021 (86 FR 47152).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–21684 Filed 10–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—American Society of Mechanical Engineers

Notice is hereby given that, on August 13, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301

et seq. (''the Act''), the American Society of American Society of Mechanical Engineers (''ASME'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, since September 6, 2019, ASME has published eight new standards, added two consensus committee charter, revised three consensus committee charter, initiated seventeen new standards activities, and withdrawn four proposed standards from consideration within the general nature and scope of ASME's standards development activities, as specified in its original notification. More detail regarding these changes can be found at *www.asme.org.* More detail regarding these changes can be found at *www.asme.org.*

On September 15, 2004, ASME filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on October 13, 2004 (84 FR 60895).

The last notification with the Attorney General was filed on September 06, 2019. A notice was filed in the **Federal Register** on November 12, 2019. (84 FR 61071).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–21690 Filed 10–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—PXI Systems Alliance, Inc.

Notice is hereby given that, on September 16, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), PXI Systems Alliance, Inc. (''PXI Systems'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Stelight Instrument Co., Ltd., Jiangsu, PEOPLE'S REPUBLIC OF CHINA, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and PXI Systems intends to file additional written notifications disclosing all changes in membership.

On November 22, 2000, PXI Systems filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 8, 2001 (66 FR 13971).

The last notification was filed with the Department on April 2, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on April 15, 2021 (86 FR 19902).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–21696 Filed 10–4–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Media Workflow Association, Inc.

Notice is hereby given that, on September 15, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Advanced Media Workflow Association, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Railroad 19, Phoenix, AZ, has been added as a party to this venture. Also, Harmonic Inc., San Jose, CA; and Mike Coleman (individual member), Portland, OR, have withdrawn as a parties to this venture.

In addition, the following was mistakenly reported on the prior filing (86 FR 40080): Christie Digital Systems, Phoenix, AZ was mistakenly reported as a party to the venture and the correct full corporate name is: Christie Digital Systems USA, Inc., Phoenix, AZ.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Advanced Media Workflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on June 25, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 26, 2021 (86 FR 40080).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–21705 Filed 10–4–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0025]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change of a Previously Approved Collection; Federal Coal Lease Request

AGENCY: Antitrust Division, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Antitrust Division (ATR), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until December 6, 2021.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Jill Ptacek, Attorney, Antitrust Division, United States Department of Justice, 450 Fifth Street NW, Suite 8000, Washington, DC 20530 (phone: 202–307–6607).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Federal Coal Lease Reserves.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form numbers are ATR–139 and ATR–140. The applicable component within the Department of Justice is the Antitrust Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for profit. Other: None. The Department of Justice evaluates the competitive impact of issuances, transfers and exchanges of federal coal leases. These forms seek information regarding a prospective coal lessee's existing coal reserves. The Department uses this information to determine whether the issuance, transfer or exchange of the federal coal lease is consistent with the antitrust laws.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 10 respondents will complete each form, with each response taking approximately two hours.

6 *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 20 annual burden hours associated with this collection, in total.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: September 30, 2021.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2021–21707 Filed 10–4–21; 8:45 am]

BILLING CODE 4410–12–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0027]

Agency Information Collection Activities; Proposed eCollection Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until December 6, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) Type of Information Collection: Extension of a currently approved collection.

(2) Title of the Form/Collection: Semi-Annual Progress Report for Grantees from the Engaging Men and Youth Program.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form Number: 1122–0027. U.S. Department of Justice, Office on Violence Against Women.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: The affected public includes the approximately 8 grantees of the Consolidated Grant Program to Address Children and Youth Experiencing Domestic and Sexual Assault and Engage Men and Boys as Allies (Consolidated Youth Program) who are implementing engaging men and youth projects. The Consolidated Youth Program creates a unique opportunity for communities to increase collaboration among non-profit victim service providers, violence prevention programs, and child and youth organizations serving victims ages 0–24. Additionally, it supports organizations and programs that promote boys' and men's role in combating violence against women and girls. Eligible applicants are nonprofit, nongovernmental entities, Indian tribes or tribal nonprofit organizations, and territorial, tribal or unit of local government entities.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: It is estimated that it will take the approximately 8 respondents (grantees from the Consolidated Youth Program who are implementing engaging men and youth projects) approximately one hour to complete a semi-annual progress report.

The semi-annual progress report is divided into sections that pertain to the different types of grantee activities.

(6) Program grantees will only be required to complete the sections of the form that pertain to their own specific activities.

(7) An estimate of the total public burden (in hours) associated with the collection: The total annual hour burden to complete the data collection forms is 16 hours, that is 8 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: September 30, 2021.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2021–21706 Filed 10–4–21; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF LABOR

[Agency Docket Number DOL–2021–XXXX]

Labor Advisory Committee for Trade Negotiations and Trade Policy

AGENCY: Bureau of International Labor Affairs, Labor.

ACTION: Meeting notice.

SUMMARY: Notice of a Labor Advisory Committee for Trade Negotiations and Trade Policy meeting.

DATES: October 18, 2021, 3:00 p.m. to 4:30 p.m.; Virtually via Zoom for Government.

FOR FURTHER INFORMATION CONTACT: Anne M. Zollner, Designated Federal Official and Division Chief, Trade Negotiations and Implementation, Office of Trade and Labor Affairs, Bureau of International Labor Affairs, Department of Labor, Frances Perkins Building, Room S–5317, 200 Constitution Ave. NW, Washington, DC 20210, telephone (202) 693–4890, *zollner.anne@dol.gov.*

SUPPLEMENTARY INFORMATION: The Labor Advisory Committee for Trade Negotiations and Trade Policy consults with and makes recommendations to the Secretary of Labor and the United States Trade Representative on general policy matters concerning labor and trade negotiations, operations of any trade agreement once entered into, and other matters arising in connection with the administration of the trade policy of the United States.

During the meeting, the Committee will review and discuss current issues that influence U.S. trade policy. The Committee will also discuss potential U.S. negotiating objectives and bargaining positions in current and anticipated trade negotiations. Pursuant to 19 U.S.C. 2155(f)(2)(A), the meeting will concern matters the disclosure of which would seriously compromise the Government's negotiating objectives or bargaining positions. Therefore, the meeting is exempt from the requirements of subsections (a) and (b) of sections 10 and 11 of the Federal Advisory Committee Act (relating to open meetings, public notice, public participation, and public availability of documents). 5 U.S.C. app. Accordingly, the meeting will be closed to the public.

Signed at Washington, DC, this 30th day of September 2021.

Thea M. Lee,

Deputy Undersecretary, Bureau of International Affairs.

[FR Doc. 2021–21681 Filed 10–4–21; 8:45 am]

BILLING CODE 4510–28–P

DEPARTMENT OF LABOR

[Docket No: DOL–2021–00##]

Privacy Act of 1974; System of Records

AGENCY: Office of Assistant Secretary for Administration and Management, DOL.

ACTION: Notice of a new system of records.

SUMMARY: As required by the Privacy Act of 1974, and Office of Management and Budget (OMB) Circular No. A–108, this notice is a new Privacy Act System of Records titled Contractor and Visitor Public Health Emergency Records DOL/OASAM–38, which include information on contractor employees who work in, as well as visitors to, Department of Labor (DOL) facilities during declared public health emergencies. The system contains information provided by the contractor's employees including such information as their applicable vaccination or medical countermeasure status and whether they are experiencing symptoms associated with the public health emergency. Each contractor with employees who will work in DOL facilities (regardless of whether the contract is with DOL or another Federal agency such as GSA) will be asked to confirm if its employees have been vaccinated or have received appropriate medical countermeasures, in addition, the contractor will be required to ensure that its employees follow the guidelines specified for working in DOL facilities, for example, to mitigate the spread of COVID–19, not fully vaccinated employees are required to wear masks and maintain physical distancing. Visitors to DOL facilities will also be asked to provide information about their vaccination or medical countermeasure status and may be asked to provide proof of their status and information about whether they are experiencing any symptoms associated with the public health emergency.

DATES:

Comment Dates: We will consider comments that we receive on or before November 4, 2021.

Applicable date: This notice is applicable upon publication, subject to a 30-day review and comment period for the routine uses.

ADDRESSES: We invite you to submit comments on this notice. You may submit comments by any of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail, hand delivery, or courier:* 200 Constitution Avenue NW, N–1301, Washington, DC. In your comment, specify Docket ID DOL–2021–00##.
- *Federal mailbox: https://dol.gov/privacy.*

All comments will be made public by DOL and will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: To submit general questions about the system, contact Rick Kryger, at telephone 292–693–4158, or email *kryger.rick.j@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL is establishing a system of records, DOL/OASAM–38, subject to the Privacy Act of 1974, 5 U.S.C. 552a. The purpose of this new system of records is to house information provided by contractors, subcontractors, their employees, and visitors needed for DOL to take appropriate actions during a public health emergency. The information collected includes medical countermeasures, such as vaccinations, diagnostic test results, whether the individual is experiencing relevant symptoms, and any other information necessary to assist DOL with determining appropriate mitigation measures to take with respect to contractor employees and visitors in DOL facilities or in the performance of duties associated with the Department.

In general, the information will be used to confirm that contractors, their employees, and visitors to DOL facilities are aware of and complying with requirements necessitated by the public

health emergency, such as those to wear masks and maintain physical distancing while working onsite or visiting a DOL facility. For onsite contractor employees, the information will be used to make decisions such as office space planning and assigning office space, assigning tasks that require individuals to work in close physical proximity, as well for operational staffing requirements for carrying out work in field operations.

Privacy Act

As required by the Privacy Act (specifically 5 U.S.C. 552a(r)) and implemented by the Office of Management and Budget (OMB) Circular A–108, DOL has provided a report of this system of records to the Office of Information and Regulatory Affairs, Office of Management and Budget; the Chairman, Committee on Government Reform and Oversight, House of Representatives; and the Chairman, Committee on Governmental Affairs, United States Senate.

SYSTEM NAME AND NUMBER:

Contractor and Visitor Public Health Emergency Records DOL/OASAM–38.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The U.S. Department of Labor (DOL) Office of Assistant Secretary and Administration and Management owns the Contractor and Visitor Public Health Emergency Records System, which is housed in secure datacenters in the continental United States. Each DOL agency that has contractors working in a DOL facility has custody of the records pertaining to its own contracts. Contact the system manager for additional information.

SYSTEM MANAGER(S):

Rick Kryger, Deputy Chief Information Officer, Office of the Assistant Secretary for Administration and Management, U.S. Department of Labor, 200 Constitution Avenue NW, N–1301, Washington, DC 20210.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Emergencies Act (50 U.S.C. 1601–1651); the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121, 5192(1)); 5 U.S.C. 301, 7901, 7902, and 7903; the Occupational Safety and Health Act (29 U.S.C. 668), Executive Order 12,196 ''Occupational safety and health programs for Federal employees;'' Workforce Innovation and Opportunity Act (WIOA) WIOA 159(g) ((29 U.S.C. 3209(g)) and WIOA 147(a)(3)(J) ((29 U.S.C. 3197(a)(3)(J)).

PURPOSE(S) OF THE SYSTEM:

To capture and report health and safety-related information during public health emergencies. Such reporting will be provided to DOL contracting officers and other authorized officials in DOL to enable the agency to use the data from the system to review submissions for compliance with applicable mitigation requirements, and, in the case of contractor employees, with contractual terms and conditions for contracts for which they are responsible.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The Contractor and Visitor Public Health Emergency Records System contains records related to employees of prime and subcontractors who are performing work on federal contract awards at any DOL facility, or in shared operations. An owner, agent, or employee of a prime or subcontractor may enter or certify information, as applicable.

The Contractor and Visitor Public Health Emergency Records System may also contain records related to visitors to DOL facilities, such as, but not limited to, volunteers, individuals from outside the DOL workforce on detail to DOL, experts/consultants, and grantees.

CATEGORIES OF RECORDS IN THE SYSTEM:

The information in the system of records consists of electronic or hard copy records, including records of vaccination status or other medical countermeasures (such as diagnostic test results), status of employees or visitors, and other health and safety information related to the public health emergency. The information in the system of records includes the name of the person entering, and as applicable, certifying, information on behalf of the prime or subcontractor, their position within the company, phone number, and email address. Categories of records include, but are not limited to: Name, unique identifier assigned by the prime or subcontractor, medical countermeasure (vaccination or diagnostic test) status, symptom questionnaires and other information relevant and necessary for mitigation purposes. Optional records that may be required for certain contracts or in certain geographic areas include: name, position, work phone number, email address, DOL facility, lands, or shared operations at which the employee will be working on-site, and other similar records related to their official responsibilities.

RECORDS SOURCE CATEGORIES:

Contract employee records are created, reviewed and, as appropriate, certified by the prime or subcontractor. Records pertaining to the individual entering and certifying data in the system may be created by the individual, by a contracting officer, or in the case of a subcontractor by the prime contractor or another subcontractor. Visitor records are created, reviewed and, as appropriate, certified by the appropriate Agency Official receiving the visitor to the DOL facility.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those universal routine uses previously published and listed at *https://www.dol.gov/agencies/sol/privacy/intro,* information in this system may be disclosed to state and local public health officials for purposed related to the public health emergency, such as contract tracing.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic records in this system of records are stored on security measure protected (for example, e-authentication, password, restricted access protocol, etc.) databases, electronically on e-media devices (computer hard drive, magnetic disc, tape, digital media, CD, DVD, etc.). Paper copies of records are stored within secured or locked facilities.

POLICIES AND PRACTICES FOR RETRIEVEAL OF RECORDS:

Records may be retrieved by the individual's name, unique identifier assigned by the prime or subcontractor, vaccination status, position, or facility at which the employee will be working on-site.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained in file folders and DOL computer systems at applicable locations as set out above under the heading ''System Location.'' System records will be retained and disposed of according to DOL's records maintenance and disposition schedules as well as any applicable General Records Schedules.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in this system of records are safeguarded in accordance with applicable rules and policies, including all applicable DOL automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the

information that is being stored. Access to the computer systems containing the records in this system of records is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

Records in the system are protected from unauthorized access and misuse through a combination of administrative, technical, and physical security measures. Administrative measures include but are not limited to policies that limit system access to individuals within an agency with a legitimate business need, and regular review of security procedures and best practices to enhance security. Technical measures include but are not limited to system design that allows prime contractor and subcontractor employees access only to data for which they are responsible; role-based access controls that allow government employees access only to data regarding contracts awarded by their agency or reporting unit; required use of strong passwords that are frequently changed; and use of encryption for certain data transfers. Physical security measures include but are not limited to the use of data centers which meet government requirements for storage of sensitive data.

RECORDS ACCESS PROCEDURES:

Prime and subcontractors enter and review their own data in the system and are responsible for ensuring that those data are correct. If an individual wishes to access their own data in the system after it has been submitted, that individual should consult the System Manager.

CONTESTING RECORD PROCEDURES:

Individuals desiring to contest or amend information maintained in the system should direct their request to the above listed System Manager and should include the reason for contesting it and the proposed amendment to the information with supporting information to show how the record is inaccurate. A request for contesting records pertaining to an individual should contain:

- Name, and
- Any other pertinent information to help identify the file.

NOTIFICATION PROCEDURES:

An individual may request information regarding this system of records or information as to whether the system contains records pertaining to the individual from the System Manager above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Milton Stewart,

Senior Agency Official for Privacy, Office of the Assistant Secretary for Administration and Management, U.S. Department of Labor.

[FR Doc. 2021–21679 Filed 10–4–21; 8:45 am]

BILLING CODE 4510–04–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (21–063)]

NASA Planetary Science Advisory Committee Meeting; Cancellation

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting cancellation.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Aeronautics and Space Administration (NASA) announces that the planned meeting on October 18–19, 2021, of the Planetary Science Advisory Committee is cancelled. This meeting was announced in the **Federal Register** on September 24, 2021, (see reference below). The cancellation of this meeting is due to NASA administrative priorities. NASA will announce the new dates for this meeting in a future **Federal Register** notice.

SUPPLEMENTARY INFORMATION:

REF: **Federal Register**/Vol. 86, No. 183/Friday September 24, 2021/Notices; page 53117–53118.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2021–21653 Filed 10–4–21; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–21–0014; NARA–2022–001]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: NARA must receive comments on the schedules listed in this notice by November 19, 2021.

ADDRESSES: You may submit comments by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* On the website, enter either of the numbers cited at the top of this notice into the search field. This will bring you to the docket for this notice, in which we have posted the records schedules open for comment. Each schedule has a 'comment' button so you can comment on that specific schedule.

Due to COVID–19 building closures, we are currently temporarily not accepting comments by mail. However, if you are unable to comment via *regulations.gov,* you may contact *request.schedule@nara.gov* for instructions on submitting your comment. You must cite the control number of the schedule you wish to comment on. You can find the control number for each schedule in parentheses at the end of each schedule's entry in the list at the end of this notice.

FOR FURTHER INFORMATION CONTACT: Kimberly Keravuori, Regulatory and External Policy Program Manager, by email at *regulation_comments@nara.gov.* For information about records schedules, contact Records Management Operations by email at *request.schedule@nara.gov* or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule.

We have uploaded the records schedules and accompanying appraisal

memoranda to the *regulations.gov* docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Defense, Defense Logistics Agency, Records related to Safety and Health (DAA–0361–2021–0016).
2. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, Controlled Correspondence (DAA–0571–2018–0008).
3. Court Services and Offender Supervision Agency for the District of Columbia, Pretrial Services Agency, Post-Release and Supervision Lists (DAA–0562–2021–0029).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2021–21500 Filed 10–4–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2022–002]

National Industrial Security Program Policy Advisory Committee (NISPPAC); Meeting

AGENCY: Information Security Oversight Office (ISOO), National Archives and Records Administration (NARA).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: We are announcing an upcoming National Industrial Security Program Policy Advisory Committee (NISPPAC) meeting in accordance with the Federal Advisory Committee Act and implementing regulations.

DATES: The meeting will be on October 27, 2021, from 10:00 a.m. to 1:00 p.m. EDT.

ADDRESSES: This meeting will be a virtual meeting. See supplementary procedures below.

FOR FURTHER INFORMATION CONTACT: Heather Harris Pagán, ISOO Senior Program Analyst, by telephone at 202.357.5351 or by email at *NISPPAC@nara.gov.* Contact ISOO at *ISOO@nara.gov.*

SUPPLEMENTARY INFORMATION: This virtual meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulations at 41 CFR 101–6. The Committee will discuss National Industrial Security Program policy matters.

Procedures: Members of the public must register in advance through the Event Services link *https://ems8.intellor.com?do=register&t=1&p=839420* if you wish to attend. NISPPAC members, ISOO employees, and speakers should send an email to *NISPPAC@nara.gov* for the appropriate registration information instead of registering with the above link.

Tasha Ford,

Committee Management Officer.

[FR Doc. 2021–21591 Filed 10–4–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Mathematical and Physical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Mathematical and Physical Sciences (#66).

Date and Time: November 3, 2021; 11:15 a.m.–4:45 p.m.; November 4, 2021; 11:20 a.m.–5:00 p.m.

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual attendance only).

To attend the virtual meeting, please send your request for the virtual meeting link to Michelle Bushey at the following email address: *mbushey@nsf.gov*.

Type of Meeting: Open.

Contact Person: Leighann Martin, National Science Foundation, 2415 Eisenhower Avenue, Room C 9000, Alexandria, Virginia 22314; Telephone: 703/292–4659.

Summary of Minutes: Minutes and meeting materials will be available on the MPS Advisory Committee website at *http://www.nsf.gov/mps/advisory.jsp* or

can be obtained from the contact person listed above.

Purpose of Meeting: To provide advice, recommendations and counsel on major goals and policies pertaining to MPS programs and activities.

Agenda

Wednesday, November 3, 2021

- Call to Order and Official Opening of the Meeting
- Approval of Prior Meeting Minutes—Catherine Hunt, MPSAC Chair
- MPS Update by Assistant Director
- Science Highlight
- MPS and the Living World Subcommittee Report Out and discussion
- Biotech discussion with MPS and BIO AC members
- Discussion with the AC: TIP
- Facilities and Infrastructure Subcommittee Report Out
- Facilities and Infrastructure Subcommittee: New Charge
- Preparation for discussion with NSF Director and COO
- Closing remarks and adjourn day 1

Thursday, November 4, 2021

- Login and register
- Welcome and Overview of Agenda
- Canvassing Committee Reflections
- LEAPS and Ascend Panels
- CEOSE Outbrief
- White paper discussions: Climate Change, Broadening Participation, and Clean Energy
- Astro 2020 Report Update
- Preparation for discussion with NSF Director and COO
- Meeting and discussion with NSF Director and COO
- Closing remarks and adjourn

Dated: September 29, 2021.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2021–21607 Filed 10–4–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Education and Human Resources; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Education and Human Resources (#1119) (Virtual Meeting).

Date and Time: Wednesday, November 3, 2021; 12:00 p.m.–5:00 p.m. and Thursday, November 4, 2021; 12:00 p.m.–5:00 p.m.

Place: Sponsored by the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314 | Virtual.

To attend the virtual meeting, all visitors must register at least 48 hours prior to the meeting.at: *https://nsf.zoomgov.com/webinar/register/WN_e5ZlM-BHS9SZlVSJAKKJ3w*.

The final agenda for the meeting will be posted to: *https://www.nsf.gov/ehr/advisory.jsp*.

Type of Meeting: Open.

Contact Person: Keaven M. Stevenson, National Science Foundation, 2415 Eisenhower Avenue, Room C11001, Alexandria, VA 22314; (703) 292–8600/*kstevens@nsf.gov*.

Summary of Minutes: Minutes and meeting materials will be available on the EHR Advisory Committee website at *http://www.nsf.gov/ehr/advisory.jsp* or can be obtained from Dr. Bonnie A. Green, National Science Foundation, 2415 Eisenhower Avenue, Room C11000, Alexandria, VA 22314; (703) 292–8600; *ehr_ac@nsf.gov*.

Purpose of Meeting: To provide advice with respect to the Foundation's science, technology, engineering, and mathematics (STEM) education and human resources programming.

Agenda

Wednesday, November 3, 2021, 12:00 p.m.–5:00 p.m. (Eastern Standard Time)

- Welcoming Remarks from the AC Chair and the EHR Acting Assistant Director
- Theme 1: Innovation Through Partnership
  - Session 1: Understanding the New Directorate for Technology, Innovation, and Partnerships (TIP)
  - Session 2: Developing and Leveraging Partnerships in STEM Higher Education
  - Session 3: Building a New Infrastructure for Partnerships with EHR & TIP

Thursday, November 4, 2021, 12:00 p.m.–5:00 p.m. (Eastern Standard Time)

- Theme 2: Innovation Through Broadening Participation in STEM
  - Session 4: Utilizing a Comprehensive Approach to Broaden Participation of Groups Underrepresented in STEM
  - Session 5: Advancing the Use of Translational Science for the Purpose of Broadening Participation Through K–12 STEM Education
  - Session 6: Encouraging Authentic and Useable Assessment for Broadening Participation
- Discussion with NSF Director and Chief Operating Officer and Closing Remarks

Dated: September 29, 2021.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2021–21608 Filed 10–4–21; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0183]

Monthly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Monthly notice.

SUMMARY: Pursuant to section 189.a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular monthly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration (NSHC), notwithstanding the pendency before the Commission of a request for a hearing from any person. This monthly notice includes all amendments issued, or proposed to be issued, from August 20, 2021, to September 16, 2021. The last monthly notice was published on September 7, 2021.

DATES: Comments must be filed by November 4, 2021. A request for a hearing or petitions for leave to intervene must be filed by December 6, 2021.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking Website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0183. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory

Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Kathy Entz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–2464, email: *Kathleen.Entz@nrc.gov*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0183, facility name, unit number(s), docket number(s), application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0183.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking Website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0183, facility name, unit number(s), docket number(s), application date, and subject, in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

For the facility-specific amendment requests shown in this document, the Commission finds that the licensees' analyses provided, consistent with section 50.91 of title 10 of *the Code of Federal Regulations* (10 CFR), ''Notice for public comment; State consultation,'' are sufficient to support the proposed determinations that these amendment requests involve NSHC. Under the Commission's regulations in 10 CFR 50.92, ''Issuance of amendment,'' operation of the facilities in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission is seeking public comments on these proposed determinations. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determinations.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue any of these license amendments before expiration of the 60-day period provided that its final determination is that the amendment involves NSHC. In addition, the Commission may issue any of these amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action on any of these amendments prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final NSHC determination for any of these amendments, any hearing will take place after issuance. The Commission expects that the need to take action on any amendment before 60 days have elapsed will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *https://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions that the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion that support the contention and on which the petitioner intends to rely

in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one that, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of NSHC, the Commission will make a final determination on the issue of NSHC. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves NSHC, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a petition is submitted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the Guidance for Electronic Submissions to the NRC (ADAMS Accession No. ML13031A056) and on the NRC website at *https://www.nrc.gov/site-help/e-submittals.html.*

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system timestamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-

free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

The following table provides the plant name, docket number, date of application, ADAMS accession number, and location in the application of the licensees' proposed NSHC determinations. For further details with respect to these license amendment applications, see the applications for amendment, which are available for public inspection in ADAMS. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

LICENSE AMENDMENT REQUEST(S)

Duke Energy Progress, LLC; Shearon Harris Nuclear Power Plant, Unit 1; Wake and Chatham Counties, NC	
Docket No(s)	50–400.
Application date	June 7, 2021.
ADAMS Accession No	ML21158A131.
Location in Application of NSHC	Pages 3–4 of Enclosure.
Brief Description of Amendment(s)	The proposed amendment would revise the technical specifications to reflect the transition of licensee-controlled plant procedure PLP–106, ''Technical Specification Equipment List Program,'' to a licensee-controlled Technical Requirements Manual.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	David Cummings, Associate General Counsel, Mail Code DEC45, 550 South Tryon Street, Charlotte NC 28202.
NRC Project Manager, Telephone Number	Michael Mahoney, 301–415–3867.
Exelon Generation Company, LLC; Braidwood Station, Units 1 and 2, Will County, IL; Byron Station, Units 1 and 2, Ogle County, IL; Exelon Generation Company, LLC; Clinton Power Station, Unit 1; DeWitt County, IL	
Docket No(s)	50–454, 50–455, 50–456, 50–457, 50–461.
Application date	July 30, 2021.
ADAMS Accession No	ML21211A585.
Location in Application of NSHC	Pages 3–5 of Attachment 1.
Brief Description of Amendment(s)	The proposed technical specification (TS) changes add explanatory text to the Safety Function Determination Program in TS 5.5.15 (Braidwood Station and Byron Station) and TS 5.5.10 (Clinton Power Station) clarifying the ''appropriate LCO for loss of function,'' and that consideration does not have to be made for a loss of power in determining loss of function.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Tamra Domeyer, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.
NRC Project Manager, Telephone Number	Joel Wiebe, 301–415–6606.
Nebraska Public Power District; Cooper Nuclear Station; Nemaha County, NE	
Docket No(s)	50–298.
Application date	July 20, 2021.
ADAMS Accession No	ML21202A200.
Location in Application of NSHC	Pages 7–9 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendment would revise Cooper Nuclear Station Technical Specifications Section 5.5.12, ''Primary Containment Leakage Rate Testing Program,'' to include an exception to the 24-calendar month interval exclusion of certain pathways during 10 CFR Part 50, Appendix J, Type A testing. Specifically, the amendment would extend the allowance to not vent and drain pathways during the Type A test, which have been Type B or C tested within the previous 24 calendar months of the Type A test, from 24 calendar months to 30 calendar months.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	John C. McClure, Nebraska Public Power District, P.O. Box 499, Columbus, NE 68602–0499.
NRC Project Manager, Telephone Number	Thomas Wengert, 301–415–4037.

LICENSE AMENDMENT REQUEST(S)—Continued

Northern States Power Company—Minnesota; Prairie Island Nuclear Generating Plant, Units 1 and 2; Goodhue County, MN	
Docket No(s)	50–282, 50–306.
Application date	August 6, 2021.
ADAMS Accession No	ML21218A093.
Location in Application of NSHC	Pages 18–21 of Enclosure 1.
Brief Description of Amendment(s)	The amendments request changes to the Prairie Island Nuclear Generating Plant, Units 1 and 2 (PINGP), licensing bases to implement a 24-month operating cycle. The amendment proposes to change the PINGP technical specifications (TSs) to support the change in the maximum surveillance intervals from 24 months to 30 months including changes to one TS allowable value in TS Table 3.3.2–1 and changes to TS 5.5.2 and 5.5.17. The proposed changes to TS 5.5.2 would implement TS Task Force (TSTF) Traveler 299 (TSTF–299) ''Administrative Controls Program 5.5.2.b Test Interval and Exceptions.'' The proposed changes to TS 5.5.17 documents the use of Generic Letter 91–04 ''Changes in Technical Specification Surveillance Intervals to Accommodate a 24-Month Fuel Cycle,'' to increase the surveillance requirement intervals.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Peter M. Glass, Assistant General Counsel, Xcel Energy, 414 Nicollet Mall—401–8, Minneapolis, MN 55401.
NRC Project Manager, Telephone Number	Robert Kuntz, 301–415–3733.
Southern Nuclear Operating Company, Inc.; Joseph M. Farley Nuclear Plant, Units 1 and 2; Houston County, AL	
Docket No(s)	50–348, 50–364.
Application date	July 29, 2021.
ADAMS Accession No	ML21210A242.
Location in Application of NSHC	Page E–10 and E–11 of Enclosure.
Brief Description of Amendment(s)	The proposed amendment would modify the licensing basis of the Joseph M. Farley Nuclear Plant, Units 1 and 2, by allowing the permanent removal of the encapsulation vessels around the first isolation valves in the recirculation suction lines for the Containment Spray and Residual Heat Removal/Low Head Safety Injection systems.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Millicent Ronnlund, Vice President and General Counsel, Southern Nuclear Operating Co., Inc., P.O. Box 1295, Birmingham, AL 35201–1295.
NRC Project Manager, Telephone Number	Stephanie Devlin-Gill, 301–415–5301.
STP Nuclear Operating Company; South Texas Project, Units 1 and 2; Matagorda County, TX	
Docket No(s)	50–498, 50–499.
Application date	August 10, 2021, as supplemented by letter dated September 9, 2021.
ADAMS Accession No	ML21222A227, ML21252A758.
Location in Application of NSHC	Pages 2–3 of the Enclosure.
Brief Description of Amendment(s)	The amendments would adopt Technical Specifications Task Force (TSTF) Traveler TSTF–577, Revision 1, ''Revised Frequencies for Steam Generator Tube Inspections.'' The amendments would modify the technical specification requirements related to steam generator tube inspections and reporting based on operating history.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Kym Harshaw, Vice President and General Counsel, STP Nuclear Operating Company, P.O. Box 289, Wadsworth, TX 77483.
NRC Project Manager, Telephone Number	Dennis Galvin, 301–415–6256.
Tennessee Valley Authority; Sequoyah Nuclear Plant, Units 1 and 2; Hamilton County, TN	
Docket No(s)	50–327, 50–328.
Application date	August 5, 2021.
ADAMS Accession No	ML21217A174.
Location in Application of NSHC	Pages 6–7 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendments would modify technical specification requirements to permit the use of risk-informed completion times in accordance with Technical Specifications Task Force (TSTF) Traveler, TSTF–505, Revision 2, ''Provide Risk-Informed Extended Completion Times—RITSTF [Risk-Informed TSTF] Initiative 4b,'' dated July 2, 2018 (ADAMS Accession No. ML18183A493).
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	David Fountain, Executive VP and General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, WT 6A, Knoxville, TN 37902.
NRC Project Manager, Telephone Number	Perry Buckberg, 301–415–1383.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last monthly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed NSHC determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated in the safety evaluation for each amendment.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated in the safety evaluation for the amendment.

For further details with respect to each action, see the amendment and associated documents such as the Commission's letter and safety evaluation, which may be obtained using the ADAMS accession numbers indicated in the following table. The safety evaluation will provide the ADAMS accession numbers for the application for amendment and the **Federal Register** citation for any environmental assessment. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

LICENSE AMENDMENT ISSUANCE(S)

Dominion Energy Nuclear Connecticut, Inc.; Millstone Power Station, Unit No. 2; New London County, CT	
Docket No(s)	50–336.
Amendment Date	September 9, 2021.
ADAMS Accession No	ML21222A230.
Amendment No(s)	343.
Brief Description of Amendment(s)	The amendment revised the Millstone 2 Technical Specification (TS) Section 6.26, ''Steam Generator (SG) Program,'' and the SG tube inspection reporting requirements in TS Section 6.9.1.9, ''Steam Generator Tube Inspection Report,'' and made several editorial changes to the Millstone 2 TSs.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Duke Energy Carolinas, LLC; Catawba Nuclear Station, Units 1 and 2; York County, SC; Duke Energy Carolinas, LLC; McGuire Nuclear Station, Units 1 and 2; Mecklenburg County, NC; Duke Energy Carolinas, LLC; Oconee Nuclear Station, Units 1, 2, and 3; Oconee County, SC; Duke Energy Progress, LLC; Brunswick Steam Electric Plant, Units 1 and 2; Brunswick County, NC; Duke Energy Progress, LLC; H. B. Robinson Steam Electric Plant, Unit No. 2; Darlington County, SC; Duke Energy Progress, LLC; Shearon Harris Nuclear Power Plant, Unit 1; Wake and Chatham Counties, NC.	
Docket No(s)	50–413, 50–414, 50–369, 50–370, 50–269, 50–270, 50–287, 50–325, 50–324, 50–261, 50–400.
Amendment Date	August 26, 2021.
ADAMS Accession No	ML21155A213.
Amendment No(s)	309 to NPF 35, 305 to NPF 52, No. 319 to NPF 9, 298 to NPF 17, 422 to DPR 38, 424 to DPR 47, 423 to DPR 55, 306 to DPR 71, 334 to DPR 62, 186 to NPF 63, and 270 to DPR 23.
Brief Description of Amendment(s)	These amendments are issued to revise and replace the site-specific emergency plans of the seven plants with the Duke Energy Common Emergency Plan (DECEP) with site-specific annexes. The DECEP was developed using the guidance in NUREG 0654/FEMA REP–1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' Revision 2.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Duke Energy Progress, LLC; Brunswick Steam Electric Plant, Units 1 and 2; Brunswick County, NC.	
Docket No(s)	50–325, 50–324.
Amendment Date	September 29, 2020.
ADAMS Accession No	ML20269A305.
Amendment No(s)	301 (Unit 1) and 329 (Unit 2).
Brief Description of Amendment(s)	The amendments revised the technical specification safety limit on minimum critical power ratio to reduce the need for cycle-specific changes to the value while still meeting the regulatory requirement for a safety limit.
Public Comments Received as to Proposed NSHC (Yes/No).	No
Entergy Operations, Inc.; Waterford Steam Electric Station, Unit 3; St. Charles Parish, LA	
Docket No(s)	50–382.
Amendment Date	August 24, 2021.
ADAMS Accession No	ML21131A243.
Amendment No(s)	260.

LICENSE AMENDMENT ISSUANCE(S)—Continued

Brief Description of Amendment(s)	The amendment revised multiple Waterford Steam Electric Station, Unit 3, technical specifications in order for the licensee to implement a modification to the existing digital microcomputers of the core protection calculator and control element assembly calculator systems.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Holtec Pilgrim, LLC and Holtec Decommissioning International; Pilgrim Nuclear Power Station; Plymouth County, MA

Docket No(s)	50–293.
Amendment Date	August 5, 2021.
ADAMS Accession No	ML21217A175.
Amendment No(s)	255.
Brief Description of Amendment(s)	The amendment revised the license to reflect the requirements associated with the security changes set forth in the revised Pilgrim Security Plan, Training and Qualification Plan, and Safeguards Contingency Plan (the Plan) for the independent spent fuel storage installation (ISFSI) only configuration, upon the permanent removal of all spent fuel from the spent fuel pool as per 10 CFR 72.212(b)(9). The changes to the Pilgrim Plan reflect changes in the status of the nuclear power reactor based on certifications that the licensee has submitted under 10 CFR 50.82(a) for permanent cessation of power operations and permanent removal of fuel from the reactor vessel and has completed the transfer of all irradiated fuel to the on-site ISFSI. The implementation of the proposed changes is predicated upon the completion of the transfer of all spent fuel to dry storage in casks within the ISFSI.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Holtec Pilgrim, LLC and Holtec Decommissioning International; Pilgrim Nuclear Power Station; Plymouth County, MA

Docket No(s)	50–293.
Amendment Date	August 24, 2021.
ADAMS Accession No	ML21203A048.
Amendment No(s)	256.
Brief Description of Amendment(s)	The NRC has issued Amendment No. 256 to Renewed Facility Operating License No. DPR–35 for the Pilgrim Nuclear Power Station (Pilgrim, the licensee) Permanently Defueled Technical Specifications in response to Holtec Decommissioning International's application dated March 17, 2021 (ADAMS Accession No. ML21076A404), and supplemental letter dated May 28, 2021, ADAMS Accession No. ML21148A199). These changes reflect the removal of all spent nuclear fuel from the spent fuel pool and its transfer to dry cask storage within an on-site independent spent fuel storage installation (ISFSI). These changes will more fully reflect the permanently shutdown status of the decommissioning facility, as well as the reduced scope of structures, systems, and components necessary to ensure plant safety now that all spent fuel has been permanently moved to the Pilgrim ISFSI (new ISFSI or ISFSI II), an activity which is scheduled to be completed in mid-November 2021.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Pacific Gas and Electric Company; Diablo Canyon Power Plant, Units 1 and 2; San Luis Obispo County, CA

Docket No(s)	50–275, 50–323.
Amendment Date	September 2, 2021.
ADAMS Accession No	ML21160A174.
Amendment No(s)	239 (Unit 1) and 240 (Unit 2).
Brief Description of Amendment(s)	The amendments revised Technical Specification 3.2.1, ''Heat Flux Hot Channel Factor (FQ(Z)),'' to implement methodology from licensing topical report WCAP 17661, Revision 1, ''Improved RAOC [Relaxed Axial Offset Control] and CAOC [Constant Axial Offset Control] FQ Surveillance Technical Specifications.''
Public Comments Received as to Proposed NSHC (Yes/No).	No.

PSEG Nuclear LLC; Salem Nuclear Generating Station, Unit Nos. 1 and 2; Salem County, NJ

Docket No(s)	50–272, 50–311.
Amendment Date	September 3, 2021.
ADAMS Accession No	ML21202A078.
Amendment No(s)	338 (Unit No. 1) and 320 (Unit No. 2).
Brief Description of Amendment(s)	These amendments adopt Technical Specifications Task Force (TSTF) Traveler TSTF–577, ''Revised Frequencies for Steam Generator Tube Inspections,'' which is an approved change to the standard technical specifications, into the Salem Nuclear Generating Station, Unit Nos. 1 and 2, technical specifications.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Limestone County, AL

Docket No(s)	50–259, 50–260, 50–296.

LICENSE AMENDMENT ISSUANCE(S)—Continued

Amendment Date	August 30, 2021.
ADAMS Accession No	ML21214A139.
Amendment No(s)	318, 341, and 301.
Brief Description of Amendment(s)	The amendments modified Technical Specification 3.8.6, ''Battery Cell Parameters,'' to clarify the operability requirements for the Unit, Shutdown Board, and Diesel Generator batteries.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Wolf Creek Nuclear Operating Corporation; Wolf Creek Generating Station, Unit 1; Coffey County, KS

Docket No(s)	50–482.
Amendment Date	September 3, 2021.
ADAMS Accession No	ML21210A247.
Amendment No(s)	230.
Brief Description of Amendment(s)	The amendment revised Technical Specification 3.6.3, ''Containment Isolation Valves,'' Condition D, to allow the use of a blind flange for Required Action D.1. In addition, the amendment changed Surveillance Requirement 3.6.3.1 to allow the use of a blind flange.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Dated: September 27, 2021.

For the Nuclear Regulatory Commission.

Michael I. Dudek,

Acting Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–21334 Filed 10–4–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0176]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; notice of opportunity to comment, request a hearing, and petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of two amendment requests. The amendment requests are for Donald C. Cook Nuclear Plant, Unit 2, and Monticello Nuclear Generating Plant. For each amendment request, the NRC proposes to determine that they involve no significant hazards consideration (NSHC). Because each amendment request contains sensitive unclassified non-safeguards information (SUNSI), an order imposes procedures to obtain access to SUNSI for contention preparation by persons who file a hearing request or petition for leave to intervene.

DATES: Comments must be filed by November 4, 2021. A request for a hearing or petitions for leave to intervene must be filed by December 6, 2021. Any potential party as defined in section 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR) who believes access to SUNSI is necessary to respond to this notice must request document access by October 15, 2021.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0176. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Karen Zeleznock, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1118, email: *Karen.Zeleznock@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0176, facility name, unit number(s), docket number(s), application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0176.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0176, facility

name, unit number(s), docket number(s), application date, and subject, in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves NSHC, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of amendments containing SUNSI.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve NSHC. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown in this document.

The Commission is seeking public comments on these proposed determinations. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determinations.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue any of these license amendments before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue any of these amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action on any of these amendments prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. If the Commission makes a final no significant hazards consideration determination for any of these amendments, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *https://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d), the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions that the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion that support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one that, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of NSHC, the Commission will make a final determination on the issue of NSHC. The final determination will serve to

establish when the hearing is held. If the final determination is that the amendment request involves NSHC, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a petition is submitted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as discussed below, is granted. Detailed guidance on electronic submissions is located in the Guidance for Electronic Submissions to the NRC (ADAMS Accession No. ML13031A056) and on the NRC website at *https://www.nrc.gov/site-help/e-submittals.html.*

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. (ET) on the due date. Upon receipt of a transmission, the E-Filing system timestamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., (ET), Monday through Friday, excluding government holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the

adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

Indiana Michigan Power Company; Donald C. Cook Nuclear Plant, Unit 2; Berrien County, MI	
Docket No(s)	50–316.
Application Date	June 15, 2021.
ADAMS Accession No	ML21210A278.
Location in Application of NSHC	Pages 23–25 of Enclosure 2.
Brief Description of Amendment(s)	The requested amendment would revise the reactor coolant system heatup and cooldown curves and low temperature overpressure protection (LTOP) requirements in Technical Specification (TS) 3.4.3 and 3.4.12, respectively. The proposed changes to the LTOP requirements in TS 3.4.12 will also require changes to be made to TS 3.4.6, 3.4.7, and 3.4.10.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Robert B. Haemer, Senior Nuclear Counsel, Indiana Michigan Power Company, One Cook Place, Bridgman, MI 49106.
NRC Project Manager, Telephone Number	Scott Wall, 301–415–2855.

Northern States Power Company; Monticello Nuclear Generating Plant; Wright County, MN	
Docket No(s)	50–263.
Application Date	July 29, 2021.
ADAMS Accession No	ML21211A594 (Package).
Location in Application of NSHC	Pages 15–17 of Enclosure.
Brief Description of Amendment(s)	The amendment would revise the Technical Specification 5.6.3 "Core Operating Limits Report (COLR)," to allow the application of advanced Framatome, Inc., methodologies for determining core operating limits in support of loading Framatome, Inc. ATRIUM 11 fuel type into the Monticello Nuclear Generating Plant core and to incorporate a new long-term reactor stability solution.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Peter M. Glass, Assistant General Counsel, Xcel Energy, 414 Nicollet Mall—401–8, Minneapolis, MN 55401.
NRC Project Manager, Telephone Number	Robert Kuntz, 301–415–3733

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Indiana Michigan Power Company; Donald C. Cook Nuclear Plant, Unit 2; Berrien County, MI

Northern States Power Company; Monticello Nuclear Generating Plant; Wright County, MN

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request access to SUNSI. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Hearings and Administration, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *RidsOgcMailCenter.Resource@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

or Affidavit, or Protective Order [2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and requisite need, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requestor may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(3) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

H. Review of Grants of Access. A party other than the requestor may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated: September 21, 2021.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requestor to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING—Continued

Day	Event/activity
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of opportunity to request a hearing and petition for leave to intervene), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2021–20848 Filed 10–4–21; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–136 and CP2021–143]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 7, 2021.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2021–136 and CP2021–143; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 203 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* September 29, 2021; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Matthew Ashford; *Comments Due:* October 7, 2021.

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2021–21642 Filed 10–4–21; 8:45 am]

BILLING CODE 7710–FW–P

RAILROAD RETIREMENT BOARD

Privacy Act of 1974; System of Records; (Railroad Retirement Board—Office of Personnel Management)

AGENCY: Railroad Retirement Board (RRB).

ACTION: Renewal of computer-matching program.

SUMMARY: As required by the Privacy Act of 1974, as amended, the RRB is issuing public notice of its renewal of an ongoing computer-matching program with the Office of Personnel Management (OPM) that expired on March 1, 2019. The purpose of this notice is to advise individuals applying for or receiving benefits under the Railroad Retirement Act of the use made by RRB of this information obtained from OPM by means of a computer match. We will file a report of this computer-matching program with the Committee on Homeland Security and Governmental Affairs of the Senate; the Committee on Oversight and Government Reform of the House of Representatives; and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).

DATES: This matching program will take effect November 4, 2021. The matching program will continue for 18 months after the effective date and may be extended for an additional 12 months, if the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met, with an expiration date of April 1, 2024.

ADDRESSES: Interested parties may comment on this publication by writing to Ms. Stephanie Hillyard, Secretary to the Board, Railroad Retirement Board,

844 North Rush Street, Chicago, Illinois 60611–1275.

FOR FURTHER INFORMATION CONTACT: Mr. Timothy Grant, Associate Chief Information Officer, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092, telephone 312–751–4869 or email at *tim.grant@rrb.gov*.

SUPPLEMENTARY INFORMATION:

A. General

The Computer Matching and Privacy Protection Act of 1988, (Pub. L. 100–503), amended by the Privacy Act of 1974, (5 U.S.C. 552a) as amended, requires a Federal agency participating in a computer matching program to publish a notice in the **Federal Register** for all matching programs.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records contained in a Privacy Act System of Records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the approval of the matching agreement by the Data Integrity Boards (DIB) of the participating Federal agencies;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating, or denying a person's benefits or payments. The last published notice for this matching program was March 1, 2018 (78 FR 70971).

B. RRB Computer Matches Subject to the Privacy Act

We have taken appropriate action to ensure that all of our computer matching programs comply with the requirements of the Privacy Act, as amended.

Notice of Computer Matching Program, RRB With the Office of Personnel Management (OPM)

Name of Participating Agencies: OPM and RRB.

Authority for Conducting the Matching Program: Sections 3(a)(1), 4(a)(1) and 4(f)(1) of the Railroad Retirement Act, as amended, 45 U.S.C. 231b(a)(1), 231c(a)(1) and 231c(f)(1) require that the RRB reduce the Railroad Retirement benefits of certain beneficiaries entitled to Railroad Retirement employee and/or spouse/widow benefits who are also entitled to a government pension based on their own non-covered earnings. We call this reduction a Public Service Pension (PSP) offset.

Section 224 of the Social Security Act, as amended, 42 U.S.C. 424a, provides for the reduction of disability benefits when the disabled worker is also entitled to a public disability benefit (PDB). We call this a PDB offset. A civil service disability benefit is considered a PDB. Section 224(h)(1) requires any Federal agency to provide RRB with information in its possession that RRB may require for the purposes of making a timely determination of the amount of reduction under section 224 of the Social Security Act. Pursuant to 5 U.S.C. Section 552a(b)(3) OPM has established routine uses to disclose the subject information to RRB.

Purpose of the Matching Program: The purpose of the match is to enable the RRB to (1) identify affected RRB annuitants who are in receipt of a Federal public pension benefit but who have not reported receipt of this benefit to the RRB, and (2) receive timely and accurate Federal public pension benefit information for affected RRB annuitants.

Categories of Individuals: Individuals receiving Federal public pensions or RRB annuities. *Categories of Records:* OPM will provide the RRB once a year via secure electronic file transfer, data extracted from its annuity and survivor master file of its Civil Service Retirement and Insurance Records. Normally on December of each year, OPM transmits to us approximately 2.5 million electronic records for matching. The records contain these data elements: Name, social security number, date of birth, civil service claim number, first potential month and year of eligibility for civil service benefits, first month, day, year of entitlement to civil service benefits, amount of current gross civil service benefits, and effective date (month, day, year) of civil service amount, and where applicable, civil service disability indicator, civil service FICA covered month indicator, and civil service total service months. The RRB will match the Social Security number, name, and date of birth contained in the OPM file against approximately the 1.2 million records in our files. For records that match, the RRB will extract the civil service payment information.

Systems of Records: The Privacy Act System of Records designation is OPM/Central-1, (Civil Service Retirement and Insurance Records), Published in the **Federal Register** on June 7, 2011 (76 FR 32997). The RRB Privacy Act System of Records is RRB–22, Railroad Retirement, Survivor, and Pensioner Benefit System, published in the **Federal Register** on May 15, 2015 (80 FR 28018).

Dated: September 30, 2021.

By authority of the Board.

Stephanie Hillyard,

Secretary to the Board.

[FR Doc. 2021–21670 Filed 10–4–21; 8:45 am]

BILLING CODE 7905–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

National Strategic Plan for Advanced Manufacturing; Request for Information

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice of request for information (RFI).

SUMMARY: On behalf of the National Science and Technology Council (NSTC), Committee on Technology, Subcommittee on Advanced Manufacturing, OSTP requests input from all interested parties on the development of a National Strategic Plan for Advanced Manufacturing. Through this RFI, OSTP seeks input from the public, on ways to improve government coordination, and on long-term guidance for Federal programs and activities in support of United States manufacturing competitiveness, including: Advanced manufacturing research and development that will create jobs, grow the economy across multiple industrial sectors, strengthen national security, enhance sustainability, contribute to climate change challenges, and improve health care. The public input provided in response to this RFI will inform OSTP and NSTC as they work with Federal agencies and other stakeholders to develop the strategic plan.

DATES: Responses are due by December 17, 2021.

ADDRESSES: Responses should be submitted online at *https://docs.google.com/forms/d/e/1FAIpQLSeZdOIhLsiSLqqOWqP0MekJHA0EHlEDb_D6mjl-H5JghM0F2g/viewform.*

Instructions: Response to this RFI is voluntary. Respondents need not reply to all questions listed. Each individual or institution is requested to submit only one response. OSTP and/or NSTC may post responses to this RFI, without change, on a Federal website. OSTP, therefore, requests that no business proprietary information, copyrighted

information, or personally identifiable information be submitted in response to this RFI. Please note that the United States Government will not pay for response preparation, or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: Said Jahanmir, *amnpo@nist.gov,* 202–819–5296.

SUPPLEMENTARY INFORMATION: The Consolidated and Further Continuing Appropriations Act 2015 (Pub. L. 113–235), incorporating the Revitalize American Manufacturing and Innovation Act of 2014, revised 42 U.S.C. 6622 to direct NSTC to develop and to update, in coordination with the National Economic Council, a strategic plan to improve government coordination and to provide long-term guidance for Federal programs and activities in support of United States manufacturing competitiveness, including advanced manufacturing research and development (R&D). The current National Strategic Plan for Advanced Manufacturing (''Plan'') was released on October 5, 2018 (*https://www.manufacturing.gov/news/announcements/2018/10/strategy-american-leadership-advanced-manufacturing*).

Advanced manufacturing is a family of activities that (1) depend on the use and coordination of information, automation, computation, software, sensing, and networking, and/or (2) make use of cutting-edge materials and emerging capabilities enabled by the physical and biological sciences, for example: Nanotechnology, chemistry, and biology. It involves both new ways to manufacture existing products, and the manufacture of new products emerging from new advanced technologies.

NSTC has commenced the development of an updated Plan to be released in 2022. Pursuant to 42 U.S.C. 6622, OSTP is soliciting public input through this RFI to obtain recommendations from a wide range of stakeholders, including representatives from diverse manufacturing companies, academia, other relevant organizations and institutions, and the general public. The public input provided in response to this RFI will inform OSTP and NSTC as they work with Federal agencies and other stakeholders to develop an updated revised Plan.

Questions To Inform Development of the Plan

OSTP seeks responses to the following questions to improve government coordination and to provide long-term guidance for Federal programs and activities in support of United States manufacturing competitiveness, including advanced manufacturing R&D.

1. Which emerging science and technology areas will be key to the next generation of advanced manufacturing for global competitiveness, sustainability, and environmental challenges?

2. What should be the near-term and long-term technology development R&D priorities for advanced manufacturing, the anticipated timeframe for achieving the objectives, and the metrics in assessing progress toward the objectives?

3. What are examples of technological, market, or business challenges that may best be addressed by public-private partnerships, and are likely to attract both participation and primary funding from industry?

4. How can Federal agencies and federally funded R&D centers supporting advanced manufacturing R&D facilitate the transfer of research results, intellectual property, and technology into commercialization and manufacturing for the benefit of society and ensure sustainability, national security, and economic security?

5. How would you assess the state of the domestic advanced manufacturing workforce in the U.S? How can Federal agencies and federally funded R&D centers develop, align, and strengthen all levels of advanced manufacturing education, training, and certification programs to ensure a high-quality, equitable, diverse, and inclusive workforce that meets the needs of the sector and drives new advanced manufacturing jobs into the future?

6. How can the Federal government assist in the development of regional public-private partnerships to achieve greater distribution of advanced manufacturing clusters or technology hubs, particularly in underserved regions of the country? What outreach and engagement strategies are most useful in promoting development in underserved regions of the country?

7. How do we assess the adequacy of the domestic advanced manufacturing supply chain and industrial base? How can Federal agencies assist small and medium sized manufacturing companies to adopt advanced technologies and to develop a robust and resilient manufacturing supply chain? What steps can these agencies take to promote the development and diffusion of technology that augments worker skills (rather than substituting for them), and ensures that manufacturing jobs are good jobs?

8. Are there useful models (at the international, national, state and/or local level) that should be expanded?

9. The current Strategy for American Leadership in Advanced Manufacturing (*https://www.manufacturing.gov/news/announcements/2018/10/strategy-american-leadership-advanced-manufacturing*) has three top-level goals, each with objectives and priorities: (1) Develop and transition new manufacturing technologies; (2) Educate, train, and connect the manufacturing workforce; and (3) Expand the capabilities of the domestic manufacturing supply chains. Are these goals appropriate for the next 4–5 years? Are there additional top-level goals to consider?

10. Is there any additional information related to advanced manufacturing in the United States, not requested above, that you believe should be considered?

Dated: September 30, 2021.

Stacy Murphy,

Operations Manager.

[FR Doc. 2021–21644 Filed 10–4–21; 8:45 am]

BILLING CODE 3270–FI–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–237, OMB Control No. 3235–0226]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 10f–3

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for extension and approval of the collections of information discussed below.

Section 10(f) of the Investment Company Act of 1940 (15 U.S.C. 80a) (the ''Act'') prohibits a registered investment company (''fund'') from purchasing any security during an underwriting or selling syndicate if the fund has certain affiliated relationships with a principal underwriter for the security. Congress enacted this provision in 1940 to protect funds and their shareholders by preventing underwriters from ''dumping''

unmarketable securities on affiliated funds.

Rule 10f–3 (17 CFR 270.10f–3) under the Act permits a fund to engage in a securities transaction that otherwise would violate Section 10(f) if, among other things: (i) The fund's directors have approved procedures for purchases made in reliance on the rule, regularly review fund purchases to determine whether they comply with these procedures, and approve necessary changes to the procedures; and (ii) a written record of each transaction effected under the rule is maintained for six years, the first two of which in an easily accessible place. The written record must state: (i) From whom the securities were acquired; (ii) the identity of the underwriting syndicate's members; (iii) the terms of the transactions; and (iv) the information or materials on which the fund's board of directors has determined that the purchases were made in compliance with procedures established by the board.

Rule 10f–3 also conditionally allows managed portions of fund portfolios to purchase securities offered in otherwise off-limits primary offerings. To qualify for this exemption, Rule 10f–3 requires that the subadviser that is advising the purchaser be contractually prohibited from providing investment advice to any other portion of the fund's portfolio and consulting with any other of the fund's advisers that is a principal underwriter or affiliated person of a principal underwriter concerning the fund's securities transactions.

These requirements provide a mechanism for fund boards to oversee compliance with the rule. The required recordkeeping facilitates the Commission staff's review of Rule 10f–3 transactions during routine fund inspections and, when necessary, in connection with enforcement actions.

The staff estimates that approximately 953 funds engage in at least one Rule 10f–3 transaction each year, for a total of 953 such transactions.[1] Rule 10f–3 requires that the purchasing fund create a written record of each transaction that includes, among other things, from whom the securities were purchased and the terms of the transaction. The staff estimates that it takes an average fund approximately 30 minutes per transaction and, in the aggregate, approximately 477 hours[2] for funds to comply with this portion of the rule.

The funds also must maintain and preserve these transactional records in accordance with the rule's recordkeeping requirement, and the staff estimates that it takes a fund approximately 20 minutes per transaction and, in the aggregate, approximately 318 hours[3] annually for the funds to comply with this portion of the rule.

In addition, fund boards must, no less than quarterly, examine each of these transactions to ensure that they comply with the fund's policies and procedures. The information or materials upon which the board relied to come to this determination also must be maintained and the staff estimates that it takes a fund 1 hour per quarter and, in the aggregate, approximately 3,812 hours[4] annually for the funds to comply with this rule requirement.

The staff estimates that reviewing and revising as needed written procedures for Rule 10f–3 transactions takes, on average for each fund, two hours of a compliance attorney's time per year.[5] Thus, annually, in the aggregate, the staff estimates that funds spend a total of approximately 1,906 hours[6] on monitoring and revising Rule 10f–3 procedures.

Based on an analysis of Form N–CEN filings, the staff estimates that approximately 146 new funds enter into subadvisory agreements each year.[7] The staff estimates that it will require approximately 0.75 hours to draft and execute additional clauses in subadvisory contracts in order for new funds and subadvisers to be able to rely on the exemptions in Rule 10f–3.[8] Assuming that all 146 funds that enter into new subadvisory contracts each year make the modification to their contract required by the rule, we estimate that the rule's contract modification requirement will result in 110 burden hours annually for new funds.[9]

The staff estimates, therefore, that Rule 10f–3 imposes an information collection burden of 6,623 hours.[10]

The collection of information required by Rule 10f–3 is necessary to obtain the benefits of the rule. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: September 29, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21590 Filed 10–4–21; 8:45 am]

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[1] These estimates are based on data from Form N–CEN filings with the Commission.

[2] This estimate is based on the following calculation: (0.5 hours × 953 = 477 hours).

[3] This estimate is based on the following calculations: (20 minutes × 953 transactions = 19,060 minutes; 19,060 minutes/60 = 318 hours).

[4] This estimate is based on the following calculation: (1 hour per quarter × 4 quarters × 953 funds = 3,812 hours).

[5] These averages take into account the fact that in most years, fund attorneys and boards spend little or no time modifying procedures and in other years, they spend significant time doing so.

[6] This estimate is based on the following calculation: (953 funds × 2 hours = 1,906 hours).

[7] Based on information in Form N–CEN filings, we estimate that approximately 139 new open-end funds and 7 new closed-end funds, or a total of 146 new funds enter into new subadvisory agreements each year (139 + 7 = 146 new funds). We understand that existing funds may also enter into new subadvisory agreements, but in many cases would benefit from having previously drafted Rule 10f–3 clauses in prior or existing subadvisory contracts.

[8] Because such clauses are identical to the clauses that a fund would need to insert in their subadvisory contracts to rely on Rules 12d3–1, 17a–10, and 17e–1, and because we believe that funds that use one such rule generally use all of these rules, we apportion this 3 hour time burden equally to all four rules. Therefore, we estimate that the burden allocated to Rule 10f–3 for this contract change would be 0.75 hours (3 hours ÷ 4 rules = 0.75 hours).

[9] These estimates are based on the following calculations: (0.75 hours × 146 portfolios = 110 burden hours).

[10] This estimate is based on the following calculation: (477 hours + 318 hours + 3,812 hours + 1,906 hours + 110 hours = 6,623 total burden hours).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–562, OMB Control No. 3235–0624]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Regulation R, Rule 701

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995

(''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Regulation R, Rule 701 (17 CFR 247.701) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Regulation R, Rule 701 requires a broker or dealer (as part of a written agreement between the bank and the broker or dealer) to notify the bank if the broker or dealer makes certain determinations regarding the financial status of the customer, a bank employee's statutory disqualification status, and compliance with suitability or sophistication standards.

The Commission estimates there are 3,560 registered brokers or dealers that would, on average, notify 1,000 banks approximately two times annually about a determination regarding a customer's high net worth or institutional status or suitability or sophistication standing as well as a bank employee's statutory disqualification status. Based on these estimates, the Commission anticipates that Regulation R, Rule 701 would result in brokers or dealers making approximately 2,000 notifications to banks per year. The Commission further estimates (based on the level of difficulty and complexity of the applicable activities) that a broker or dealer would spend approximately 15 minutes per notice to a bank. Therefore, the estimated total annual third party disclosure burden for the requirements in Regulation R, Rule 701 is 500 [1] hours for brokers or dealers.

The retention period for the recordkeeping requirement under Rule 17Ad–2(c), (d), and (h) is not less than two years following the date the notice is submitted. The recordkeeping requirement under this rule is mandatory to assist the Commission in monitoring transfer agents who fail to meet the minimum performance standards set by the Commission rule. This rule does not involve the collection of confidential information. Please note that a transfer agent is not required to file under the rule unless it does not meet the minimum performance standards for turnaround, processing or forwarding items received for transfer during a month.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: September 29, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21585 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93206; File No. SR–FINRA–2021–025]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Establish an Administration and Delivery Fee for the Municipal Advisor Principal Examination

September 30, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 27, 2021, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as ''establishing or changing a due, fee or other charge'' under Section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend Section 4(c) of Schedule A to the FINRA By-Laws to establish an administration and delivery fee for the new Municipal Advisor Principal Examination (''Series 54 examination'').

Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

Schedule A to the By-Laws of the Corporation

* * * * *

Section 4—Fees [5]

(a) through (b) No Change.

(c) The following fees shall be assessed to each individual who takes an examination as described below. These fees are in addition to the registration fee described in paragraph (b) and any other fees that the owner of an examination that FINRA administers may assess.

Examination No.	Examination name	Examination fee
N/A	Securities Industry Essentials (SIE) Examination	$60
Series 4	Registered Options Principal Examination	105
Series 6	Investment Company Products and Variable Contracts Representative Examination	40
Series 7	General Securities Representative Examination	245
Series 9	General Securities Sales Supervisor Examination—Options Module	80
Series 10	General Securities Sales Supervisor Examination—General Module	125

[1] 1,000 banks × 2 notices = 2,000 notices; (2,000 notices × 15 minutes) = 30,000 minutes/60 minutes = 500 hours.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] Amendments to some Examination Fees in Section 4 of Schedule A to the FINRA By-Laws were approved in SR–FINRA–2020–032 and become effective on January 1, 2022. *See* Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–032).

Examination No.	Examination name	Examination fee
Series 14	Compliance Official Examination	350
Series 16	Supervisory Analyst Examination	240
Series 22	Direct Participation Programs Representative Examination	40
Series 23	General Securities Principal Examination—Sales Supervisor Module	100
Series 24	General Securities Principal Examination	120
Series 26	Investment Company Products and Variable Contracts Principal Examination	100
Series 27	Financial and Operations Principal Examination	120
Series 28	Introducing Broker-Dealer Financial and Operations Principal Examination	100
Series 39	Direct Participation Programs Principal Examination	95
Series 50	Municipal Advisor Representative Examination	115
Series 51	Municipal Fund Securities Limited Principal Examination	105
Series 52	Municipal Securities Representative Examination	110
Series 53	Municipal Securities Principal Examination	115
Series 54	*Municipal Advisor Principal Examination*	*115*
Series 57	Securities Trader Examination	60
Series 79	Investment Banking Representative Examination	245
Series 82	Private Securities Offering Representative Examination	40
Series 86	Research Analyst Examination—Analysis	185
Series 87	Research Analyst Examination—Regulatory	130
Series 99	Operations Professional Examination	40

(1) through (4) No Change.

(d) through (i) No Change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA is proposing amendments to Schedule A to the FINRA By-Laws to establish an administration and delivery fee for the Series 54 examination. The Municipal Securities Rulemaking Board (''MSRB'') has established qualification classifications for municipal advisor professionals. The Commission approved amendments to MSRB Rule G–3 that established two new registration classifications for municipal advisors: [6] (1) Municipal advisor representatives (*i.e.,* those individuals who engage in municipal advisory activities); and (2) municipal advisor principals (*i.e.,* those individuals who engage in the management, direction or supervision of the municipal advisory activities of the municipal advisor or its associated persons).[7] Both municipal advisor representatives and municipal advisor principals are required to pass the Municipal Advisor Representative Examination (''Series 50 examination'') to be qualified in accordance with MSRB rules.[8]

MSRB Rule G–3(e)(ii)(A) was amended to establish additional qualification requirements for municipal advisor principals, including the requirement to pass the Series 54 examination.[9] Under the amended rule, municipal advisor principals are required to pass both the Series 50 examination and the Series 54 examination prior to becoming qualified as a municipal advisor principal.[10]

To provide persons who function as municipal advisor principals with sufficient time to satisfy the requirement to pass the new Series 54 examination, the MSRB initially included a one-year grace period from the effective date of the Series 54 examination, during which a person functioning as a municipal advisor principal would be permitted to continue to engage in the management, direction or supervision of the municipal advisory activities of the municipal advisor and its associated persons so long as such person is qualified with the Series 50 examination.[11]

The date by which individuals are required to become qualified with the Series 54 examination has been extended three times due to impacts related to the pandemic. In April 2020, the MSRB extended the date by which individuals were required to become qualified with the Series 54 examination from November 12, 2020 to March 31, 2021.[12] In December 2020, the MSRB further extended the time period from March 31, 2021 to November 12, 2021.[13] In September 2021, the MSRB further extended the time period from November 12, 2021 to November 30, 2021.[14]

FINRA develops, maintains, and delivers all FINRA qualification examinations for individuals who are registered or seeking registration with FINRA. FINRA also administers and delivers examinations developed by the

[6] The term ''municipal advisor'' is defined to mean a person that: (i) Provides advice to or on behalf of a municipal entity or obligated person with respect to municipal financial products or the issuance of municipal securities, including advice with respect to the structure, timing, terms, and other similar matters concerning such financial products or issues; or (ii) undertakes a solicitation of a municipal entity. The definition includes financial advisors, guaranteed investment contract brokers, third-party marketers, placement agents, solicitors, finders, and swap advisors that are engaged in municipal advisory activities, unless they are statutorily excluded. The definition does not include a municipal entity or an employee of a municipal entity. *See* 15 U.S.C. 78*o*–4(e)(4).

[7] *See* Securities Exchange Act Release No. 74384 (February 26, 2015), 80 FR 11706 (March 4, 2015) (Notice of Filing of Amendment Nos. 1 & 2 and Order Granting Accelerated Approval of File No. SR–MSRB–2014–08).

[8] *See* Securities Exchange Act Release No. 75865 (September 9, 2015), 80 FR 55407 (September 15, 2015) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2015–031).

[9] *See* Securities Exchange Act Release No. 84630 (November 20, 2018), 83 FR 60927 (November 27, 2018) (Order Approving File No. SR–MSRB–2018–07).

[10] *Supra* note 9.

[11] *Supra* note 9.

[12] *See* Securities Exchange Act Release No. 88694 (April 20, 2020), 85 FR 23088 (April 24, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–MSRB–2020–01).

[13] *See* Securities Exchange Act Release No. 90621 (December 9, 2020), 85 FR 81254 (December 15, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–MSRB–2020–09).

[14] *See* Securities Exchange Act Release No. 92938 (September 10, 2020), 86 FR 51696 (September 16, 2021) (Notice of Filing and Immediate Effectiveness of File No. SR–MSRB–2021–05).

MSRB and other self-regulatory organizations.[15] The SEC has designated FINRA to administer and deliver the Series 54 examination for municipal advisors.[16]

FINRA currently administers examinations electronically through the PROCTOR® system [17] at testing centers operated by vendors under contract with FINRA.[18] For qualification examinations sponsored by a FINRA client and administered by FINRA, FINRA charges an administration and delivery fee that represents either a portion of or the entire examination fee. Consistent with this practice, FINRA charges an administration and delivery fee of $115 for the Series 50 examination.[19]

The proposed administration and delivery fee for the Series 54 exam is also $115.[20] The proposed administration and delivery fee will offset FINRA's costs associated with the administration and delivery of the Series 54 examination and, as discussed below, contribute to supporting FINRA's other operations.

FINRA has filed the proposed rule change for immediate effectiveness. The effective date and the implementation date will be the date of filing.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[21] which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls.

Reasonableness of the Proposed Fee

FINRA believes that the proposed administration and delivery fee for the Series 54 examination is reasonable. In establishing an administration and delivery fee of $115 for the Series 54 examination, FINRA applied the same criteria as it does for establishing the fees for other examinations with similar characteristics related to test length and volume. In particular, the Series 54 examination fee is consistent with the fee charged for the Series 50 examination, which has the same number of questions (and thus requires the same testing time).

The proposed administration and delivery fee will be used to cover FINRA's costs associated with the administration and delivery of the Series 54 examination, including the fees that vendors charge FINRA for delivering qualification examinations through their test delivery networks and PROCTOR system maintenance and enhancement expenses. The proposed fee also will contribute to supporting FINRA's other operations. As FINRA has explained previously, it is not feasible to associate a direct affiliated revenue stream for each of its programs and thus numerous operations and services must be funded by other revenue sources, which include both general regulatory assessments and use-based fees.[22]

The Proposed Fee Is Equitable and Not Unfairly Discriminatory

FINRA believes that the proposed administration and delivery fee for the Series 54 examination is equitable and not unfairly discriminatory. The proposed fee is a use-based fee and FINRA will charge the fee each time a municipal advisor representative accesses the content. Thus, the exam for municipal advisor principals will be available on the same terms to every municipal advisor representative.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA believes that the establishment of the administration and delivery fee for the Series 54 examination will have a limited economic impact on the industry.

MSRB rules require every municipal advisor to have at least one municipal advisor principal.[23] There are approximately 500 registered municipal advisors.[24] The administration and delivery fees may be paid by the individuals taking the examination or their associated firms.

FINRA administers this examination as a service provider to the MSRB as designated by the SEC. In providing this service, FINRA is not exercising regulatory discretion and therefore is not itself imposing burdens on those individuals who may choose to sit for the examination. FINRA does exercise discretion in establishing the administration and delivery fee. Regardless of whether individuals pay the fee or some part of the fee is paid by firms, FINRA believes that the proposal is likely to have minimal effects on firms' costs or liquidity. The proposal will therefore have at most minimal competitive effects.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [25] and paragraph (f)(2) of Rule 19b–4 thereunder.[26] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of

[15] In this regard, the Exchange Act provides that a registered securities association shall administer required qualification examinations for municipal securities brokers and municipal securities dealers who are members of the association. *See* 15 U.S.C. 78*o*–4(c)(7)(A)(i).

[16] *See* Securities Exchange Act Release No. 75714 (August 17, 2015) 80 FR 50883 (August 21, 2015) (Designation of the Financial Industry Regulatory Authority to Administer Professional Qualification Tests for Associated Persons of Registered Municipal Advisors). Section 15B(c)(7)(A)(iii) of the Exchange Act requires that the SEC or its designee administer qualification examinations for municipal advisors. The SEC previously designated FINRA to examine FINRA members' activities as registered municipal advisors and evaluate compliance by such members with federal securities laws, SEC rules and regulations, and MSRB rules applicable to municipal advisors. *See* Securities Exchange Act Release No. 70462 (September 20, 2013), 78 FR 67468 (November 12, 2013) (S7–45–10) (Registration of Municipal Advisors).

[17] PROCTOR is a computer system that is specifically designed for the administration and delivery of computer-based testing and training.

[18] The MSRB has temporarily allowed the Series 54 examination to be taken online as an interim accommodation for individuals who need to become appropriately qualified as a municipal advisor principal before the compliance date. *See supra* note 14.

[19] The administration and delivery fee represents a portion of the entire examination fee when a FINRA client has established an additional fee for an examination that it sponsors. The fee to take the Series 50 examination is $265. Of this amount, $115 is the FINRA administration and delivery fee, and $150 is the development fee determined by the FINRA client, the MSRB. *See* MSRB Rule A–16. *See also supra* note 8.

[20] The fee to take the Series 54 examination is $265. Of this amount, $115 is the FINRA administration and delivery fee, and $150 is the development fee determined by the FINRA client, the MSRB. *See* MSRB Rule A–16. See *also* Securities Exchange Act Release No. 85135 (February 14, 2019), 84 FR 5513, 5514 n.15 (February 21, 2019) (Notice of Filing and Immediate Effectiveness of File No. SR–MSRB–2019–02).

[21] 15 U.S.C. 78*o*–3(b)(5).

[22] *See supra* note 5.

[23] MSRB Rule G–3(e)(iii).

[24] *See MSRB-Registered Municipal Advisor Firms with Series–50 Qualified Representatives* (Sept. 20, 2021, 2:06 p.m.), *https://msrb.org/MARegistrants.*

[25] 15 U.S.C. 78s(b)(3)(A).

[26] 17 CFR 240.19b–4(f)(2).

the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2021–025 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2021–025. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2021–025 and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21746 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–263, OMB Control No. 3235–0275]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 17Ad–13

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17Ad–13 (17 CFR 240.17Ad–13), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17Ad–13 requires certain registered transfer agents to file annually with the Commission and the transfer agent's appropriate regulatory authority a report prepared by an independent accountant on the basis of a study and evaluation of the transfer agent's system of internal accounting controls for the transfer of record ownership and the safeguarding of related securities and funds. If the independent accountant's report specifies any material inadequacy in a transfer agent's system, the rule requires the transfer agent to notify the Commission and its appropriate regulatory agency in writing, within sixty calendar days after the transfer agent receives the independent accountant's report, of any corrective action taken or proposed to be taken by the transfer agent. In addition, Rule 17Ad–13 requires that transfer agents maintain the independent accountant's report and any other documents required by the rule for at least three years, the first year in an easily accessible place. These recordkeeping requirements assist the Commission and other regulatory agencies with monitoring transfer agents and ensuring compliance with the rule. Small transfer agents and transfer agents that service only their own companies' securities are exempt from Rule 17Ad–13.

Approximately 100 professional independent transfer agents must file with the Commission one report prepared by an independent accountant pursuant to Rule 17Ad–13 each year. Commission staff estimates that, on average, the annual internal time burden for each transfer agent to submit the independent accountant's report to the Commission is minimal or zero. The time required for an independent accountant to conduct the study and evaluation of a transfer agent's system of internal accounting controls and complete the report varies depending on the size and nature of the transfer agent's operations. Commission staff estimates that, on average, each Rule 17Ad–13 report can be completed by the independent accountant in 120 hours. In light of Commission staff's review of previously filed Rule 17Ad–13 reports and Commission staff's conversations with transfer agents and accountants, Commission staff estimates that 120 hours are needed to perform the study and prepare the report on an annual basis. Commission staff estimates that the average hourly rate of an independent accountant is $260, resulting in an annual external cost burden of $31,200 for each of the approximately 100 professional independent transfer agents. The aggregate total annual external cost for the 100 respondents is approximately $3,120,000.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have any practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

[27] 17 CFR 200.30–3(a)(12).

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: September 29, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21589 Filed 10–4–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–776, OMB Control No. 3235–0730]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Form N–PORT

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

The title for the collection of information is ''Form N–PORT under the Investment Company Act of 1940.'' Form N–PORT requires funds to report portfolio holdings information in a structured, XML format. The form is filed electronically using the Commission's electronic filing system (Electronic Data Gathering, Analysis and Retrieval or ''EDGAR''). The purpose of Form N–PORT is to satisfy the filing and disclosure requirements of Section 30(b) of the Investment Company Act, and of Rule 30b1–9 thereunder.

We estimate that 11980 entities will be required to submit reports on Form N–PORT. We estimate that 35% of funds will file reports on Form N–PORT in house and the remaining 65% of funds will retain the services of a third party to prepare and file reports on Form N–PORT on the fund's behalf. The estimated annual hourly burden associated with Form N–PORT 1,839,903 hours for an average of 153.6 hours per entity. The total annual internal time cost associated with Form N–PORT is $654,658,288. The total annual external cost associated with Form N–PORT is $113,858,133.

The requirements of this collection of information are mandatory. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: September 29, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21588 Filed 10–4–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33–10993; 34–93204; 39–2541; IC–34392; File No. S7–12–21]

Potential Technical Changes to EDGAR Filer Access and Filer Account Management Processes

AGENCY: Securities and Exchange Commission.

ACTION: Request for comment.

SUMMARY: The Securities and Exchange Commission (''Commission'') is requesting comment on potential technical changes related to how entities and individuals access the Commission's Electronic Data Gathering, Analysis, and Retrieval system (''EDGAR'') to make submissions, and how these entities and individuals (''filers'') manage the permissions of individuals who may file on EDGAR on their behalf. Individuals who seek to file on EDGAR on behalf of a filer would be directed to a third-party service provider to create individual user account credentials and to enable multifactor authentication. Each filer would designate a ''filer administrator''—analogous to the current filer contact person who receives the filer's EDGAR access codes—to manage the permissions of the filer's individual users through a new filer management tool on EDGAR.

DATES: *Comments should be received on or before the later of:* December 1, 2021, or November 4, 2021.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/submitcomments.htm*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–12–21 on the subject line.

Paper Comments

- Send paper comments to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number S7–12–21. This file number should be included on the subject line if email is used. To help the Commission process and review comments more efficiently, please use only one method of submission. The Commission will post all submitted comments on our website (*http://www.sec.gov*). Typically, comments are also available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Operating conditions may limit access to the Commission's Public Reference Room. All comments received will be posted without change. Persons submitting comments are cautioned that the Commission does not redact or edit personal identifying information from comment submissions. Please submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Rosemary Filou, Deputy Director and Chief Counsel; Daniel Chang, Senior Special Counsel; EDGAR Business Office, at 202–551–3900, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Commission is seeking public comment on potential technical changes to the EDGAR access process that include the addition of individual user account credentials as well as a tool on EDGAR through which filers would manage their EDGAR accounts. During the comment period, the Commission will open an EDGAR ''Beta'' environment where pre-enrolled EDGAR filers may preview and test many of the potential access changes. The Commission plans to provide more information regarding

the Beta environment for the potential technical changes and what functions can be tested in the Beta environment through an information page on *SEC.gov*.

I. Introduction and Background

Individuals and entities seek to access EDGAR to make electronic submissions with the Commission to comply with various provisions of the federal securities laws. Prospective EDGAR filers currently apply for access in accord with 17 CFR 232.10 (Rule 10 of Regulation S–T) by completing the online uniform application for EDGAR access codes (''Form ID'') [1] on the EDGAR Filer Management website [2] and submitting a notarized copy of that application signed by an authorized individual of the filer.[3]

If the Form ID application is approved, the contact person listed on the Form ID receives an EDGAR account number unique to the filer known as a central index key (''CIK''), if needed,[4] and information regarding EDGAR access codes. EDGAR access codes include the EDGAR password, central index key confirmation code (''CCC''), password modification authorization code (''PMAC''), and passphrase.[5] Filings on EDGAR are not currently linked to a specific authorized individual, but rather associated with the CIK generally. Additionally, multifactor authentication is not presently available to validate individuals accessing EDGAR and simplify password retrieval.

The Commission is considering potential technical changes to the EDGAR filer access and filer account management processes (''potential access changes'') to enhance the security of EDGAR, improve the ability of filers to securely maintain access to their EDGAR accounts, facilitate the responsible management of EDGAR filer credentials, and simplify procedures for accessing EDGAR.

Individuals who seek to file on EDGAR would be directed to a third-party service provider to create individual user account credentials, including a unique username and password (''account credentials''), and to enable multifactor authentication. The filer would designate a ''filer administrator'' analogous to the current filer contact person who receives access codes. The filer administrator would manage the permissions of the filer's EDGAR ''users''—individuals with account credentials authorized by the filer to make submissions on its behalf.[6] A new EDGAR filer management tool would allow the filer administrator to add and remove users and filer administrators, elevate a user to filer administrator, and change a filer administrator to a user. This tool would assist filers in complying with their existing obligation to securely maintain access to their EDGAR account.[7]

The filer management tool would be accessed through the EDGAR Filer Management website, which would be redesigned with a new layout and features. The new account credentials would be used to access the other two EDGAR websites—EDGAR Filing and EDGAR Online Forms; however, those websites would remain largely unchanged.[8]

The potential access changes would eliminate the EDGAR password,[9] PMAC, and passphrase. Users would make submissions by using the filer's CIK and CCC after logging in with their new account credentials. The potential access changes would enable the Commission to identify the unique user making each filing on EDGAR while allowing a filer administrator to manage the permissions of users authorized to make submissions on the filer's behalf.

In conjunction with this request for comment, the Commission will allow pre-enrolled filers to access an EDGAR Beta environment, where filers will be able to preview and test many of the potential access changes. As with any change to EDGAR code, the potential access changes to EDGAR may affect custom code that filers have created in their systems to interact with EDGAR. The Beta environment generally should allow filers to determine what changes would be needed to their custom code to accommodate the potential access changes and to provide targeted technical feedback to the Commission about the potential access changes. The Commission currently anticipates that the Beta environment will be available in October 2021. All filers will be eligible to enroll to participate in the EDGAR Beta environment, which may be made available for future EDGAR changes. The Commission will provide more information regarding the Beta environment for the potential access changes and what functions can be tested in the Beta environment through an information page on *SEC.gov*.

We have established an information page explaining the potential access changes on the EDGAR—Information for Filers web page on *SEC.gov*,[10] leveraging the recently introduced EDGAR—How Do I guide [11] for filers, and providing additional filer assistance such as in-context help, live webinars, and on-demand how-to videos. Our goal is to make the transition as easy as possible for filers. We will also provide a help desk devoted to assisting filers with the potential access changes.

If the potential access changes are implemented, the Commission anticipates that it would adopt amendments to certain Commission rules and forms to reflect the potential access changes. The corresponding amendments would include changes to Rule 10 of Regulation S–T, Form ID and associated rules,[12] and the EDGAR Filer Manual, which is incorporated by reference in the Code of Federal

[1] *See* Form ID, uniform application for access codes to file on EDGAR, 17 CFR 239.63, 249.446, 269.7, and 274.402.

[2] *See* EDGAR Filer Management website at *https://www.filermanagement.edgarfiling.sec.gov.*

[3] *See* EDGAR Filer Manual, Volume I, at Section 3. The EDGAR Filer Manual specifies the instructions filers must follow when making electronic filings on EDGAR and is incorporated by reference in the Code of Federal Regulations by 17 CFR 232.301 (Rule 301 of Regulation S–T). Rule 10 of Regulation S–T and the EDGAR Filer Manual permit manual, electronic, and remote online notarizations, authorized by the law of any state or territory of the United States or the District of Columbia. *See* 17 CFR 232.10 and EDGAR Filer Manual, Volume I, at Section 3. An ''authorized individual'' for purposes of the Form ID notarization process includes, for example, the Chief Executive Officer, Chief Financial Officer, partner, corporate secretary, officer, director, or treasurer of a company filer; or for individual filers, the individual filer or a person with a power of attorney from the individual filer. *See* EDGAR Filer Manual, Volume I, at Section 3.

[4] Currently, most applicants completing the Form ID for EDGAR access have not previously been assigned a CIK. However, a small number of other applicants have already been assigned a CIK, but have not filed electronically on EDGAR. These applicants continue to use the same CIK when they receive access to EDGAR and are not assigned a new CIK.

[5] *See* EDGAR Filer Manual, Volume I, at Section 4. For a discussion of the functions of these access codes, please see the ''Understand and utilize EDGAR CIKs, passphrases and access codes'' section of EDGAR—How Do I, at *https://www.sec.gov/edgar/filer-information/how-do-i.*

[6] For purposes of this request for comment, the term ''users'' includes filer administrators unless otherwise indicated.

[7] *See* EDGAR Filer Manual, Volume I, at Section 4.

[8] EDGAR Gateway Filing website at *https://www.edgarfiling.sec.gov/Welcome/EDGARLogin.htm;* and EDGAR Online Forms Management website at *https://www.edgarfiling.sec.gov/Welcome/EDGAROnlineFormsLogin.htm.* The three EDGAR filing websites would also remind filers of their obligations to comply with the rules and regulations governing access to EDGAR.

[9] The EDGAR password would be replaced by the password in the account credentials obtained from the third-party service provider.

[10] *See* EDGAR—Information for Filers web page at *https://www.sec.gov/edgar/filer-information.*

[11] *See* EDGAR—How Do I at *https://www.sec.gov/edgar/filer-information/how-do-i.*

[12] *See* Form ID, uniform application for access codes to file on EDGAR, 17 CFR 239.63, 249.446, 269.7, and 274.402.

Regulations by Rule 301 of Regulation S–T.

We would expect to implement a phased transition of existing filers to the potential access changes, as discussed below, to make the transition a user-friendly experience for filers.

II. Discussion

We are considering potential technical changes to the method by which filers access EDGAR to make submissions and manage their EDGAR accounts.

A. Individual Account Credentials

Under the potential access changes, each individual seeking to make submissions on EDGAR on behalf of a filer would be required to obtain individual account credentials from a third-party service provider. The Commission is considering using as the third-party service provider *Login.gov*, an official website of the U.S. Government that provides a sign-in service for use by the public and Federal agencies.[13] When an individual creates account credentials with the third-party service provider, the individual would be prompted to provide an email address and select an authentication option.[14] After the individual confirms the email address and completes the authentication, the third-party service provider would assign the individual unique account credentials.

Multifactor authentication adds a layer of validation each time an individual signs in to EDGAR. For example, if the telephone authentication option is selected, the individual would enter a one-time passcode received by text message/SMS or from a telephone call to the provided telephone number each time the individual logs in to a filer's EDGAR account. Multifactor authentication would be used only for purposes of validation, and individuals would be reminded on EDGAR to provide only a business email account and relevant business information when creating account credentials. EDGAR would no longer employ the EDGAR password, PMAC, and passphrase codes.

If the individual enters their account credentials and successfully completes the multifactor authentication process, the individual would be able to access the EDGAR Filer Management website. To make submissions on behalf of a certain filer on the three EDGAR filing websites,[15] however, individuals would also need to be authorized as a user by the relevant filer administrator.

B. Filer Administrators

As part of the changes we are considering, a filer would designate which of its users would act as filer administrator(s) to manage the filer's EDGAR account, analogous to the contact person who currently receives access codes. A filing entity would be required to designate at least two filer administrators. Employees at filing entities often change; therefore, designating two filer administrators would increase the chances that management of the filer's EDGAR account would be uninterrupted. For individual filers, one filer administrator would be required. Both filing entities and individual filers would be permitted to have additional filer administrators.

Under the potential access changes, prospective filers would designate their filer administrator during the initial Form ID application process while existing filers would enroll their filer administrators during a transition period. EDGAR would contain a link to the third-party service provider's website, where the prospective filer administrator could obtain account credentials. After the prospective filer administrator obtains account credentials, the prospective filer administrator would be automatically redirected to the EDGAR Filer Management website to access the Form ID application. We would permit a third party to be a filer administrator if the third party submits a Form ID listing the third party as filer administrator and includes a notarized power of attorney from an authorized individual of the filer that grants authority to the third party.[16]

The filer administrator would replace the current filer contact person to manage the filer's access to EDGAR. As described in more detail below, the filer administrator would manage and confirm the permissions of users through the new filer management tool. All filer administrators would be able to manage and confirm permissions of users regardless of whether they are listed on the Form ID or added as filer administrators through the filer management tool.

On the Form ID, prospective filers would include the names and business contact information of two filer administrators for filing entities or one filer administrator for individual filers. The prospective filer would then electronically submit the Form ID and upload a notarized copy of the Form ID signed by an authorized individual of the prospective filer, as currently required.

If the Form ID application is approved, EDGAR would provide the filer administrator with a CCC code and a link to the EDGAR Filer Management website, similar to the current process. The filer administrator could then access the filer's account and the filer management tool by logging onto the EDGAR Filer Management website with the filer administrator's account credentials.

The Commission would require existing filers to transition to the potential access process. Each existing filer would designate an individual to function as filer administrator. The filer administrator for the existing filer would obtain account credentials through the third-party service provider; log in to a transition page in EDGAR; and enter the filer's CIK, CCC, EDGAR password, and passphrase. Once existing filers transition to the potential access changes, they will no longer be able to use the current login method. Existing filers that do not have active EDGAR access codes would be required to complete a new Form ID to reapply for access.

C. Filer Management Tool and Annual Confirmation of Permissions

The potential access changes would include a new filer management tool on the EDGAR Filer Management website where a filer administrator, acting on behalf of the filer, could view, add, remove, and confirm users. The filer administrator could also change the permissions of a user to filer administrator and vice versa. Further, on the filer management tool, filer administrators could delegate filing authority to third parties—such as filing agents—and remove such delegations. Thus, the filer management tool would allow filer administrators to view and manage the permissions of all of the filer's users.

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[13] *See https://www.login.gov/.*

[14] *Login.gov* authentication options include: (1) A security key; (2) government employee or military PIV or CAC cards; (3) authentication application; (4) text message/SMS or telephone call; and (5) backup codes, with (1), (2), and (3) being the most secure method, and (5) being the least secure authentication option according to *Login.gov. See generally Login.gov*, Authentication Options at *https://www.login.gov/help/get-started/authentication-options/. See also generally Login.gov*, Privacy and security: Our security practices at *https://login.gov/policy/our-security-practices/* for information on *Login.gov's* security practices.

[15] *See supra* note 8.

[16] Currently, we permit a person with a power of attorney from an individual filer to sign the Form ID application for the individual filer; in that case, the power of attorney document must accompany the notarized Form ID application. *See* EDGAR Filer Manual, Volume I, at Section 3. Existing Commission practice also permits the Form ID to be signed by an individual with a power of attorney from a filing entity, such as a corporation.

Once the filer administrator adds a user on the filer management tool, that user would have access to the EDGAR filing websites when the user obtains account credentials and logs in to the websites. Unlike the filer administrator, a user could only view the user's permissions on the filer management tool, not those of the filer administrator or other users; and the only action the user could take on the tool would be to remove their own ability to file on behalf of the filer.

Filer administrators and users included on the filer management tool would be able to make submissions, submit correspondence, and manage certain filer information.

Filers are currently required to change their EDGAR password annually (a filer's EDGAR password expires 12 months after it was created or last changed), or have their access deactivated. Because the potential access changes would eliminate the EDGAR password, an annual confirmation of permissions on the filer management tool would replace the present requirement to change the EDGAR password annually.

EDGAR would notify filer administrators to access the EDGAR Filer Management website to review the list of the filer's users, including other filer administrators, and annually confirm on the filer management tool the accuracy of the permissions of those authorized to file on behalf of the filer. EDGAR would also notify each user to confirm annually the user's permissions. The annual confirmation of permissions would help the filer remain aware of who makes submissions on EDGAR on its behalf and provide an opportunity to update information about users no longer associated with the filer or no longer authorized to file on its behalf.

Filers are currently deactivated if they do not timely change their EDGAR password on an annual basis, and, under the potential access changes, if no filer administrator timely confirms permissions for a filer, that filer would be deactivated. The deactivated filer would have to resubmit a Form ID application; if approved, staff would reactivate the permissions of the filer administrator(s) listed on the Form ID application. The filer administrator could then reactivate other filer administrators and users using the filer management tool. Where filer administrators or users become deactivated because they have not confirmed their own permissions, other filer administrators could reactivate those users and filer administrators using the filer management tool.

D. Transition Period

There are approximately 180,000 EDGAR filer accounts in which a filing has been made in the last two years, approximately 115,000 of which represent filing entities and approximately 65,000 of which represent individual filers.[17] If the potential access changes are implemented, the Commission would require filers to transition these accounts to the potential access process on a gradual basis over a six month period, likely beginning in spring 2022. During the transition period, existing accounts could access EDGAR through the current process until they transition to the potential access changes.

After all active accounts have transitioned, the Commission would address the transition of an additional approximately 600,000 inactive EDGAR filer accounts to the potential access changes. The Commission would inform filers of its plans regarding inactive accounts before it proceeds with those plans.

III. Questions

The Commission is providing an opportunity for the EDGAR filing community and other interested parties to provide feedback on the potential technical changes to the EDGAR filer access and account management processes. The Commission welcomes input on the following:

1. Does the filing community have experience with obtaining account credentials from third-party service providers including or similar to *Login.gov* that the Commission should consider? If so, which third-party service party service providers, and what experience? Would the use of third-party service providers give rise to any security concerns for individual or entity filers?

2. Under the potential access changes, there would need to be at least two filer administrators for filing entities and one filer administrator for individual filers; filers could designate as many filer administrators as they would like. Is this appropriate? If not, why? Should filing entities be required to have more than two filer administrators? For filing entities, would one filer administrator be adequate? Should individual filers be required to have more than one filer administrator? If so, why? Should there be a limit on the number of filer administrators?

3. With the filer management tool, the filer administrator could view, add, remove, and confirm users and other filer administrators as well as change the permissions of a user to administrator and vice-versa. Users could similarly use the tool to view and remove their own permissions. In addition, both filer administrators and users would use the filer management tool to confirm current permissions on an annual basis. Are there other functions that should be incorporated into the filer management tool or any other information that administrators or users should be able to view? Should any of these functions not be included on the filer management tool?

4. With the filer management tool, the filer administrator could delegate filing authority to third parties such as filing agents and remove such delegations. Should filer administrators be able to delegate filing authority to third parties and remove such delegations? Do commenters have any concerns with this function or any suggested modifications? Should ''filing agents'' be limited to entities listed in EDGAR as ''filing agents'' based on their Form ID filing or should it also include entities that function as filing agents but who identified themselves on their Form ID filing as ''filer?''

5. Are there alternatives to the filer management tool that the Commission should consider? For example, are there alternative methods that would enable filers to take the same actions as they would using the filer management tool that would be easier to implement or more user-friendly? Do commenters have experience with alternatives to the filer management tool, whether positive or negative, that the Commission should consider?

6. Filer administrators and users would confirm their access permissions annually. The annual confirmation of permissions would help the filer remain aware of who makes submissions on EDGAR on its behalf. Should the confirmation be annual or at more or less frequent intervals? Are there concerns that the Commission should be aware of for filers that only make submissions annually or less frequently? Should both filer administrators and users confirm permissions annually, or only filer administrators? Should the requirement to apply for access again occur automatically upon failure by a filer to confirm the access permissions or should there be a grace period if the filer administrator fails to confirm the access permissions within a specified time period? If there should be a grace period, how long should it be? Would the annual confirmation create any additional burden on filers or filing agents compared to the current annual EDGAR password update requirement?

[17] In total, regardless of account activity, there are approximately 785,000 filer accounts in EDGAR.

If so, are there any improvements to the annual confirmation as currently described that would reduce the burden for filers or filing agents?

7. Would the potential access changes facilitate the responsible management of EDGAR filer credentials? Are there additional changes to the access process that we should make to encourage such responsible management? For example, should administrators be required to update their account permissions within a reasonable period of time following the separation of employment of a user from the filer or a change in the user's filing responsibilities? Would the potential access changes create any undue burdens for filers or filing agents? If so, how could the potential access changes be modified to ease such burdens? Are there any other concerns that the Commission should be aware of with the transition to the potential access changes?

8. Are there any issues specific to certain types of filers that should be considered with regard to the potential access changes? For example, asset-backed securities (ABS) issuers often create one or more serial companies each year, each of which is a separate legal entity with its own CIK, even though it generally has the same contact information as the ABS issuer. If the potential technical changes are implemented, should new serial companies have their user and filer administrator information automatically copied from the ABS issuer's user and filer administrator information? If so, in order to ensure that the ABS issuer has user and filer administrator information that could be copied to the new serial company, would there be any issues associated with requiring ABS issuers to have transitioned to *Login.gov* before the ABS issuer can create new serial companies? Separately, should we allow the annual confirmations of users and filer administrators for an ABS issuer to also apply to the serial companies associated with that ABS issuer, if the same users and filer administrators were associated with each serial company?

9. How long would it take existing filers to adjust to the potential access changes? Should we transition existing active accounts to the potential access changes on a gradual basis over a several month period, possibly beginning in spring 2022? If so, how? For example, should the transition period be tiered based on the volume of filings made by a filer or a filing agent on an annual basis? Should another method be used? What is an appropriate length of time for the transition period?

10. What other changes to the EDGAR filer access and account management processes should the Commission consider in the future?

IV. General Request for Public Comment

We request and encourage any interested person to submit comments on any aspect of the potential technical changes to the EDGAR filer access and filer account management processes, and suggestions for additional changes. In particular, we request comment on obtaining and using third-party service provider account credentials to access EDGAR, the filer administrator managing the permissions of users associated with the filer's EDGAR account, and the filer management tool. Comments are of particular assistance if accompanied by analysis of the issues addressed in those comments and any data that may support the analysis. We urge commenters to be as specific as possible.

By the Commission.

Dated: September 30, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–21697 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93179; File No. SR–NYSEArca–2021–73]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To List and Trade Shares of the Franklin Responsibly Sourced Gold ETF Under NYSE Arca Rule 8.201–E

September 29, 2021.

On August 23, 2021, NYSE Arca, Inc. filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the Franklin Responsibly Sourced Gold ETF. The proposed rule change was published for comment in the **Federal Register** on September 8, 2021.[3] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is October 23, 2021. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates December 7, 2021 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2021–73).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21617 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93181; File No. SR–NYSENAT–2021–18]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend NYSE National Rule 7.2

September 30, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2021, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 92840 (September 1, 2021), 86 FR 50385.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE National Rule 7.2 (Holidays) to make Juneteenth National Independence Day a holiday of the Exchange. Juneteenth National Independence Day was designated a legal public holiday in June 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE National Rule 7.2 (Holidays) to make Juneteenth National Independence Day a holiday of the Exchange.

On June 17, 2021, Juneteenth National Independence Day was designated a legal public holiday.[3] Consistent with broad industry sentiment [4] and the approach recommended by the Securities Industry and Financial Markets Association (''SIFMA''),[5] the Exchange proposes to add ''Juneteenth National Independence Day'' to the existing list of holidays in the first paragraph of NYSE National Rule 7.2. As a result, the Exchange will not be open for business on Juneteenth National Independence Day, which falls on June 19 of each year. In accordance with the second paragraph of NYSE National Rule 7.2, when the holiday falls on a Saturday, the Exchange will not be open for business on the preceding Friday, and when it falls on a Sunday, the Exchange will not be open for business on the succeeding Monday.[6]

The first paragraph of the revised rule would read as follows (proposed additions *italicized*):

The Exchange will not be open for business on New Year's Day, Martin Luther King Jr. Day, Presidents' Day, Good Friday, Memorial Day, *Juneteenth National Independence Day,* Independence Day, Labor Day, Thanksgiving Day and Christmas Day.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed amended rule would clearly state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The change would thereby promote clarity and transparency in the Exchange rules by updating the list of holidays of the Exchange.

The proposed change does not raise any new or novel issues.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[9] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather to amend the Exchange rule regarding holidays.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) [12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative prior to 30 days after the date of the filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because the proposed rule change, as described above, would state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken

[3] Public Law 117–17.

[4] *See, e.g. https://www.bloomberg.com/news/articles/2021-06-18/bofa-makes-juneteenth-a-holiday-joining-jpmorgan-wells-fargo?sref=Hhue1scO.*

[5] SIFMA recommends a full market close in observance of Juneteenth National Independence Day. *See https://www.sifma.org/resources/general/holiday-schedule/. See also https://www.sifma.org/resources/news/sifma-revises-2022-fixed-income-market-close-recommendations-in-the-u-s-to-include-full-close-for-juneteenth-national-independence-day/.*

[6] NYSE National Rule 7.2. There is an exception to the practice if unusual business conditions exist, such as the ending of a monthly or yearly accounting period. *Id.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(8).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

off if June 19 fell on a Saturday or Sunday. The Exchange further states that the proposed change does not raise any new or novel issues. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2021–18 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2021–18. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2021–18, and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21740 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

[14] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–541, OMB Control No. 3235–0620]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 22c–2

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 22c–2 (17 CFR 270.22c–2) under the Investment Company Act of 1940 (15 U.S.C. 80a) (the ''Investment Company Act'' or ''Act'') requires the board of directors (including a majority of independent directors) of most registered open-end investment companies (''funds'') to either approve a redemption fee of up to two percent or determine that imposition of a redemption fee is not necessary or appropriate for the fund. Rule 22c–2 also requires a fund to enter into written agreements with their financial intermediaries (such as broker-dealers and retirement plan administrators) under which the fund, upon request, can obtain certain shareholder identity and trading information from the intermediaries. The written agreement must also allow the fund to direct the intermediary to prohibit further purchases or exchanges by specific shareholders that the fund has identified as being engaged in transactions that violate the fund's market timing policies. These requirements enable funds to obtain the information that they need to monitor the frequency of short-term trading in omnibus accounts and enforce their market timing policies.

The rule includes three ''collections of information'' within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[1] First, the rule requires boards to either approve a redemption fee of up to two percent or determine that imposition of a redemption fee is not necessary or appropriate for the fund. Second, funds must enter into information sharing agreements with all of their ''financial intermediaries'' [2] and maintain a copy of the written information sharing agreement with each intermediary in an easily accessible place for six years. Third, pursuant to the information sharing agreements, funds must have systems that enable them to request frequent trading information upon demand from their intermediaries, and to enforce any restrictions on trading required by funds under the rule.

The collections of information created by rule 22c–2 are necessary for funds to effectively assess redemption fees, enforce their policies in frequent trading, and monitor short-term trading,

[1] 44 U.S.C. 3501–3520.

[2] The rule defines a Financial Intermediary as: (i) Any broker, dealer, bank, or other person that holds securities issued by the fund in nominee name; (ii) a unit investment trust or fund that invests in the fund in reliance on section 12(d)(i)(E) of the Act; and (iii) in the case of a participant directed employee benefit plan that owns the securities issued by the fund, a retirement plan's administrator under section 316(A) of the Employee Retirement Security Act of 1974 (29 U.S.C. 1002(16)(A) or any person that maintains the plans' participant records. Financial Intermediary does not include any person that the fund treats as an individual investor with respect to the fund's policies established for the purpose of eliminating or reducing any dilution of the value of the outstanding securities issued by the fund. Rule 22c–2(c)(1).

including market timing, in omnibus accounts. These collections of information are mandatory for funds that redeem shares within seven days of purchase. The collections of information also are necessary to allow Commission staff to fulfill its examination and oversight responsibilities.

Rule 22c–2(a)(1) requires the board of directors of all registered open-end management investment companies and series thereof (except for money market funds, ETFs, or funds that affirmatively permit short-term trading of its securities) to approve a redemption fee for the fund, or instead make a determination that a redemption fee is either not necessary or appropriate for the fund. Commission staff understands that the boards of all funds currently in operation have undertaken this process for the funds they currently oversee, and the rule does not require boards to review this determination periodically once it has been made. Accordingly, we expect that only boards of newly registered funds or newly created series thereof would undertake this determination. Commission staff estimates that 36 funds (excluding money market funds and ETFs) are newly formed each year and would need to make this determination.[3]

Based on conversations with fund representatives,[4] Commission staff estimates that it takes 2 hours of the board's time as a whole (at a rate of $4,465 per hour)[5] to approve a redemption fee or make the required determination on behalf of all series of the fund. In addition, Commission staff estimates that it takes compliance personnel of the fund 8 hours (at a rate of $72 per hour)[6] to prepare trading, compliance, and other information regarding the fund's operations to enable the board to make its determination, and takes internal compliance counsel of the fund 3 hours (at a rate of $373 per hour)[7] to review this information and present its recommendations to the board. Therefore, for each fund board that undertakes this determination process, Commission staff estimates it expends 13 hours[8] at a cost of $10,625.[9] As a result, Commission staff estimates that the total time spent for all funds on this process is 468 hours at a cost of $382,500.[10]

Rule 22c–2(a)(2) also requires a fund to enter into information-sharing agreements with each of its financial intermediaries. Commission staff understands that all currently registered funds have already entered into such agreements with their intermediaries. Funds enter into new relationships with intermediaries from time to time, however, which requires them to enter into new information sharing agreements. Commission staff understands that, in general, funds enter into information-sharing agreement when they initially establish a relationship with an intermediary, which is typically executed as an addendum to the distribution agreement. The Commission staff understands that most shareholder information agreements are entered into by the fund group (a group of funds with a common investment adviser), and estimates that there are currently 840 currently active fund groups.[11] Commission staff estimates that, on average, each active fund group enters into relationships with 3 new intermediaries each year. Commission staff understands that funds generally use a standard information sharing agreement, drafted by the fund or an outside entity, and modifies that agreement according to the requirements of each intermediary. Commission staff estimates that negotiating the terms and entering into an information sharing agreement takes a total of 4 hours of attorney time (at a rate of $425 per hour)[12] per intermediary (representing 2.5 hours of fund attorney time and 1.5 hours of intermediary attorney time). Accordingly, Commission staff estimates that it takes 12 hours at a cost of $5,100 each year[13] to enter into new information sharing agreements, and all existing market participants incur a total of 10,080 hours at a cost of $4,284,000.[14]

In addition, newly created funds advised by new entrants (effectively new fund groups) must enter into information sharing agreements with all of their financial intermediaries. Commission staff estimates that there are 41 new fund groups that form each year that will have to enter into information sharing agreements with each of their intermediaries.[15] Commission staff estimates that fund groups formed by new advisers typically have relationships with significantly fewer intermediaries than existing fund groups, and estimates that new fund groups will typically enter into 100 information sharing agreements with their intermediaries when they begin operations.[16] As discussed previously, Commission staff estimates that it takes 4 hours of attorney time (at a rate of $425 per hour)[17] per intermediary to enter into information sharing agreements. Therefore, Commission staff estimates that each newly formed fund group will incur 400 hours of attorney time at a cost of $170,000[18] and that all newly formed fund groups will incur a total of 16,400 hours at a cost of $6,970,000 to enter into information sharing agreements with their intermediaries.[19]

[3] This estimate is based on the number of registrants filing initial Form N–1A or N–3 from 2017 to 2019. This estimate does not carve out money market funds, ETFs, or funds that affirmatively permit short-term trading of their securities, so this estimate corresponds to the outer limit of the number of registrants that would have to make this determination.

[4] Unless otherwise stated, estimates throughout this analysis are derived from a survey of funds and conversations with fund representatives.

[5] The estimate of $4,465 per hour for the board's time as a whole is based on conversations with representatives of funds and their legal counsel.

[6] The $72 per hour figure for a compliance clerk is from SIFMA's *Office Salaries in the Securities Industry 2013,* modified by Commission staff to account for an 1,800-hour work-year and inflation, and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead.

[7] The $373 per hour figure for internal compliance counsel is from SIFMA's *Management & Professional Earnings in the Securities Industry 2013,* modified by Commission staff to account for an 1,800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

[8] This calculation is based on the following estimates: (2 hours of board time + 3 hours of internal compliance counsel time + 8 hours of compliance clerk time = 13 hours).

[9] This calculation is based on the following estimates: ($8,930 ($4,465 board time × 2 hours = $8,930) + $576 ($72 compliance time × 8 hours = $576) + $1,119 ($373 attorney time × 3 hours = $1,119) = $10,625).

[10] This calculation is based on the following estimates: (13 hours × 36 funds = 468 hours); ($10,625 × 36 funds = $382,500).

[11] ICI, 2020 Investment Company Fact Book at Fig 2.12 (2020) (*https://www.ici.org/research/stats/factbook*).

[12] The $425 per hour figure for attorneys is from SIFMA's *Management & Professional Earnings in the Securities Industry 2013,* modified by Commission staff to account for an 1,800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

[13] This estimate is based on the following calculations: (4 hours × 3 new intermediaries = 12 hours); (12 hours × $425 = $5,100).

[14] This estimate is based on the following calculations: (12 hours × 840 fund groups = 10,080 hours); (10,080 hours × $425 = $4,284,000).

[15] ICI, 2020 Investment Company Fact Book at Fig 2.12 (2020) (*https://www.ici.org/research/stats/factbook*).

[16] Commission staff understands that funds generally use a standard information sharing agreement, drafted by the fund or an outside entity, and then modifies that agreement according to the requirements of each intermediary.

[17] The $425 per hour figure for an attorney is from SIFMA's Management & Professional Earnings in the Securities Industry 2013, modified by Commission staff to account for an 1,800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

[18] This estimate is based on the following calculations: (4 hours × 100 intermediaries = 400 hours); (400 hours × $425 = $170,000).

[19] This estimate is based on the following calculations: (41 fund groups × 400 hours = 16,400 hours); ($425 × 16,400 = $6,970,000).

Rule 22c–2(a)(3) requires funds to maintain records of all information-sharing agreements for 6 year*s in an easily* accessible place. Commission staff understands that most shareholder information agreements are stored at the fund group level and estimates that there are currently approximately 840 fund groups.[20] Commission staff understands that information-sharing agreements are generally included as addendums to distribution agreements between funds and their intermediaries, and that these agreements would be stored as required by the rule as a matter of ordinary business practice. Therefore, Commission staff estimates that maintaining records of information-sharing agreements requires 10 minutes of time spent by a general clerk (at a rate of $64 per hour) [21] per fund, each year. Accordingly, Commission staff estimates that all funds will incur 140 hours at a cost of $8,960 [22] in complying with the recordkeeping requirement of rule 22c–2(a)(3).

Therefore, Commission staff estimates that to comply with the information sharing agreement requirements of rule 22c–2(a)(2) and (3), it requires a total of 26,620 hours at a cost of $11,262,960.[23]

The Commission staff estimates that on average, each fund group requests shareholder information once a week, and gives instructions regarding the restriction of shareholder trades every day, for a total of 417 responses related to information sharing systems per fund group each year, and a total 350,280 responses for all fund groups annually.[24] In addition, as described above, the staff estimates that funds make 36 responses related to board determinations, 2,520 responses related to new intermediaries of existing fund groups, 4,100 responses related to new fund group information sharing agreements, and 840 responses related to recordkeeping, for a total of 7,496 responses related to the other requirements of rule 22c–2. Therefore, the Commission staff estimates that the total number of responses is 357,776 (350,280 + 7,496 = 357,776).

The Commission staff estimates that the total hour burden for rule 22c–2 is 27,088 hours at a cost of $11,645,460.[25] Responses provided to the Commission will be accorded the same level of confidentiality accorded to other responses provided to the Commission in the context of its examination and oversight program. Responses provided in the context of the Commission's examination and oversight program are generally kept confidential. Complying with the information collections of rule 22c–2 is mandatory for funds that redeem their shares within 7 days of purchase. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: September 29, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21583 Filed 10–4–21; 8:45 am]

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[20] ICI, 2020 Investment Company Fact Book at Fig 2.12 (2020) (*https://www.ici.org/research/stats/factbook*).

[21] The $64 per hour figure for a general clerk is derived from SIFMA's Office Salaries in the Securities Industry 2013 modified to account for an 1800-hour work-year and inflation, and multiplied by 2.93 to account for bonuses, firm size, employee benefits, and overhead.

[22] This estimate is based on the following calculations: (10 minutes × 840 fund groups = 8,400 minutes); (8,400 minutes/60 = 140 hours); (140 hours × $64 = $8,960).

[23] This estimate is based on the following calculations: (10,080 hours + 16,400 hours + 140 hours = 26,620 hours); ($4,284,000 + $6,970,000 + $8,960 = $11,262,960).

[24] This estimate is based on the following calculations: (52 + 365 = 417); (417 × 840 fund groups = 350,280).

[25] This estimate is based on the following calculations: (468 hours (board determination) + 26,620 hours (information sharing agreements) = 27,088 total hours); ($382,500 (board determination) + $11,262,960 (information sharing agreements) = $11,645,460).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93177; File No. SR–ICC–2021–019]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to the ICC CDS Instrument On-Boarding Policies and Procedures

September 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4,[2] notice is hereby given that on September 22, 2021, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise the CDS Instrument On-boarding Policies and Procedures (''Instrument On-boarding Policy''). These revisions do not require any changes to the ICC Clearing Rules (''Rules'').

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change, security-based swap submission, or advance notice and discussed any comments it received on the proposed rule change, security-based swap submission, or advance notice. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC proposes to amend the Instrument On-boarding Policy. This document provides an overview of ICC's on-boarding process for new instruments, which includes selecting new instruments for clearing, configuring internal systems, notifying and receiving feedback from stakeholders, and ensuring operational readiness by ICC and its Clearing Participants (''CPs''). The proposed changes amend the guiding principles that ICC maintains for instrument selection. ICC believes that such changes will facilitate the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions for which it is responsible. ICC proposes to make such changes effective following Commission approval of the proposed rule change. The proposed rule change is described in detail as follows.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

ICC proposes amendments to the Subsection III.A which discusses the guiding principles that ICC maintains for considering instruments for clearing. Such principles are designed to ensure that ICC proceeds in a prudent manner with respect to instrument selection while also providing the best opportunity for CPs to minimize their risk. The proposed changes incorporate an additional guiding principle to consider instruments that are constituents of the currently clearable On-The-Run (''OTR'') indices to become clearing eligible in order to provide additional instruments to hedge and mitigate indirect risk exposure from the OTR indices. For other instruments that are not constituents of currently clearable OTR indices, the current guiding principles would remain and ICC would continue to consider instrument open interest and volume. For all instruments, ICC would continue to consider instruments that can be cleared through ICC's systems and processes and to support industry wide initiatives and protocols.

(b) Statutory Basis

ICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act [3] and the regulations thereunder applicable to it, including the applicable standards under Rule 17Ad–22.[4] In particular, Section 17A(b)(3)(F) of the Act [5] requires that the rule change be consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest. As described above, the proposed changes incorporate an additional guiding principle that ICC consider instruments that are constituents of the currently clearable OTR indices to become clearing eligible in order to provide additional instruments to hedge and mitigate indirect risk exposure from the OTR indices. ICC believes that such changes would support and enhance the guiding principles and ensure that ICC continues to proceed in a prudent manner with respect to instrument selection while also providing CPs the best opportunity to minimize their risk. Moreover, the Instrument On-boarding Policy will continue to ensure that ICC's risk models adequately capture the risks associated with proposed new instruments and that the end-of-day price discovery process operates effectively and provides reliable prices for proposed new instruments, including through the risk management and pricing configuration and evaluation and the dress rehearsal. The proposed rule change is therefore consistent with the prompt and accurate clearing and settlement of the contracts cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.[6]

The amendments would also satisfy relevant requirements of Rule 17Ad–22.[7] Rule 17Ad–22(e)(2)(i) and (v) [8] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent and specify clear and direct lines of responsibility. The Instrument On-boarding Policy continues to describe the roles and responsibilities of relevant stakeholders with respect to instrument selection and subject new instruments to ICC's governance process. As such, in ICC's view, the proposed rule change continues to ensure that ICC maintains policies and procedures that are reasonably designed to provide for clear and transparent governance arrangements and specify clear and direct lines of responsibility, consistent with Rule 17Ad–22(e)(2)(i) and (v).[9]

Rule 17Ad–22(e)(4)(ii) [10] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining additional financial resources at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the two participant families that would potentially cause the largest aggregate credit exposure for the covered clearing agency in extreme but plausible market conditions. The proposed changes distinguish a category of instruments that are constituents of the currently clearable OTR indices to provide additional instruments to hedge and mitigate indirect risk exposure from the OTR indices. New instruments will continue to be subject to the risk management and pricing configuration and evaluation and the dress rehearsal under the Instrument On-boarding Policy to ensure that ICC's risk models adequately capture the risks associated with new instruments and that the end-of-day price discovery process operates effectively, thereby supporting ICC's ability to maintain its financial resources and withstand the pressures of defaults, consistent with the requirements of Rule 17Ad–22(e)(4)(ii).[11]

Rule 17Ad–22(e)(17) [12] requires, in relevant part, each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to manage its operational risks by (i) identifying the plausible sources of operational risk, both internal and external, and mitigating their impact through the use of appropriate systems, policies, procedures, and controls; and (ii) ensuring that systems have a high degree of security, resiliency, operational reliability, and adequate, scalable capacity. The Instrument On-boarding Policy continues to describe the process, including testing and preparation, for the introduction of new instruments to ensure that ICC and its CPs are operationally ready and that ICC proceeds in a controlled manner, thereby supporting ICC's ability to identify the plausible sources of operational risk and mitigate their impact and ensure that systems have a high degree of security, resiliency, operational reliability, and adequate, scalable capacity, consistent with the requirements of Rule 17Ad–22(e)(17).[13]

Rule 17Ad–22(e)(21) [14] requires, among other things, that each covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to be efficient and effective in meeting the requirements of its participants and the markets it serves. The proposed changes are designed to provide additional instruments to hedge and mitigate indirect risk exposure from the OTR indices. Such changes would support and enhance the guiding principles by ensuring that ICC continues to proceed in a prudent manner with respect to instrument selection while also providing CPs the best opportunity to

[3] 15 U.S.C. 78q–1.

[4] 17 CFR 240.17Ad–22.

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] *Id.*

[7] 17 CFR 240.17Ad–22.

[8] 17 CFR 240.17Ad–22(e)(2)(i) and (v).

[9] *Id.*

[10] 17 CFR 240.17Ad–22(e)(4)(ii).

[11] *Id.*

[12] 17 CFR 240.17Ad–22(e)(17)(i) and (ii).

[13] *Id.*

[14] 17 CFR 240.17Ad–22(e)(21).

minimize their risk, thereby allowing ICC to be efficient and effective in meeting the requirements of its participants and the markets it serves, consistent with Rule 17Ad–22(e)(21).[15]

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act. The proposed changes to the Instrument On-boarding Policy will apply uniformly across all market participants. Therefore, ICC does not believe the proposed rule change imposes any burden on competition not necessary or appropriate in furtherance of the purpose of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICC–2021–019 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–ICC–2021–019. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.theice.com/clear-credit/regulation.* All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2021–019 and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21615 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

[15] *Id.*

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93195; File No. SR–OCC–2021–009]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Revise the Options Clearing Corporation's Schedule of Fees

September 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2021, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by OCC. OCC filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii)[3] of the Act and Rule 19b–4(f)(2)[4] thereunder so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change by OCC would revise OCC's schedule of fees to implement a fee holiday for the period beginning November 1, 2021, and ending December 31, 2021. OCC's schedule of fees is included as Exhibit 5 to File No. SR–OCC–2021–009. Material proposed to be added to OCC's schedule of fees as currently in effect is underlined and material proposed to be deleted is marked in strikethrough text. All capitalized terms not defined herein have the same meaning as set forth in the OCC By-Laws and Rules.[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] OCC's By-Laws and Rules can be found on OCC's public website: *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

The purpose of this proposed rule change is to revise OCC's schedule of fees to implement a fee holiday for the period beginning November 1, 2021, and ending December 31, 2021. OCC's Capital Management Policy (''Policy'') provides that OCC reviews its fee schedule on a periodic basis in consideration of factors including, but not limited to, projected operating expenses, projected volumes, anticipated cash flows, and capital needs.[6] Provided that OCC's shareholders' equity (''Equity''), less the minimum persistent amount of capital that OCC maintains exclusively to address losses or liquidity shortfalls arising from member defaults (the ''Minimum Corporate Contribution''),[7] exceeds 110% of the Target Capital Requirement [8] (''Early Warning'') [9] plus any amount approved for capital expenditures, OCC's Board, or a Committee the Board has delegated, may use tools as it considers appropriate to lower costs for Clearing Members. Such tools for reducing the cost of clearing include lowering fees, declaring a fee holiday, or issuing refunds.[10]

OCC has experienced record volumes in 2021 while maintaining expenses at or around the budgeted amount. These strong financial results put OCC in a position to continue to invest resources in OCC's initiative to update and upgrade its technology infrastructure for critical clearing and settlement services, risk systems and data management,[11] while at the same time lowering the cost of clearing for the users of the markets OCC serves. Accordingly, effective June 1, 2021, OCC lowered its clearing fee from $0.045 per contract to $0.02 per contract.[12]

As of June 30, 2021, OCC maintained Equity of approximately $693 million, or approximately $418 million more than the Early Warning.[13] Based on projections of contract volume and expenses, OCC believes that it can implement a two-month fee holiday while maintaining sufficient revenue to support OCC's operations and capital needs, including 2021 cash needs related to OCC's technology infrastructure transformation.[14] Accordingly, OCC proposes to modify its fee schedule to decrease both its per contract and per trade clearing fees to $0 for the last two months of 2021.[15]

Fee schedule		Proposed fee holiday from November 1, 2021 to December 31, 2021	
Clearing Fees		Clearing Fees	
Trades with contracts of 0–2,750	$0.02/contract	Trades with contracts of 0–2,750	$0/contract.
Trades with contracts of more than 2,750	$55/trade	Trades with contracts of more than 2,750	$0/trade.

OCC proposes to make the fee change effective November 1, 2021, because OCC believes that this date is the first date that the industry could be prepared to process the new fee without disruption based on consultations with market participants.[16] Effective the first trading day of 2022, clearing fees will revert to the fee schedule in effect before November 1, 2021 and OCC will remove the fee holiday from its schedule of fees.

(2) Statutory Basis

Section 17A(b)(3)(D) of the Act [17] requires that the rules of a clearing agency provide for the equitable allocation of reasonable dues, fees, and other charges among its participants. OCC believes that the proposed fee holiday is reasonable because it is designed to decrease the cost of clearing while maintaining sufficient reserves in the form of liquid net assets to cover OCC's operating expenses and address potential business or operational losses so that OCC can continue to meet its obligations as a systemically important financial market utility to Clearing Members and the general public if such losses were to materialize (including through a recovery or orderly wind-down of critical operations and services) and thereby facilitating compliance with certain requirements of Rule 17Ad–22(e)(15)(ii).[18]

In determining the appropriateness of a fee holiday, the CPC considered a variety of factors, including the projected revenue loss that would result from a two-month fee holiday, projected expenses, projected average daily volume, and a scenario analysis modeling the sensitivity of operating income, adjusting for different clearing fee levels.[19] The CPC also considered OCC's cash needs through 2021 to support its technology transformation initiative. OCC believes that the proposed fee holiday is reasonable and consistent with its existing By-Laws and Rules. OCC also believes that the proposed fee holiday would result in an equitable allocation of fees among its participants because it would be equally applicable to all market participants. As a result, OCC believes that the proposed fee holiday provides for the equitable

[6] *See* Exchange Act Release No. 88029 (Jan. 24, 2020), 85 FR 5500, 5502 (Jan. 30, 2020) (File No. SR–OCC–2019–007) (''Order Approving Policy''); Exchange Act Release No. 87257 (Oct. 8, 2019), 84 FR 55194, 55196 (Oct. 15, 2019) (File No. SR–OCC–2019–805) (''Notice of No-Objection to Policy'').

[7] *See* Exchange Act Release No. 92038 (May 27, 2021), 86 FR 29861 (Jun. 3, 2021) (File No. SR–OCC–2021–003) (order approving proposed rule change to establish OCC's persistent minimum skin-in-the-game); Exchange Act Release No. 91491 (Apr. 7, 2021), 86 FR 19061 (Apr. 12, 2021) (File No. SR–OCC–2021–801) (notice of no objection to advance notice relating to OCC's establishment of persistent minimum skin-in-the-game).

[8] The Target Capital Requirement is the amount of Equity recommended by Management and approved by the Board to ensure compliance with regulatory capital requirements and to keep such additional amount the Board may approve for capital expenditures. *See* OCC Rule 101.

[9] The Early Warning is one of the thresholds under OCC's plan for replenishing capital in the event OCC's Equity falls close to or below OCC's regulatory capital requirements, as required by SEC Rule 17Ad–22(e)(15)(iii). *See* 17 CFR 17Ad–22(e)(15)(iii).

[10] *See* Order Approving Policy, 85 FR at 5502; Notice of No-Objection to Policy, 84 FR at 55196.

[11] *See* OCC Technology Changes + Enhancements Reference Guide, *available at https://www.theocc.com/Participant-Resources* (last updated July 21, 2021).

[12] Exchange Act Release No. 91920 (May 18, 2021), 86 FR 27916 (May 24, 2021) (File No. SR–OCC–2021–006).

[13] *See* OCC Schedule of Fees, *available at https://www.theocc.com/Company-Information/Schedule-of-Fees* (under OCC Capital Management Reporting, unaudited as of June 30, 2021).

[14] OCC has provided confidential data and analysis to the Commission in Exhibit 3 to File No. SR–OCC–2021–009.

[15] These changes are also reflected in Exhibit 5 to File No. SR–OCC–2021–009.

[16] OCC notes that a mid-month change to clearing fees could introduce operational disruption to Clearing Members due to the impact on their billing processes.

[17] 15 U.S.C. 78q–1(b)(3)(D).

[18] 17 CFR 240.17Ad–22(e)(15)(ii).

[19] A summary of the analyses is included in confidential Exhibit 3 to File No. SR–OCC–2021–009.

allocation of reasonable fees in accordance with Section 17A(b)(3)(D) of the Act.[20]

The proposed rule change is not inconsistent with the existing rules of OCC, including any other rules proposed to be amended.

(B) Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act[21] requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. OCC does not believe that the proposed rule change would have any impact or impose a burden on competition. Although this proposed rule change affects clearing members, their customers, and the markets that OCC serves, OCC believes that the proposed rule change would not disadvantage or favor any particular user of OCC's services in relationship to another user because the proposed fee holiday applies equally to all users of OCC. Accordingly, OCC does not believe that the proposed rule change would have any impact or impose a burden on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)(ii)[22] of the Act, and Rule 19b–4(f)(2) thereunder,[23] the proposed rule change is filed for immediate effectiveness as it constitutes a change in fees charged to OCC's members. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.[24]

[20] 15 U.S.C. 78q–1(b)(3)(D).

[21] 15 U.S.C. 78q–1(b)(3)(I).

[22] 15 U.S.C. 78s(b)(3)(A)(ii).

[23] 17 CFR 240.19b–4(f)(2).

[24] Notwithstanding its immediate effectiveness, implementation of this rule change will be delayed until this change is deemed certified under CFTC Regulation 40.6.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–OCC–2021–009 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2021–009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–OCC–2021–009 and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21625 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93186; File No. SR–NYSEArca–2021–85]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend NYSE Arca Rules 7.2–E and 7.2–O

September 30, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2021, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Arca Rules 7.2–E and 7.2–O (Holidays) to make Juneteenth National Independence Day a holiday of the Exchange. Juneteenth National Independence Day was designated a legal public holiday in June 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Arca Rules 7.2–E and 7.2–O (Holidays) to make Juneteenth National Independence Day a holiday of the Exchange.

On June 17, 2021, Juneteenth National Independence Day was designated a legal public holiday.[3] Consistent with broad industry sentiment [4] and the approach recommended by the Securities Industry and Financial Markets Association (''SIFMA''),[5] the Exchange proposes to add ''Juneteenth National Independence Day'' to the existing list of holidays in the first paragraph of NYSE Arca Rules 7.2–E and 7.2–O. As a result, the Exchange will not be open for business on Juneteenth National Independence Day, which falls on June 19 of each year. In accordance with the second paragraph of NYSE Arca Rules 7.2–E and 7.2–O, when the holiday falls on a Saturday, the Exchange will not be open for business on the preceding Friday, and when it falls on a Sunday, the Exchange will not be open for business on the succeeding Monday.[6]

The first paragraph of the revised rule would read as follows (proposed additions *italicized*):

The Exchange will not be open for business on New Year's Day, Martin Luther King Jr. Day, Presidents' Day, Good Friday, Memorial Day, *Juneteenth National Independence Day,* Independence Day, Labor Day, Thanksgiving Day and Christmas Day.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed amended rule would clearly state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The change would thereby promote clarity and transparency in the Exchange rules by updating the list of holidays of the Exchange.

The proposed change does not raise any new or novel issues.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[9] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather to amend the Exchange rule regarding holidays.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) [12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative prior to 30 days after the date of the filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because the proposed rule change, as described above, would state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The Exchange further states that the proposed change does not raise any new or novel issues. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings

[3] Public Law 117–17.

[4] *See, e.g. https://www.bloomberg.com/news/articles/2021-06-18/bofa-makes-juneteenth-a-holiday-joining-jpmorgan-wells-fargo?sref=Hhue1scO.*

[5] SIFMA recommends a full market close in observance of Juneteenth National Independence Day. *See https://www.sifma.org/resources/general/holiday-schedule/. See also https://www.sifma.org/resources/news/sifma-revises-2022-fixed-income-market-close-recommendations-in-the-u-s-to-include-full-close-for-juneteenth-national-independence-day/.*

[6] NYSE Arca Rules 7.2–E and 7.2–O. There is an exception to the practice if unusual business conditions exist, such as the ending of a monthly or yearly accounting period. *Id.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(8).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2021–85 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2021–85. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2021–85, and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21743 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93174; File No. SR–CboeBZX–2021–052]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To List and Trade Shares of the Global X Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

September 29, 2021.

On August 3, 2021, Cboe BZX Exchange, Inc. (''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the Global X Bitcoin Trust under BZX Rule 14.11(e)(4). The proposed rule change was published for comment in the **Federal Register** on August 23, 2021.[3] The Commission has received comments on the proposed rule change.[4]

Section 19(b)(2) of the Act[5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is October 7, 2021. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the comments received. Accordingly, pursuant to Section 19(b)(2) of the Act,[6] the Commission designates November 21, 2021, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–CboeBZX–2021–052).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21612 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–318, OMB Control No. 3235–0361]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: U.S. Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Form ADV–E

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form ADV–E (17 CFR 279.8) is the cover sheet for certificates of accounting filed pursuant to rule 206(4)–2 under the Investment Advisers Act of 1940 (17 CFR 275.206(4)–2). The rule further requires that the public accountant file with the Commission a Form ADV–E and accompanying statement within four business days of the resignation, dismissal, removal or other termination of its engagement.

The Commission has estimated that compliance with the requirement to complete Form ADV–E imposes a total burden of approximately 0.05 hours (3 minutes) per respondent. Based on current information from advisers

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 92689 (Aug. 17, 2021), 86 FR 47176 (Aug. 23, 2021).

[4] Comments received on the proposed rule change are available at: *https://www.sec.gov/comments/sr-cboebzx-2021-052/srcboebzx2021052.htm.*

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

registered with the Commission, the Commission staff estimates that 1,743 filings will be submitted with respect to surprise examinations and 33 filings will be submitted with respect to termination of accountants. Based on these estimates, the total estimated annual burden would be 88.80 hours ((1,743 filings × .05 hours) + (33 filings × .05 hours)).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication. An agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

Please direct your written comments to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, C/O Cynthia Roscoe, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: September 29, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21587 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–298, OMB Control No. 3235–0337]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 17Ac2–2 and Form TA–2

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17Ac2–2(17 CFR 240.17Ac2–2) and Form TA–2 under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17Ac2–2 and Form TA–2 require registered transfer agents to file an annual report of their business activities with the Commission. These reporting requirements are designed to ensure that all registered transfer agents are providing the Commission with sufficient information on an annual basis about the transfer agent community and to permit the Commission to effectively monitor business activities of transfer agents.

The amount of time needed to comply with the requirements of Rule 17Ac2–2 and Form TA–2 varies. Of the total 362 registered transfer agents, approximately 9.2% (or 33 registrants) would be required to complete only questions 1 through 3 and the signature section of Form TA–2, which the Commission estimates would take each registrant approximately 30 minutes, for a total burden of approximately 17 hours (33 × .5 hours). Approximately 26.5% of registrants (or 96 registrants) would be required to answer questions 1 through 5, question 11 and the signature section, which the Commission estimates would take approximately 1 hour and 30 minutes, for a total of approximately 144 hours (96 × 1.5 hours). Approximately 64.2% of the registrants (or 232 registrants) would be required to complete the entire Form TA–2, which the Commission estimates would take approximately 6 hours, for a total of approximately 1,392 hours (232 × 6 hours). The aggregate annual burden on all 362 registered transfer agents is thus approximately 1,553 hours (17 hours + 144 hours + 1,392 hours) and the average annual burden per transfer agent is approximately 4.29 hours (1,553 ÷ 362).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: September 29, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21586 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–373; OMB Control No. 3235–0422]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 23c–3 and Form N–23c–3

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 23c–3 (17 CFR 270.23c–3) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) permits a registered closed-end investment company (''closed-end fund'' or ''fund'') that meets certain requirements to repurchase common stock of which it is the issuer from shareholders at periodic intervals, pursuant to repurchase offers made to all holders of the stock. The rule enables these funds to offer their shareholders a limited ability to resell their shares in a manner that previously was available only to open-end investment company shareholders.

There have been recent regulatory developments put forth by the Commission that will provide shareholders of closed-end funds with

additional benefits. Effective August 1, 2021, rule 23c–3 will be amended by including a new subparagraph (e) that will permit a fund that relies on rule 23c–3 to register an indefinite amount of securities, under Section 24 of the Investment Company Act upon the effectiveness of a fund's registration statement.[1] In addition, concurrent with the implementation of rule 23c–3(e), the Commission adopted an amendment to rule 24f–2 under the Investment Company Act, permitting closed-end funds to compute registration fees on an annual net basis.[2] The Commission's intent in proposing and adopting rules 23c–3(e) and 24f–2(a) respectively, was to avoid the possibility a closed-end fund of inadvertently selling more shares than it had registered.[3] These revisions to rule 23c–3 do not impose additional collections of information.

Notwithstanding these recent regulatory developments, a closed-end fund that relies on rule 23c–3 must send shareholders a notification that contains specified information each time the fund makes a repurchase offer (on a quarterly, semi-annual, or annual basis, or, for certain funds, on a discretionary basis not more often than every two years). The fund also must file copies of the shareholder notification with the Commission (electronically through the Commission's Electronic Data Gathering, Analysis, and Retrieval System (''EDGAR'')) on Form N–23c–3, a filing that provides certain information about the fund and the type of offer the fund is making.[4] The fund must describe in its annual report to shareholders the fund's policy concerning repurchase offers and the results of any repurchase offers made during the reporting period. The fund's board of directors must adopt written procedures designed to ensure that the fund's investment portfolio is sufficiently liquid to meet its repurchase obligations and other obligations under the rule. The board periodically must review the composition of the fund's portfolio and change the liquidity procedures as necessary. The fund also must file copies of advertisements and other sales literature with the Commission as if it were an open-end investment company subject to Section 24 of the Investment Company Act (15 U.S.C. 80a–24) and the rules that implement Section 24. Rule 24b–3 under the Investment Company Act (17 CFR 270.24b–3), however, exempts the fund from that requirement if the materials are filed instead with the Financial Industry Regulatory Authority (''FINRA'').

The requirement that the fund send a notification to shareholders of each offer is intended to ensure that a fund provides material information to shareholders about the terms of each offer. The requirement that copies be sent to the Commission is intended to enable the Commission to monitor the fund's compliance with the notification requirement. The requirement that the shareholder notification be attached to Form N–23c–3 is intended to ensure that the fund provides basic information necessary for the Commission to process the notification and to monitor the fund's use of repurchase offers. The requirement that the fund describe its current policy on repurchase offers and the results of recent offers in the annual shareholder report is intended to provide shareholders current information about the fund's repurchase policies and its recent experience. The requirement that the board approve and review written procedures designed to maintain portfolio liquidity is intended to ensure that the fund has enough cash or liquid securities to meet its repurchase obligations, and that written procedures are available for review by shareholders and examination by the Commission. The requirement that the fund file advertisements and sales literature as if it were an open-end fund is intended to facilitate the review of these materials by the Commission or FINRA to prevent incomplete, inaccurate, or misleading disclosure about the special characteristics of a closed-end fund that makes periodic repurchase offers.

The Commission staff estimates that 60 funds make use of rule 23c–3 annually, including 32 funds that are relying upon rule 23c–3 for the first time. The Commission staff estimates that on average a fund spends 89 hours annually in complying with the requirements of the rule and Form N–23c–3, with funds relying upon rule 23c–3 for the first time incurring an additional one-time burden of 28 hours. The Commission therefore estimates the total annual hour burden of the rule's and form's paperwork requirements to be 6,236 hours. In addition to the burden hours, the Commission staff estimates that the average yearly cost to each fund that relies on rule 23c–3 to print and mail repurchase offers to shareholders is about $32,744.13. The Commission estimates total annual cost is therefore about $1,964,647.

Estimates of average burden hours and costs are made solely for purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms. Compliance with the collection of information requirements of the rule and form is mandatory only for those funds that rely on the rule in order to repurchase shares of the fund. The information provided to the Commission on Form N–23c–3 will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website:*www.reginfo.gov*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*.

Dated: September 29, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21584 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

[1] 17 CFR 270.23c–3(e).

[2] 17 CFR 270.24f–2(a).

[3] Securities Offering Reform for Closed-End Investment Companies (SEC Rel. No. IC–33427) (Mar. 20, 2019) [84 FR 14448 (Apr. 10, 2019)] at 64.

[4] Form N–23c–3, entitled ''Notification of Repurchase Offer Pursuant to Rule 23c–3,'' requires the fund to state its registration number, its full name and address, the date of the accompanying shareholder notification, and the type of offer being made (periodic, discretionary, or both).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93178; File No. SR–ICEEU–2021–014]

Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change, as Modified by Partial Amendment No. 1, Relating to the ICE Clear Europe Clearing Membership Policy and Clearing Membership Procedures

September 29, 2021.

I. Introduction

On August 2, 2021, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities

Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt a new Clearing Membership Policy (the ''Policy'') and new Clearing Membership Procedures (the ''Procedures,'' and together with the Policy, the ''Documents''). The proposed Documents would consolidate and summarize ICE Clear Europe's existing clearing membership criteria and document certain existing processes and procedures concerning the membership application process. On August 11, 2021, ICE Clear Europe filed Partial Amendment No. 1 to the proposed rule change.[3] Notice of the proposed rule change, as modified by Partial Amendment No. 1, was published in the **Federal Register** on August 18, 2021.[4] The Commission did not receive comments on the proposed rule change, as modified by Partial Amendment No. 1. For the reasons discussed below, the Commission is approving the proposed rule change, as modified by Partial Amendment No. 1 (hereafter referred to as the ''proposed rule change'').

II. Description of the Proposed Rule Change

As described in more detail below, ICE Clear Europe proposes to adopt the Documents to consolidate and summarize its existing clearing membership criteria and to document certain existing processes and procedures concerning its membership application and monitoring processes to ensure that Clearing Members meet admission criteria upon initial membership and continue to meet such criteria throughout their membership.[5]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ICE Clear Europe filed Partial Amendment No. 1 to delete from the filed Exhibit 5B, Clearing Membership Procedures, certain statements in sections 2.4.1 and 2.4.2 of such Procedures concerning the termination of clearing membership by a Clearing Member. Specifically, ICE Clear Europe proposes to remove the statements that it will define a minimum notice period and may publish a Circular confirming that a Termination Notice has been issued, because the appropriate minimum notice period and requirements for publishing a Circular are set forth in existing Clearing Rule 209, which is not proposed to be amended. Partial Amendment No. 1 did not otherwise make any changes to the substance of the filing or the text of the proposed rule change.

[4] Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change, as Modified by Partial Amendment No. 1, Relating to the ICE Clear Europe Clearing Membership Policy and Clearing Membership Procedures, Exchange Act Release No. 92652 (August 12, 2021), 86 FR 46290 (August 18, 2021) (SR–ICEEU–2021–014) (''Notice'').

[5] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules (the ''Rules''). The description herein of the proposed rule change is substantially excerpted from the Notice.

A. Clearing Membership Policy

The proposed new Policy would consolidate and summarize ICE Clear Europe's existing clearing membership criteria, which are set forth in full detail in the Rules, and its related processes for assessing applicants for membership, variations of permissions concerning membership class, and termination of membership, all of which would be documented in more detail in the proposed Procedures as described below.

The Policy would describe ICE Clear Europe's membership risks and state the objectives of the Policy to ensure that such risks are properly managed, and that clearing membership admission criteria are non-discriminatory, transparent, and objective to ensure fair and open access, and designed to meet relevant regulatory requirements. The Policy also would describe how such objectives are met by ICE Clear Europe through setting and monitoring appropriate membership criteria, establishing a due diligence process, and requiring prompt notifications from Clearing Members of any changes to their businesses that may impact a Clearing Member's ability to meet the membership criteria. The core clearing membership criteria, including holding sufficient capital, being a party to a Clearing Membership Agreement, and other financial and operational criteria, would be summarized in the Policy, with the full criteria set out in Rule 201 and the CDS Procedures.

In addition to a summary of the core clearing membership criteria, the Policy would provide that ICE Clear Europe has established processes for clearing membership application, permission variations, and clearing membership termination which are described in further detail in the Procedures. The Policy also would address the ongoing monitoring of membership criteria, including periodic in-depth counterparty reviews, periodic review of financial positions, updates to ICE Clear Europe's counterparty rating system, the maintenance of a watch list, requiring an annual member return from Clearing Members, and other operational monitoring processes such as daily margin calls and CDS end-of-day (''EOD'') price submissions.

Proposed section 5 of the Policy would provide document governance arrangements for breach management, ongoing reviews, and exception handling. Consistent with the document governance arrangements for other ICE Clear Europe policies and procedures, proposed section 5 would state that (i) the document owner is responsible for ensuring that documents remain up-to-date and are reviewed in accordance with ICE Clear Europe's governance processes, (ii) the document owner will report material breaches or unapproved deviations from the Policy document to the document owner's Head of Department, the Chief Risk Officer, and the Head of Compliance (or their delegates), who together will determine if further escalation should be made to relevant senior executives, the Board, and/or competent authorities, and (iii) exceptions to the Policy are approved in accordance with ICE Clear Europe's governance process for the approval of changes to the Policy document.

B. Clearing Membership Procedures

The proposed new Procedures would describe in further detail the processes for reviewing and approving applications for clearing membership, variations of membership permissions, ongoing monitoring, and membership termination. The stated objective of the Procedures would be to establish a due diligence process to ensure applicants meet ICE Clear Europe's membership criteria at the time of application and on an ongoing basis, and also provide notifications of any changes to their businesses that could impact their ability to meet the membership criteria.

The Procedures would describe each phase of the Clearing Member application process, starting with the Membership Department providing applicants with all relevant application documentation; the internal due diligence of applications by relevant ICE Clear Europe departments, including Operations, Risk, Treasury, Membership, AML/KYC, Risk Oversight, Compliance, and Legal; the process for approval or rejection of applications by the Executive Risk Committee under authority delegated by the Board, and the right to appeal to the Board; notifications of new applications for clearing membership to the relevant Product Risk Committees after their approval by the Executive Risk Committee; additional membership conditions or criteria that ICE Clear Europe may, in its discretion, require prior to approval; and additional information requests that ICE Clear Europe may make during the application process. The Procedures also would describe the process for a Clearing Member to obtain membership to a different membership class at ICE Clear Europe (*i.e.,* a CDS Clearing Member authorized to clear credit default swap (''CDS'') contracts, or an F&O Clearing Member authorized to become party to Energy Contracts or Financials & Softs Contracts, or both).

Regarding termination of clearing membership, the Procedures would cross-reference the procedures in existing Rule 209 for a Clearing Member to resign its clearing membership, and for ICE Clear Europe to terminate a Clearing Member's clearing membership.

The Procedures would provide detailed core membership requirements and additional information on core membership criteria, which would include minimum capital requirements as well as a description of additional financial requirements that ICE Clear Europe may impose on Clearing Members to meet the minimum capital requirement. The Procedures would address certain aspects of the calculation of member capital, including the disallowance of certain assets from such calculation as well as the methods that Clearing Members may use to add capital, where necessary, including the use of subordinated debt and controller guarantees if approved by ICE Clear Europe. The Procedures also would reference Guaranty Fund contributions for CDS and F&O clearing services, including the required replenishment of contributions in the event of application of the funds and the need to meet any additional assessment; the margin-to-capital ratio requirement; default management capabilities; and EOD price submissions, which apply only to CDS Clearing Members as required by the CDS EOD Price Discovery Policy.

The Procedures also would summarize ICE Clear Europe's ongoing monitoring of Clearing Members that include the following: (i) Periodic review of the financial position and compliance with the relevant membership requirements of each Clearing Member; (ii) quarterly review of Clearing Members' capital situation and financial information, and monthly reviews of the financial information of FCM/BD Clearing Members; (iii) quarterly counterparty rating system report, which aggregates risk factors covering credit, market price, liquidity, and operational risk for each Clearing Member; (iv) the watch list highlighting Clearing Members with special risk situations; (v) annual member returns pursuant to which Clearing Members must provide certain information to ICE Clear Europe on Anti-Money Laundering/Know Your Client (''AML/KYC'') requirements, authorized signatories, compliance with the Rules, and key contact information; and (vi) daily monitoring of Clearing Member operational performance in fulfilling financial obligations to cover cash payments, margin collateral, Guaranty Fund contributions, and delivery obligations.

Finally, the Procedures would also set out the same document governance arrangements for breach management, ongoing reviews, and exception handling as those described above with respect to the Policy.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.[6] For the reasons given below, the Commission finds that the proposed rule change, as modified by Partial Amendment No. 1, is consistent with Section 17A(b)(3)(F) of the Act[7] and Rules 17Ad–22(e)(2)(i) and (v), and (e)(18) thereunder.[8]

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of ICE Clear Europe be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, as well as to assure the safeguarding of securities and funds which are in the custody or control of ICE Clear Europe or for which it is responsible.[9]

As discussed above, the proposed rule change would adopt a new Clearing Membership Policy and new Clearing Membership Procedures. The proposed Documents would consolidate and summarize existing clearing membership criteria and related processes in the Rules that govern clearing membership at ICE Clear Europe. For the reasons discussed below, the Commission believes that the proposed rule change would enable ICE Clear Europe to manage and mitigate the risks posed by Clearing Members, including the risk of membership defaults and the potential loss of mutualized funds resulting from Clearing Member failures to meet clearing membership criteria. The Commission further believes that, in turn, managing effectively such risks would enable ICE Clear Europe to promote the prompt and accurate clearance and settlement of securities transactions and help assure the safeguarding of securities and funds which are in the custody or control of ICE Clear Europe or for which it is responsible.

i. Clearing Membership Policy

As discussed above, the proposed rule change would establish a new Policy that consolidates and summarizes ICE Clear Europe's existing clearing membership criteria and the existing processes that ICE Clear Europe undertakes to assess applicants for membership, monitor Clearing Member adherence to the membership criteria on an ongoing basis, authorize variations of permissions to Clearing Members, and terminate membership, whether initiated by the Clearing Member or by ICE Clear Europe. The Policy would state that it is designed to ensure that membership risks are properly managed, and that clearing membership admission criteria are non-discriminatory, transparent, and objective to ensure fair and open access, and also meet relevant regulatory requirements. The Policy would summarize how ICE Clear Europe achieves such objectives by setting appropriate membership criteria and monitoring ongoing adherence to such criteria; establishing a due diligence process that ensures that applicants meet the membership criteria when admitted and on a continuing basis; and requiring prompt notifications from Clearing Members of any changes to their businesses that may impact a Clearing Member's ability to meet the membership criteria. The Policy also would establish document governance and procedures for breach management and exceptions and changes to the Policy document.

By creating a consolidated summary of existing clearing membership criteria for admitting applicants and the related processes that ICE Clear Europe currently undertakes for monitoring and terminating Clearing Members, the Commission believes that the Policy would facilitate ICE Clear Europe's ability to implement the membership risk management objectives of the Policy and thereby enhance its overall risk management. In the Commission's view, enhanced management of membership risks is critical to mitigating the risk of Clearing Member defaults that could undermine ICE Clear Europe's ability to maintain prompt and accurate clearance and settlement of securities transactions and the safeguarding of securities and funds at ICE Clear Europe. For example, ICE Clear Europe relies on accurate end-of-day prices to generate margin

[6] 15 U.S.C. 78s(b)(2)(C).

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 17 CFR 240.17Ad–22(e)(2)(i) and (v), and (e)(18).

[9] 15 U.S.C. 78q–1(b)(3)(F).

requirements, which it uses to manage the risks associated with clearing CDS portfolios. Similarly, ICE Clear Europe relies on its default management tools to help manage and reduce the risks associated with a defaulting Clearing Member's portfolio. Such risks, if not properly managed, could cause ICE Clear Europe to realize losses on such portfolios and could disrupt ICE Clear Europe's ability to promptly and accurately clear CDS and other derivative transactions and safeguard securities and funds which are in the custody or control of ICE Clear Europe or for which it is responsible. For these reasons, the Commission believes that the proposed rule change, in establishing a new Policy that clearly and succinctly documents membership criteria and the related processes for admitting, monitoring, and terminating Clearing Members, would promote the prompt and accurate clearance and settlement of securities transactions and help assure the safeguarding of securities and funds which are in the custody or control of ICE Clear Europe or for which it is responsible. Finally, the Commission believes that, in defining the responsibilities of the document owner in document governance, breach management, and exception handling, the Policy would help to ensure ongoing and consistent compliance with ICE Clear Europe's clearing membership criteria and related processes for admission to membership, monitoring, and termination of membership, as well as establish a process to modify the Policy as needed.

ii. Clearing Membership Procedures

As discussed above, the new Procedures would describe in further detail ICE Clear Europe's existing processes for reviewing applications for clearing membership, variations of membership permissions, ongoing monitoring, and membership termination. The Procedures would have a stated objective for the membership application process to establish a due diligence process to ensure applicants meet ICE Clear Europe's membership criteria at the time of application and on an ongoing basis after admission, and also provide notifications of any changes to their businesses that could impact their ability to meet the membership criteria. The Procedures would provide the same document governance arrangements for breach management, ongoing reviews, and exception handling as those described above with respect to the Policy.

By creating a consolidated summary that would describe the application of ICE Clear Europe's existing procedures and processes for reviewing applications for clearing membership, variations of membership permissions, ongoing monitoring, and termination of membership, the Commission believes that the Procedures would enhance ICE Clear Europe's ability to implement the complementary objectives of the Documents and thereby enhance its membership risk management policies and procedures that contribute to the effectiveness of its overall risk management. Also, in defining the responsibilities of the document owner in document governance, breach management, and exception handling, the Procedures would help to ensure ongoing and consistent compliance with ICE Clear Europe's general governance and exceptions process for the Procedures document.

iii. Promoting the Prompt and Accurate Clearance and Settlement of Securities Transactions, and Assuring the Safeguarding of Securities and Funds

For the reasons discussed above, the Commission believes that the proposed rule change would help to ensure that ICE Clear Europe effectively manages the potential risks posed by its Clearing Members in the clearance and settlement of CDS and other derivative contracts and transactions cleared at ICE Clear Europe. Moreover, the Commission believes that such membership risks, if not properly managed, could threaten ICE Clear Europe's ability to operate and thereby clear and settle cleared contracts, and also could threaten access to securities and funds in ICE Clear Europe's control. Accordingly, the Commission believes that, in ensuring that ICE Clear Europe has clear and effective processes and procedures for identifying and managing membership risks by setting appropriate membership criteria; assessing applicants for membership based on such criteria; monitoring Clearing Member adherence to the membership criteria on an ongoing basis; authorizing variations of permissions to Clearing Members; terminating membership; and establishing clear document governance procedures for the Documents, the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions and help assure the safeguarding of securities and funds which are in the custody or control of the ICE Clear Europe or for which it is responsible.

Therefore, the Commission finds that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, and assure the safeguarding of securities and funds in ICE Clear Europe's custody or control, consistent with the Section 17A(b)(3)(F) of the Act.[10]

B. Consistency With Rule 17Ad–22(e)(2)(i) and (v) Under the Act

Rule 17Ad–22(e)(2)(i) and (v) require that ICE Clear Europe establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent and specify clear and direct lines of responsibility, respectively.[11] As discussed above, each of the Documents would establish the general governance and exceptions process for that document, and this process would be identical between the Documents. The Commission believes that, in doing so, the Documents would establish clear and transparent arrangements for ensuring that ICE Clear Europe personnel adhere to the Documents and for modifying the Documents as needed. The Commission also believes that the Documents would define clearly the roles and responsibilities of the document owner, the Head of Department, the Chief Risk Officer, and the Head of Compliance for document governance, breach management, and exception handling. The Commission believes that these lines of responsibility would be clear and transparent because they would be defined and readily available for review in the Documents.

As discussed above, the Procedures would define the roles and responsibilities of the relevant departments within ICE Clear Europe in the application process prior to submission of applications to the Executive Risk Committee for approval. The Procedures would specify that applications for membership are formally considered, and approved and rejected by, the Executive Risk Committee, and that the relevant Product Risk Committees are notified of approved applications. The Commission believes that these aspects of the proposed rule change would help to ensure that the governance regarding review and approval of applicants is clear and transparent, and also establishes a clear and direct line of responsibility, by clearly specifying that the Executive Risk Committee would approve or disapprove applications under delegated authority from the Board. The Commission believes this would therefore clearly specify the

[10] 15 U.S.C. 78q–1(b)(3)(F).

[11] 17 CFR 240.17Ad–22(e)(2)(i) and (v).

responsibility of ICE Clear Europe management in approving or rejecting applicants.

For these reasons, the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(e)(2)(i) and (v).[12]

C. Consistency With Rule 17Ad–22(e)(18) Under the Act

Rule 17Ad–22(e)(18) requires that ICE Clear Europe establish, implement, maintain, and enforce written policies and procedures reasonably designed to establish objective, risk-based, and publicly disclosed criteria for participation, which permit fair and open access by direct and, where relevant, indirect participants and other financial market utilities, to require participants to have sufficient financial resources and robust operational capacity to meet obligations arising from participation in the clearing agency, and monitor compliance with such participation requirements on an ongoing basis.[13]

As discussed above, the Documents would summarize the core membership requirements and additional information on core membership criteria, which would include minimum capital requirements as well as a description of additional financial requirements that ICE Clear Europe may impose on Clearing Members to meet the minimum capital requirement. In particular, the Procedures would address more detailed aspects of the calculation of member capital; Guaranty Fund contributions for both CDS and F&O clearing services; the margin-to-capital ratio requirement; default management capabilities; and EOD price submissions for CDS Clearing Members. The Commission believes that these aspects of the proposed rule change would establish objective, risk-based, and disclosed clearing membership criteria that require applicants for clearing membership to prove that they have sufficient financial resources and robust operational capacity to meet obligations arising from participation in ICE Clear Europe. Moreover, the Commission believes that these criteria represent objective criteria which any applicant for clearing membership could potentially satisfy, thereby permitting fair and open access to membership at ICE Clear Europe.

As discussed above, the Documents also would summarize ICE Clear Europe's ongoing monitoring of Clearing Members that would include: (i) Periodic review of the financial position and compliance with the relevant membership requirements of each Clearing Member; (ii) quarterly review of Clearing Members' capital situation and financial information, and monthly reviews of the financial information of FCM/BD Clearing Members; (iii) quarterly counterparty rating system report, which aggregates risk factors covering credit, market price, liquidity, and operational risk for each Clearing Member; (iv) the watch list highlighting Clearing Members with special risk situations; (v) annual member returns pursuant to which Clearing Members must provide certain information to ICE Clear Europe on AML/KYC requirements, authorized signatories, compliance with the Rules, and key contact information; and (vi) daily monitoring of Clearing Member operational performance in fulfilling financial obligations to cover cash payments, margin collateral, Guaranty Fund contributions, and delivery obligations. The Commission believes that these aspects of the proposed rule change would facilitate ICE Clear Europe's ability to monitor compliance by Clearing Members with its participation requirements on an ongoing basis and thereby mitigate the risks posed by Clearing Members who may no longer meet the requirements for continuing participation in ICE Clear Europe.

For these reasons, the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(e)(18).[14]

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act, and in particular, with the requirements of Section 17A(b)(3)(F) of the Act[15] and Rules 17Ad–22(e)(2)(i) and (v), and (e)(18) thereunder.[16]

It is therefore ordered pursuant to Section 19(b)(2) of the Act[17] that the proposed rule change (SR–ICEEU–2021–014), be, and hereby is, approved.[18]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21616 Filed 10–4–21; 8:45 am]

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[12] 17 CFR 240.17Ad–22(e)(2)(i) and (v).

[13] 17 CFR 240.17Ad–22(e)(18).

[14] 17 CFR 240.17Ad–22(e)(18).

[15] 15 U.S.C. 78q–1(b)(3)(F).

[16] 17 CFR 240.17Ad–22(e)(2)(i) and (v), and (e)(18).

[17] 15 U.S.C. 78s(b)(2).

[18] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93203; File No. SR–NYSE–2021–57]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Related to the Market-Wide Circuit Breaker in Rule 7.12

September 30, 2021.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on September 29, 2021, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot related to the market-wide circuit breaker in Rule 7.12 to the close of business on March 18, 2022. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries,

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the pilot related to the market-wide circuit breaker in Rule 7.12 to the close of business on March 18, 2022.

Background

The Market-Wide Circuit Breaker (''MWCB'') rules, including the Exchange's Rule 7.12, provide an important, automatic mechanism that is invoked to promote stability and investor confidence during periods of significant stress when cash equities securities experience extreme market-wide declines. The MWCB rules are designed to slow the effects of extreme price declines through coordinated trading halts across both cash equity and equity options securities markets.

The cash equities rules governing MWCBs were first adopted in 1988 and, in 2012, all U.S. cash equity exchanges and FINRA amended their cash equities uniform rules on a pilot basis (the ''Pilot Rules,'' *i.e.,* Rule 7.12 (a)–(d)).[4] The Pilot Rules currently provide for trading halts in all cash equity securities during a severe market decline as measured by a single-day decline in the S&P 500 Index (''SPX'').[5] Under the Pilot Rules, a market-wide trading halt will be triggered if SPX declines in price by specified percentages from the prior day's closing price of that index. The triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. and before 3:25 p.m. would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. would not halt market-wide trading. (Level 1 and Level 2 halts may occur only once a day.) A market decline that triggers a Level 3 halt at any time during the trading day would halt market-wide trading for the remainder of the trading day.

The Commission approved the Pilot Rules, the term of which was to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS (the ''LULD Plan''),[6] including any extensions to the pilot period for the LULD Plan.[7] In April 2019, the Commission approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[8] In conjunction with the proposal to make the LULD Plan permanent, the Exchange amended Rule 80B to untie the Pilot Rules' effectiveness from that of the LULD Plan and to extend the Pilot Rules' effectiveness to the close of business on October 18, 2019.[9] The Exchange subsequently amended Rule 80B [10] and the corresponding Pillar rule, Rule 7.12, to extend the Pilot Rules' effectiveness for an additional year to the close of business on October 18, 2020,[11] and later, on October 18, 2021.[12]

The Exchange now proposes to amend Rule 7.12 [13] to extend the pilot to the close of business on March 18, 2022. This filing does not propose any substantive or additional changes to Rule 7.12.

The MWCB Task Force and the March 2020 MWCB Events

In late 2019, Commission staff requested the formation of a MWCB Task Force (''Task Force'') to evaluate the operation and design of the MWCB mechanism. The Task Force included representatives from the SROs, the Commission, CME, the Commodity Futures Trading Commission (''CFTC''), and the securities industry and conducted several organizational meetings in December 2019 and January 2020.

In Spring 2020, the MWCB mechanism proved itself to be an effective tool for protecting markets through turbulent times. In March 2020, at the outset of the worldwide COVID–19 pandemic, U.S. equities markets experienced four MWCB Level 1 halts, on March 9, 12, 16, and 18, 2020. In each instance, the markets halted as intended upon a 7% drop in the S&P 500 Index, and resumed as intended 15 minutes later.

In response to these events, in the Spring and Summer of 2020, the Task Force held ten meetings that were attended by Commission staff, with the goal of performing an expedited review of the March 2020 halts and identifying any areas where the MWCB mechanism had not worked properly. Given the risk of unintended consequences, the Task Force did not recommend changes that were not rooted in a noted deficiency. The Task Force recommended creating a process for a backup reference price in the event that SPX were to become unavailable, and enhancing functional MWCB testing. The Task Force also asked CME to consider modifying its rules to enter into a limit-down state in the futures pre-market after a 7% decline instead of 5%. CME made the requested change, which became effective on October 12, 2020.[14]

The MWCB Working Group's Study

On September 17, 2020, the Director of the Commission's Division of Trading and Markets asked the SROs to conduct a more complete study of the design and operation of the Pilot Rules and the LULD Plan during the period of volatility in the Spring of 2020.

In response to the request, the SROs created a MWCB ''Working Group'' composed of SRO representatives and industry advisers that included members of the advisory committees to both the LULD Plan and the NMS Plans governing the collection, consolidation, and dissemination of last-sale transaction reports and quotations in NMS Stocks. The Working Group met regularly from September 2020 through March 2021 to consider the

[4] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–BATS–2011–038; SR–BYX–2011–025; SR–BX–2011–068; SR–CBOE–2011–087; SR–C2–2011–024; SR–CHX–2011–30; SR–EDGA–2011–31; SR–EDGX–2011–30; SR–FINRA–2011–054; SR–ISE–2011–61; SR–NASDAQ–2011–131; SR–NSX–2011–11; SR–NYSE–2011–48; SR–NYSEAmex–2011–73; SR–NYSEArca–2011–68; SR–Phlx–2011–129) (''Pilot Rules Approval Order'').

[5] The rules of the equity options exchanges similarly provide for a halt in trading if the cash equity exchanges invoke a MWCB Halt. *See, e.g.,* NYSE Arca Rule 6.65–O(d)(4).

[6] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012). The LULD Plan provides a mechanism to address extraordinary market volatility in individual securities.

[7] *See* Securities Exchange Act Release Nos. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–NYSE–2011–48) (Approval Order); and 68784 (January 31, 2013), 78 FR 8662 (February 6, 2013) (SR–NYSE–2013–10).

[8] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019).

[9] *See* Securities Exchange Act Release No. 85560 (April 9, 2019), 84 FR 15247 (April 15, 2019) (SR–NYSE–2019–19). At that time, Rule 7.12 existed but was not operative with respect to Exchange-listed securities and was not amended to extend its effectiveness through October 18, 2019. Subsequently, all Exchange-listed securities transitioned to the Pillar trading platform. *See* Securities Exchange Act Release No. 85962 (May 29, 2019), 84 FR 26188 (June 5, 2019) (SR–NYSE–2019–05).

[10] Rule 80B is no longer operative. *See* Securities Exchange Act Release No. 88402 (March 17, 2020), 85 FR 16436 (March 23, 2020) (SR–NYSE–2020–20).

[11] *See* Securities Exchange Act Release No. 87016 (September 19, 2019), 84 FR 50502 (September 25, 2019) (SR–NYSE–2019–51).

[12] *See* Securities Exchange Act Release No. 90134 (October 8, 2020), 85 FR 65107 (October 14, 2020) (SR–NYSE–2020–84).

[13] Rule 80B is no longer operative. *See* Securities Exchange Act Release No. 88402 (March 17, 2020), 85 FR 16436 (March 23, 2020) (SR–NYSE–2020–20).

[14] *See https://www.cmegroup.com/content/dam/cmegroup/market-regulation/rule-filings/2020/9/20-392_1.pdf; https://www.cmegroup.com/content/dam/cmegroup/market-regulation/rule-filings/2020/9/20–392_2.pdf.*

Commission's request, review data, and compile its study. The Working Group's efforts in this respect incorporated and built on the work of an MWCB Task Force.

The Working Group submitted its study to the Commission on March 31, 2021 (the ''Study'').[15] In addition to a timeline of the MWCB events in March 2020, the Study includes a summary of the analysis and recommendations of the MWCB Task Force; an evaluation of the operation of the Pilot Rules during the March 2020 events; an evaluation of the design of the current MWCB system; and the Working Group's conclusions and recommendations.

In the Study, the Working Group concluded: (1) The MWCB mechanism set out in the Pilot Rules worked as intended during the March 2020 events; (2) the MWCB halts triggered in March 2020 appear to have had the intended effect of calming volatility in the market, without causing harm; (3) the design of the MWCB mechanism with respect to reference value (SPX), trigger levels (7%/13%/20%), and halt times (15 minutes) is appropriate; (4) the change implemented in Amendment 10 to the Plan to Address Extraordinary Market Volatility (the ''Limit Up/Limit Down Plan'' or ''LULD Plan'') did not likely have any negative impact on MWCB functionality; and (5) no changes should be made to the mechanism to prevent the market from halting shortly after the opening of regular trading hours at 9:30 a.m.

In light of the foregoing conclusions, the Working Group also made several recommendations, including that the Pilot Rules should be permanent without any changes.[16]

Proposal To Extend the Operation of the Pilot Rules Pending the Commission's Consideration of the Exchange's Filing To Make the Pilot Rules Permanent

On July 16, 2021, the Exchange proposed a rule change to make the Pilot Rules permanent, consistent with the Working Group's recommendations.[17] On August 27, 2021, the Commission extended its time to consider the proposed rule change to October 20, 2021.[18] The Exchange now proposes to extend the expiration date of the Pilot Rules to the end of business on March 18, 2022.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[19] in general, and furthers the objectives of Section 6(b)(5) of the Act,[20] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The market-wide circuit breaker mechanism under Rule 7.12 is an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. Extending the market-wide circuit breaker pilot for an additional five months would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Commission reviews the Exchange's proposed rule change to make the Pilot Rules permanent.

The Exchange also believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning when and how to halt trading in all stocks as a result of extraordinary market volatility. Based on the foregoing, the Exchange believes the benefits to market participants from Pilot Rules should continue on a pilot basis because they will promote fair and orderly markets and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Commission reviews the Exchange's proposed rule change to make the Pilot Rules permanent.

Further, the Exchange understands that FINRA and other national securities exchanges will file proposals to extend their rules regarding the market-wide circuit breaker pilot. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[21] and Rule 19b–4(f)(6) thereunder.[22] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[23] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[24] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange asked that the Commission waive the 30 day operative delay so that the proposal may become operative immediately upon filing. Extending the pilot Rules' effectiveness to the close of business on March 18, 2022 will extend the protections provided by the Pilot Rules, which would otherwise expire in less than 30 days. Waiver of the operative delay would therefore permit uninterrupted continuation of the MWCB pilot while the Commission reviews the Exchange's proposed rule change to make the Pilot Rules permanent. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[25]

[15] *See Report of the Market-Wide Circuit Breaker (''MWCB'') Working Group Regarding the March 2020 MWCB Events,* submitted March 31, 2021 (the ''Study''), available at *https://www.nyse.com/publicdocs/nyse/markets/nyse/Report_of_the_Market-Wide_Circuit_Breaker_Working_Group.pdf.*

[16] *See id.* at 46.

[17] *See* Securities Exchange Act Release No. 92428 (July 16, 2021), 86 FR 38776 (July 22, 2021) (SR–NYSE–2021–40).

[18] *See* Securities Exchange Act Release No. 92785A (August 27, 2021), 86 FR 50202 (September 7, 2021) (SR–NYSE–2021–40).

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78s(b)(3)(A)(iii).

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6).

[24] 17 CFR 240.19b–4(f)(6)(iii).

[25] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on

Continued

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [26] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2021–57 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2021–57. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2021–57 and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

J. Matthew DeLesDernier,

Assistant Secretary.

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efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[26] 15 U.S.C. 78s(b)(2)(B).

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, October 7, 2021.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: September 30, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–21667 Filed 10–1–21; 4:15 pm]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93188; File No. SR–EMERALD–2021–31]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule To Adopt a Tiered-Pricing Structure for Additional Limited Service MIAX Emerald Express Interface Ports

September 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2021, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the Exchange's Fee Schedule (the ''Fee Schedule'') to amend certain port fees.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald,* at MIAX's principal office, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to adopt a tiered-pricing structure for additional Limited Service MIAX Emerald Express Interface (''MEI'') Ports [3] available to Market Makers.[4] The Exchange believes a tiered-pricing structure will encourage Market Makers to be more efficient and economical when determining how to connect to the Exchange. This should also enable the Exchange to better monitor and provide access to the Exchange's network to ensure sufficient capacity and headroom in the System.[5]

The Exchange initially filed the proposed fee changes on August 2, 2021, with the changes being immediately effective.[6] The First Proposed Rule Change was published for comment in the **Federal Register** on August 19, 2021.[7] The Commission received one comment letter on the First Proposed Rule Change.[8] The Exchange withdrew the First Proposed Rule Change on September 27, 2021 and resubmitted its proposal.[9] The Exchange withdrew the Second Proposed Rule Change and now submits this proposal, which is immediately effective.

Additional Limited Service MEI Port Tiered-Pricing Structure

The Exchange proposes to amend the fees for additional Limited Service MEI Ports. Currently, the Exchange allocates two (2) Full Service MEI Ports [10] and two (2) Limited Service MEI Ports [11] per matching engine [12] to which each Market Maker connects. Market Makers may also request additional Limited Service MEI Ports for each matching engine to which they connect. The Full Service MEI Ports, Limited Service MEI Ports and the additional Limited Service MEI Ports all include access to the Exchange's primary and secondary data centers and its disaster recovery center. Market Makers may request additional Limited Service MEI Ports for which they are assessed a $100 monthly fee for each additional Limited Service MEI Port for each matching engine.

The Exchange now proposes to move from a flat monthly fee per additional Limited Service MEI Port for each matching engine to a tiered-pricing structure for additional Limited Service MEI Ports for each matching engine under which the monthly fee would vary depending on the number of additional Limited Service MEI Ports the Market Maker elects to purchase. Specifically, the Exchange will continue to provide the first and second additional Limited Service MEI Ports for each matching engine free of charge, as described above, per the initial allocation of Limited Service MEI Ports that Market Makers receive. The Exchange now proposes the following tiered-pricing structure: (i) The third and fourth additional Limited Service MEI Ports for each matching engine will increase from the current flat monthly fee of $100 to $200 per port; (ii) the fifth and sixth additional Limited Service MEI Ports for each matching engine will increase from the current flat monthly fee of $100 to $300 per port; and (iii) the seventh to the twelfth additional Limited Service MEI Ports will increase from the current monthly flat fee of $100 to $400 per port (collectively, the ''Proposed Access Fees'').

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [13] in general, and furthers the objectives of Section 6(b)(4) of the Act [14] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among Exchange Members and issuers and other persons using any facility or system which the Exchange operates or controls. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [15] in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees for services and products, in addition to order flow, to remain competitive with other exchanges. The Exchange believes that the proposed changes reflect this competitive environment.

The Exchange believes the proposal to move from a flat fee per month to a tiered-pricing structure is reasonable, equitably allocated and not unfairly discriminatory because the Exchange believes the proposed structure would encourage firms to be more economical and efficient in the number of additional Limited Service MEI Ports

[3] The MIAX Emerald Express Interface (''MEI'') is a connection to the MIAX Emerald System that enables Market Makers to submit simple and complex electronic quotes to MIAX Emerald. *See* the Definitions Section of the Fee Schedule.

[4] The term ''Market Makers'' refers to Lead Market Makers (''LMMs''), Primary Lead Market Makers (''PLMMs''), and Registered Market Makers (''RMMs'') collectively. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[5] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[6] *See* Securities Exchange Act Release No. 92662 (August 13, 2021), 86 FR 46726 (August 19, 2021) (SR–EMERALD–2021–25) (the ''First Proposed Rule Change'').

[7] *Id.*

[8] *See* Letter from Richard J. McDonald, Susquehanna International Group, LLC (''SIG''), to Vanessa Countryman, Secretary, Commission, dated September 7, 2021 (''SIG Comment Letter'').

[9] *See* SR–EMERALD–2021–30 (the ''Second Proposed Rule Change'').

[10] ''Full Service MEI Ports'' means a port which provides Market Makers with the ability to send Market Maker simple and complex quotes, eQuotes, and quote purge messages to the MIAX Emerald System. Full Service MEI Ports are also capable of receiving administrative information. Market Makers are limited to two Full Service MEI Ports per Matching Engine. *See* the Definitions Section of the Fee Schedule.

[11] ''Limited Service MEI Ports'' means a port which provides Market Makers with the ability to send simple and complex eQuotes and quote purge messages only, but not Market Maker Quotes, to the MIAX Emerald System. Limited Service MEI Ports are also capable of receiving administrative information. Market Makers initially receive two Limited Service MEI Ports per Matching Engine. *See* the Definitions Section of the Fee Schedule.

[12] ''Matching Engine'' means a part of the MIAX Emerald electronic system that processes options orders and trades on a symbol-by-symbol basis. Some Matching Engines will process option classes with multiple root symbols, and other Matching Engines may be dedicated to one single option root symbol (for example, options on SPY may be processed by one single Matching Engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated Matching Engine. A particular root symbol may not be assigned to multiple Matching Engines. *See* the Definitions Section of the Fee Schedule.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78f(b)(5).

they purchase. The Exchange believes this will enable the Exchange to better monitor and provide access to the Exchange's network to ensure sufficient capacity and headroom in the System.

The Exchange notes that firms that are primarily order routers seeking best-execution do not utilize Limited Service MEI Ports on MIAX Emerald. Therefore, the fees described in the proposed tiered-pricing structure will only be allocated to market making firms that engage in advanced trading strategies and typically request multiple Limited Service MEI Ports, beyond the two per matching engine that are free. Accordingly, the firms engaged in market making business generate higher costs by utilizing more of the Exchange's resources. The market making firms that purchase higher amounts of Limited Service MEI Ports tend to have specific business oriented market making and trading strategies, as opposed to firms engaging solely in order routing as part of their best-execution obligations. The use of such additional Limited Service MEI Ports is a voluntary business decision of each market maker.

The Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the requirements of the Act that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among market participants. The Exchange believes this high standard is especially important when an exchange imposes various access fees for market participants to access an exchange's marketplace. The Exchange deems port fees to be access fees. It records these fees as part of its ''Access Fees'' revenue in its financial statements. The Exchange believes that it is important to demonstrate that these fees are based on its costs and reasonable business needs. The Exchange believes the Proposed Access Fees will allow the Exchange to offset expense the Exchange has and will incur, and that the Exchange is providing sufficient transparency (as described below) into how the Exchange determined to charge such fees. Accordingly, the Exchange is providing an analysis of its revenues, costs, and profitability associated with the Proposed Access Fees. This analysis includes information regarding its methodology for determining the costs and revenues associated with the Proposed Access Fees.

In order to determine the Exchange's costs to provide the access services associated with the Proposed Access Fees, the Exchange conducted an extensive cost review in which the Exchange analyzed nearly every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the Proposed Access Fees, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the access services. The sum of all such portions of expenses represents the total cost to the Exchange to provide the access services associated with the Proposed Access Fees. For the avoidance of doubt, no expense amount was allocated twice. The Exchange is also providing detailed information regarding the Exchange's cost allocation methodology—namely, information that explains the Exchange's rationale for determining that it was reasonable to allocate certain expenses described in this filing towards the cost to the Exchange to provide the access services associated with the Proposed Access Fees.

In order to determine the Exchange's projected revenues associated with the Proposed Access Fees, the Exchange analyzed the number of Market Makers currently utilizing Limited Service MEI Ports, and, utilizing a recent monthly billing cycle representative of 2021 monthly revenue, extrapolated annualized revenue on a going-forward basis. The Exchange does not believe it is appropriate to factor into its analysis future revenue growth or decline into its projections for purposes of these calculations, given the uncertainty of such projections due to the continually changing access needs of market participants, discounts that can be achieved due to lower trading volume and vice versa, market participant consolidation, etc. Additionally, the Exchange similarly does not factor into its analysis future cost growth or decline. The Exchange is presenting its revenue and expense associated with the Proposed Access Fees in this filing in a manner that is consistent with how the Exchange presents its revenue and expense in its Audited Unconsolidated Financial Statements. The Exchange's most recent Audited Unconsolidated Financial Statement is for 2020. However, since the revenue and expense associated with the Proposed Access Fees were not in place in 2020 or for the first seven months of 2021, the Exchange believes its 2020 Audited Unconsolidated Financial Statement is not representative of its current total annualized revenue and costs associated with the Proposed Access Fees. Accordingly, the Exchange believes it is more appropriate to analyze the Proposed Access Fees utilizing its 2021 revenue and costs, as described herein, which utilize the same presentation methodology as set forth in the Exchange's previously-issued Audited Unconsolidated Financial Statements. Based on this analysis, the Exchange believes that the Proposed Access Fees are fair and reasonable because they will not result in excessive pricing or supra-competitive profit when comparing the Exchange's total annual expense associated with providing the services associated with the Proposed Access Fees versus the total projected annual revenue the Exchange will collect for providing those services.

* * * * *

On March 29, 2019, the Commission issued its Order Disapproving Proposed Rule Changes to Amend the Fee Schedule on the BOX Market LLC Options Facility to Establish BOX Connectivity Fees for Participants and Non-Participants Who Connect to the BOX Network (the ''BOX Order'').[16] On May 21, 2019, the Commission issued the Staff Guidance on SRO Rule Filings Relating to Fees.[17] Accordingly, the Exchange believes that the Proposed Access Fees are consistent with the Act because they (i) are reasonable, equitably allocated, not unfairly discriminatory, and not an undue burden on competition; (ii) comply with the BOX Order and the Guidance; (iii) are supported by evidence (including comprehensive revenue and cost data and analysis) that they are fair and reasonable because they will not result in excessive pricing or supra-competitive profit; and (iv) utilize a cost-based justification framework that is substantially similar to a framework previously used by the Exchange, and its affiliates MIAX PEARL, LLC (''MIAX Pearl'') and Miami International Securities Exchange, LLC (''MIAX''), to establish or increase other non-transaction fees.[18] Accordingly, the Exchange believes that the Commission should find that the Proposed Access Fees are consistent with the Act.

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As of September 27, 2021, the Exchange had a market share of only

[16] *See* Securities Exchange Act Release No. 85459 (March 29, 2019), 84 FR 13363 (April 4, 2019) (SR–BOX–2018–24, SR–BOX–2018–37, and SR–BOX–2019–04).

[17] *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019), at *https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees* (the ''Guidance'').

[18] See Securities Exchange Act Release Nos. 90981 (January 25, 2021), 86 FR 7582 (January 29, 2021) (SR–PEARL–2021–01) (proposal to increase connectivity fees); 90980 (January 25, 2021), 86 FR 7602 (January 29, 2021) (SR–MIAX–2021–02) (proposal to increase connectivity fees).

4.99% of the U.S. equity options industry for the month of September 2021.[19] The Exchange is not aware of any evidence that a market share of approximately 4–5% provides the Exchange with anti-competitive pricing power. If the Exchange were to attempt to establish unreasonable pricing, then no market participant would join or access the Exchange, and existing market participants would discontinue all or some of their access services. If the Exchange were to attempt to establish unreasonable pricing for any of its means provided to access the Exchange, market participants may look to access the Exchange via other means such as through a third party service provider, or look to connect to the Exchange via a competing exchange with cheaper access alternatives that also provides routing services to the Exchange. In addition, existing market participants that are connected to the Exchange may choose to disconnect from the Exchange or reduce their number of connections to the Exchange as a means to reduce their overall costs.

The proposed tiered-pricing structure and proposed fees for additional Limited Service MEI Ports are less than or similar to fees charged by competing options exchanges for similar access on those exchanges. The Exchange believes that it provides a better value through its enhanced network monitoring, customer reporting, and superior network infrastructure than markets with higher market shares and more expensive access alternatives. For example, NYSE American, LLC (''Amex'') (equity options market share of 7.86% as of September 23, 2021 for the month of September) [20] and NYSE Arca, Inc. (''Arca'') (equity options market share of 12.58% as of September 23, 2021 for the month of September) [21] both charge $450 per port for order/quote entry ports 1–40 and $150 per port for ports 41 and greater,[22] all on a per matching engine basis, with Amex and Arca having 17 match engines and 19 match engines, respectively.[23] Similarly, The Nasdaq Stock Market LLC (''NASDAQ'') (equity options market share of 7.81% as of September 23, 2021 for the month of September) [24] charges $1,500 per port for SQF ports 1–5, $1,000 per SQF port for ports 6–20, and $500 per SQF port for ports 21 and greater,[25] all on a per matching engine basis, with NASDAQ having multiple matching engines.[26] The NASDAQ SQF Interface Specification provides that PHLX/NOM/BX Options trading infrastructures may consist of multiple matching engines with each matching engine trading only a range of option underlyings. Further, the SQF infrastructure is such that the firms connect to one or more servers residing directly on the matching engine infrastructure. Since there may be multiple matching engines, firms will need to connect to each engine's infrastructure in order to establish the ability to quote the symbols handled by that engine.[27]

In the each of the above cases, the Exchange's highest tier in the proposed tiered-pricing structure is lower than that of competing options exchanges. Further, as described in more detail below, those exchanges generate higher operating profit margins and higher ''access fees'' than the Exchange, even with the proposed fee change. Despite proposing lower or similar fees to that of competing options exchanges with similar market share, the Exchange believes that it provides a better overall value to its Members and non-Members via a highly deterministic System, enhanced network monitoring and customer reporting, and a superior network infrastructure than markets with higher market shares and more expensive access alternatives. Each of the port rates in place at competing options exchanges were filed with the Commission for immediate effectiveness and remain in place today.

Separately, the Exchange is not aware of any reason why market participants could not simply drop their access (or not initially access an exchange) if an exchange were to establish prices for its non-transaction fees that, in the determination of such market participant, did not make business or economic sense for such market participant to access such exchange. No options market participant is required by rule, regulation, or competitive forces to be a Member of the Exchange. As evidence of the fact that market participants can and do drop their access to exchanges based on non-transaction fee pricing, R2G Services LLC (''R2G'') filed a comment letter after BOX's proposed rule changes to increase its connectivity fees (SR–BOX–2018–24, SR–BOX–2018–37, and SR–BOX–2019–04). The R2G Letter stated, ''[w]hen BOX instituted a $10,000/month price increase for connectivity; we had no choice but to terminate connectivity into them as well as terminate our market data relationship. The cost benefit analysis just didn't make any sense for us at those new levels.'' Similarly, the Exchange noted in a recent filing that once MIAX Emerald issued a notice that it was instituting MEI Port fees, among other non-transaction fees, one MIAX Emerald Member dropped its access to MIAX Emerald as a result of those fees.[28] Accordingly, these examples show that if a market participant believes, based on its business model, that an exchange charges too high of a fee for ports and/or other non-transaction fees, including other access fees for its relevant marketplace, market participants can choose to drop their access to such exchange.

In order to provide more detail and to quantify the Exchange's costs associated with providing access to the Exchange in general, the Exchange notes that there are material costs associated with providing the infrastructure and headcount to fully-support access to the Exchange. The Exchange incurs technology expense related to establishing and maintaining Information Security services, enhanced network monitoring and customer reporting, as well as Regulation SCI mandated processes, associated with its network technology. While some of the expense is fixed, much of the expense is not fixed, and thus increases as the services associated with the Proposed Access Fees increase. For example, new Members to the Exchange may require the purchase of additional hardware to support those Members as well as enhanced monitoring and reporting of customer performance that the Exchange and its affiliates provide. Further, as the total number Members increases, the Exchange and its affiliates

[19] *See* ''The market at a glance,'' *available at https://www.miaxoptions.com/* (last visited September 27, 2021).

[20] *See* ''The market at a glance,'' *available at https://www.miaxoptions.com/* (last visited September 23, 2021).

[21] *See id.*

[22] *See* NYSE American Options Fee Schedule, Section V.A., Port Fees; NYSE Arca Options Fee Schedule, Port Fees.

[23] *See* NYSE Technology FAQ and Best Practices: Options, Section 5.1 (How many matching engines are used by each exchange?) (September 2020) (providing a link to an Excel file detailing the number of matching engines per options exchange).

[24] *See supra* note 20.

[25] *See* Nasdaq Stock Market, Nasdaq Options 7 Pricing Schedule, Section 3, Nasdaq Options Market—Ports and Other Services.

[26] *See* Nasdaq Specialized Quote Interface (SQF) Specification, Version 6.4 (October 2017), Section 2, Architecture (the ''NASDAQ SQF Interface Specification'').

[27] *See id.*

[28] *See* Securities Exchange Act Release No. 91460 (April 2, 2021), 86 FR 18349 (April 8, 2021) (SR–EMERALD–2021–11) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule To Adopt Port Fees, Increase Certain Network Connectivity Fees, and Increase the Number of Additional Limited Service MIAX Emerald Express Interface Ports Available to Market Makers) (adopting tiered MEI Port fee structure ranging from $5,000 to $20,500 per month).

may need to increase their data center footprint and consume more power, resulting in increased costs charged by their third-party data center provider. Accordingly, the cost to the Exchange and its affiliates to provide access to its System for market participants is not fixed. The Exchange believes the Proposed Access Fees are a reasonable attempt to offset a portion of the costs to the Exchange associated with providing access to its network infrastructure.

The Exchange only has four primary sources of revenue: Transaction fees, access fees (which includes the Proposed Access Fees), regulatory fees, and market data fees. Accordingly, the Exchange must cover all of its expenses from these four primary sources of revenue.

The Exchange believes that the Proposed Access Fees are fair and reasonable because they will not result in excessive pricing or supra-competitive profit, when comparing the total annual expense that the Exchange projects to incur in connection with providing these access services versus the total annual revenue that the Exchange projects to collect in connection with services associated with the Proposed Access Fees. For 2021, [29] the total annual expense for providing the access services associated with the Proposed Access Fees is projected to be approximately $0.88 million. The approximately $0.88 million in projected total annual expense is comprised of the following, all of which are directly related to the access services associated with the Proposed Access Fees: (1) Third-party expense, relating to fees paid by the Exchange to third-parties for certain products and services; and (2) internal expense, relating to the internal costs of the Exchange to provide the services associated with the Proposed Access Fees.[30] As noted above, the Exchange believes it is more appropriate to analyze the Proposed Access Fees utilizing its 2021 revenue and costs, which utilize the same presentation methodology as set forth in the Exchange's previously-issued Audited Unconsolidated Financial Statements.[31] The $0.88 million in projected total annual expense is directly related to the access services associated with the Proposed Access Fees, and not any other product or service offered by the Exchange. It does not include general costs of operating matching systems and other trading technology, and no expense amount was allocated twice.

As discussed, the Exchange conducted an extensive cost review in which the Exchange analyzed nearly every expense item in the Exchange's general expense ledger (this includes over 150 separate and distinct expense items) to determine whether each such expense relates to the access services associated with the Proposed Access Fees, and, if such expense did so relate, what portion (or percentage) of such expense actually supports those services, and thus bears a relationship that is, ''in nature and closeness,'' directly related to those services. The sum of all such portions of expenses represents the total cost of the Exchange to provide access services associated with the Proposed Access Fees.

For 2021, total third-party expense, relating to fees paid by the Exchange to third-parties for certain products and services for the Exchange to be able to provide the access services associated with the Proposed Access Fees, is projected to be $0.05 million. This includes, but is not limited to, a portion of the fees paid to: (1) Equinix, for data center services, for the primary, secondary, and disaster recovery locations of the Exchange's trading system infrastructure; (2) Zayo Group Holdings, Inc. (''Zayo'') for network services (fiber and bandwidth products and services) linking the Exchange's office locations in Princeton, New Jersey and Miami, Florida, to all data center locations; (3) Secure Financial Transaction Infrastructure (''SFTI''),[32] which supports connectivity and feeds for the entire U.S. options industry; (4) various other services providers (including Thompson Reuters, NYSE, Nasdaq, and Internap), which provide content, connectivity services, and infrastructure services for critical components of options connectivity and network services; and (5) various other hardware and software providers (including Dell and Cisco, which support the production environment in which Members connect to the network to trade, receive market data, etc.). For clarity, only a portion of all fees paid to such third-parties is included in the third-party expense herein, and no expense amount is allocated twice. Accordingly, the Exchange does not allocate its entire information technology and communication costs to the access services associated with the Proposed Access Fees.

For clarity, only a portion of all fees paid to such third-parties is included in the third-party expense herein, and no expense amount is allocated twice. Accordingly, the Exchange does not allocate its entire information technology and communication costs to the access services associated with the Proposed Access Fees. Further, the Exchange notes that, with respect to the expenses included herein, those expenses only cover the MIAX Emerald market; expenses associated with MIAX Pearl for its options and equities markets and MIAX, are accounted for separately and are not included within the scope of this filing. As noted above, the percentage allocations used in this proposed rule change may differ from past filings from the Exchange or its affiliates due to, among other things, changes in expenses charged by third-parties, adjustments to internal resource allocations, and different system architecture of the Exchange as compared to its affiliates. Further, as part its ongoing assessment of costs and expenses, the Exchange recently conducted a periodic thorough review of its expenses and resource allocations which, in turn, resulted in a revised percentage allocations in this filing.

The Exchange believes it is reasonable to allocate such third-party expense described above towards the total cost to the Exchange to provide the access services associated with the Proposed Access Fees. In particular, the Exchange believes it is reasonable to allocate the identified portion of the Equinix expense because Equinix operates the data centers (primary, secondary, and disaster recovery) that host the Exchange's network infrastructure. This includes, among other things, the necessary storage space, which continues to expand and increase in

[29] The Exchange has not yet finalized its 2021 year end results.

[30] The percentage allocations used in this proposed rule change may differ from past filings from the Exchange or its affiliates due to, among other things, changes in expenses charged by third-parties, adjustments to internal resource allocations, and different system architecture of the Exchange as compared to its affiliates.

[31] For example, the Exchange previously noted that all third-party expense described in its prior fee filing was contained in the information technology and communication costs line item under the section titled ''Operating Expenses Incurred Directly or Allocated From Parent,'' in the Exchange's 2019 Form 1 Amendment containing its financial statements for 2018. *See* Securities Exchange Act Release No. 87877 (December 31, 2019), 85 FR 738 (January 7, 2020) (SR–EMERALD–2019–39). Accordingly, the third-party expense described in this filing is attributed to the same line item for the Exchange's 2021 Form 1 Amendment, which will be filed in 2022.

[32] In fact, on October 22, 2019, the Exchange was notified by SFTI that it is again raising its fees charged to the Exchange by approximately 11%, without having to show that such fee change complies with the Act by being reasonable, equitably allocated, and not unfairly discriminatory. It is unfathomable to the Exchange that, given the critical nature of the infrastructure services provided by SFTI, that its fees are not required to be rule-filed with the Commission pursuant to Section 19(b)(1) of the Act and Rule 19b–4 thereunder. *See* 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4, respectively.

cost, power to operate the network infrastructure, and cooling apparatuses to ensure the Exchange's network infrastructure maintains stability. Without these services from Equinix, the Exchange would not be able to operate and support the network and provide the access services associated with the Proposed Access Fees to its Members and their customers. The Exchange did not allocate all of the Equinix expense toward the cost of providing the access services associated with the Proposed Access Fees, only that portion which the Exchange identified as being specifically mapped to providing the access services associated with the Proposed Access Fees, approximately 2.05% of the total applicable Equinix expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees, and not any other service, as supported by its cost review.[33]

The Exchange believes it is reasonable to allocate the identified portion of the Zayo expense because Zayo provides the internet, fiber and bandwidth connections with respect to the network, linking the Exchange with its affiliates, MIAX Pearl and MIAX, as well as the data center and disaster recovery locations. As such, all of the trade data, including the billions of messages each day per exchange, flow through Zayo's infrastructure over the Exchange's network. Without these services from Zayo, the Exchange would not be able to operate and support the network and provide the access services associated with the Proposed Access Fees. The Exchange did not allocate all of the Zayo expense toward the cost of providing the access services associated with the Proposed Access Fees, only the portion which the Exchange identified as being specifically mapped to providing the Proposed Access Fees, approximately 1.64% of the total applicable Zayo expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees, and not any other service, as supported by its cost review.[34]

The Exchange believes it is reasonable to allocate the identified portions of the SFTI expense and various other service providers' (including Thompson Reuters, NYSE, Nasdaq, and Internap) expense because those entities provide connectivity and feeds for the entire U.S. options industry, as well as the content, connectivity services, and infrastructure services for critical components of the network. Without these services from SFTI and various other service providers, the Exchange would not be able to operate and support the network and provide access to its Members and their customers. The Exchange did not allocate all of the SFTI and other service providers' expense toward the cost of providing the access services associated with the Proposed Access Fees, only the portions which the Exchange identified as being specifically mapped to providing the access services associated with the Proposed Access Fees, approximately 2.05% of the total applicable SFTI and other service providers' expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees.[35]

The Exchange believes it is reasonable to allocate the identified portion of the other hardware and software provider expense because this includes costs for dedicated hardware licenses for switches and servers, as well as dedicated software licenses for security monitoring and reporting across the network. Without this hardware and software, the Exchange would not be able to operate and support the network and provide access to its Members and their customers. The Exchange did not allocate all of the hardware and software provider expense toward the cost of providing the access services associated with the Proposed Access Fees, only the portions which the Exchange identified as being specifically mapped to providing the access services associated with the Proposed Access Fees, approximately 1.23% of the total applicable hardware and software provider expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees.[36]

For 2021, total projected internal expense, relating to the internal costs of the Exchange to provide the access services associated with the Proposed Access Fees, is projected to be $0.83 million. This includes, but is not limited to, costs associated with: (1) Employee compensation and benefits for full-time employees that support the access services associated with the Proposed Access Fees, including staff in network operations, trading operations, development, system operations, and business that support those employees and functions (including an increase as a result of the higher determinism project); (2) depreciation and amortization of hardware and software used to provide the access services associated with the Proposed Access Fees, including equipment, servers, cabling, purchased software and internally developed software used in the production environment to support the network for trading; and (3) occupancy costs for leased office space for staff that provide the access services associated with the Proposed Access Fees. The breakdown of these costs is more fully-described below. For clarity, only a portion of all such internal expenses are included in the internal expense herein, and no expense amount is allocated twice. Accordingly, the Exchange does not allocate its entire costs contained in those items to the access services associated with the Proposed Access Fees.

The Exchange believes it is reasonable to allocate such internal expense described above towards the total cost to the Exchange to provide the access services associated with the Proposed Access Fees. In particular, the Exchange's employee compensation and benefits expense relating to providing the access services associated with the Proposed Access Fees is projected to be approximately $0.76 million, which is only a portion of the $9.74 million total projected expense for employee compensation and benefits. The Exchange believes it is reasonable to allocate the identified portion of such expense because this includes the time spent by employees of several departments, including Technology, Back Office, Systems Operations, Networking, Business Strategy Development (who create the business requirement documents that the Technology staff use to develop network features and enhancements), and Trade Operations. As part of the extensive cost review conducted by the Exchange, the Exchange reviewed the amount of time spent by each employee on matters relating to the provision of access services associated with the Proposed Access Fees. Without these employees,

[33] As noted above, the percentage allocations used in this proposed rule change may differ from past filings from the Exchange or its affiliates due to, among other things, changes in expenses charged by third-parties, adjustments to internal resource allocations, and different system architecture of the Exchange as compared to its affiliates. Again, as part its ongoing assessment of costs and expenses, the Exchange recently conducted a periodic thorough review of its expenses and resource allocations which, in turn, resulted in a revised percentage allocations in this filing.

[34] *Id.*

[35] *Id.*

[36] *Id.*

the Exchange would not be able to provide the access services associated with the Proposed Access Fees to its Members and their customers. The Exchange did not allocate all of the employee compensation and benefits expense toward the cost of the access services associated with the Proposed Access Fees, only the portions which the Exchange identified as being specifically mapped to providing the access services associated with the Proposed Access Fees, approximately 7.81% of the total applicable employee compensation and benefits expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees, and not any other service, as supported by its cost review.[37]

The Exchange's depreciation and amortization expense relating to providing the services associated with the Proposed Access Fees is projected to be $0.06 million, which is only a portion of the $3.13 million total projected expense for depreciation and amortization. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network and provide the access services associated with the Proposed Access Fees. Without this equipment, the Exchange would not be able to operate the network and provide the access services associated with the Proposed Access Fees to its Members and their customers. The Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing the access services associated with the Proposed Access Fees, only the portion which the Exchange identified as being specifically mapped to providing the access services associated with the Proposed Access Fees, approximately 1.92% of the total applicable depreciation and amortization expense, as these access services would not be possible without relying on such. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees, and not any other service, as supported by its cost review.[38]

The Exchange's occupancy expense relating to providing the services associated with the Proposed Access Fees is projected to be $0.01 million, which is only a portion of the $0.52 million total projected expense for occupancy. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense represents the portion of the Exchange's cost to rent and maintain a physical location for the Exchange's staff who operate and support the network, including providing the access services associated with the Proposed Access Fees. This amount consists primarily of rent for the Exchange's Princeton, NJ office, as well as various related costs, such as physical security, property management fees, property taxes, and utilities. The Exchange operates its Network Operations Center (''NOC'') and Security Operations Center (''SOC'') from its Princeton, New Jersey office location. A centralized office space is required to house the staff that operates and supports the network. The Exchange currently has approximately 150 employees. Approximately two-thirds of the Exchange's staff are in the Technology department, and the majority of those staff have some role in the operation and performance of the access services associated with the Proposed Access Fees. Without this office space, the Exchange would not be able to operate and support the network and provide the access services associated with the Proposed Access Fees to its Members and their customers. Accordingly, the Exchange believes it is reasonable to allocate the identified portion of its occupancy expense because such amount represents the Exchange's actual cost to house the equipment and personnel who operate and support the Exchange's network infrastructure and the access services associated with the Proposed Access Fees. The Exchange did not allocate all of the occupancy expense toward the cost of providing the access services associated with the Proposed Access Fees, only the portion which the Exchange identified as being specifically mapped to operating and supporting the network, approximately 1.93% of the total applicable occupancy expense. The Exchange believes this allocation is reasonable because it represents the Exchange's cost to provide the access services associated with the Proposed Access Fees, and not any other service, as supported by its cost review.[39]

The Exchange notes that a material portion of its total overall expense is allocated to the provision of access services (including connectivity, ports, and trading permits). The Exchange believes this is reasonable and in line, as the Exchange operates a technology-based business that differentiates itself from its competitors based on its trading systems that rely on access to a high performance network, resulting in significant technology expense. Over two-thirds of Exchange staff are technology-related employees. The majority of the Exchange's expense is technology-based. As described above, the Exchange has only four primary sources of fees to recover their costs; thus, the Exchange believes it is reasonable to allocate a material portion of their total overall expense towards access fees.

Accordingly, based on the facts and circumstances presented, the Exchange believes that its provision of the access services associated with the Proposed Access Fees will not result in excessive pricing or supra-competitive profit. To illustrate, on a going-forward, fully-annualized basis, the Exchange projects that annualized revenue for providing the access services associated with the Proposed Access Fees would be approximately $2.07 million per annum, based on a recent billing cycle. This revenue number includes the revenue the Exchange projects to collect only from the fees the Exchange will charge for additional Limited Service MEI Ports after the first two Limited Service MEI Ports that Market Makers receive for free. The Exchange projects that its annualized expense for providing the services associated with the Proposed Access Fees will be approximately $0.88 million per annum. This expense includes the costs related to all Limited Service MEI Ports, including the two Limited Service MEI Ports that Market Makers receive for free. Accordingly, on a fully-annualized basis, the Exchange believes its total projected revenue for providing the access services associated with the Proposed Access Fees will not result in excessive pricing or supra-competitive profit, as the Exchange will make a profit margin of approximately 58% ($2.07 million in total revenue minus $.088 [sic] million in expense = $1.19 million in profit per annum). Additionally, this profit margin does not take into account the cost of capital expenditures (''CapEx'') the Exchange projects to spend each year on CapEx going forward.

[37] *Id.*

[38] *Id.*

[39] *Id.*

For the avoidance of doubt, none of the expenses included herein relating to the access services associated with the Proposed Access Fees relate to the provision of any other services offered by the Exchange or its affiliates. Stated differently, no expense amount of the Exchange is allocated twice. The Exchange notes that, with respect to expenses associated with the Exchange's affiliates, MIAX Pearl and MIAX, those expenses are accounted for separately and are not included within the scope of this filing. Stated differently, no expense amount of the Exchange is also allocated to MIAX Pearl or MIAX.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to allocate the respective percentages of each expense category described above towards the total cost to the Exchange of operating and supporting the network, including providing the access services associated with the Proposed Access Fees because the Exchange performed a line-by-line item analysis of nearly every expense of the Exchange, and has determined the expenses that directly relate to providing access to the Exchange. Further, the Exchange notes that, without the specific third-party and internal items listed above, the Exchange would not be able to provide the access services associated with the Proposed Access Fees to its Members and their customers. Each of these expense items, including physical hardware, software, employee compensation and benefits, occupancy costs, and the depreciation and amortization of equipment, have been identified through a line-by-line item analysis to be integral to providing access services. The Proposed Access Fees are intended to recover the Exchange's costs of providing access to its System. Accordingly, the Exchange believes that the Proposed Access Fees are fair and reasonable because they do not result in excessive pricing or supra-competitive profit, when comparing the actual costs to the Exchange versus the projected annual revenue from the Proposed Access Fees.

The Exchange believes the proposed changes are reasonable, equitably allocated and not unfairly discriminatory, and do not result in a ''supra-competitive'' [40] profit. Of note, the Guidance defines ''supra-competitive profit'' as profits that exceed the profits that can be obtained in a competitive market.[41] With the proposed changes, the Exchange anticipates that its profit margin will be approximately 58%, inclusive of the Proposed Access Fees. In order to achieve a consistent, premium network performance, the Exchange must build out and continue to maintain a network that has the capacity to handle the message rate requirements of not only firms that consume minimal ports resources of the Exchange, but also those firms that most heavily consume port resources of the Exchange, network consumers, and purchasers of numerous Limited Service MEI Ports, which handle billions of messages per day across the Exchange's network. These billions of messages per day consume the Exchange's resources and significantly contribute to the overall network port expense for storage and network transport capabilities. Given that purchasers of the greatest amount of Limited Service MEI Ports utilize the most resources across the network, the Exchange believes that it is reasonable to operate at a profit margin of approximately 58% for these ports, inclusive of the Proposed Access Fees. Such profit margin should enable the Exchange to continue to invest in its network and systems, maintain its current infrastructure, support future enhancements to ports and network connectivity, and continue to offer enhanced customer reporting and monitoring services.

While the proposed fees are similar or less than that of other options exchanges,[42] as discussed above, the incremental increase in revenue generated from the 58% profit margin for Limited Service MEI Ports will allow the Exchange to further invest in its System architecture and matching engine functionality to the benefit of all market participants. The ability to continue to invest in technology and systems will also enable the Exchange to improve the determinism and overall performance of not only its logical ports, but overall performance including the resiliency and efficiency of its matching engines. The revenue generated under the proposed rule change would also provide the Exchange with the resources necessary to further innovate and enhance its systems and seek additional improvements or functionality to offer market participants generally. The Exchange believes that these investments, in turn, will benefit all investors by encouraging other exchanges to further invest, innovate, and improve their own systems in response.

Based on the 2020 Audited Financial Statements of competing options exchanges (since the 2021 Audited Financial Statements will likely not become publicly available until early July 2022, after the Exchange has submitted this filing), the Exchange's revenue that is derived from its access fees is in line with the revenue that is derived from access fees of competing exchanges. For example, the total revenue from ''access fees'' [43] for 2020 for MIAX Emerald was $7,244,000. MIAX Emerald projects that the total revenue from ''access fees'' for 2021 for MIAX Emerald will be $20,910,179, inclusive of the Proposed Access Fees described herein. The Exchanges notes that the projected 2021 ''access fee'' revenue also includes projected revenue due to the Exchange's recent proposal to move to a tiered-pricing structure for its 10Gb ULL connectivity (SR–EMERALD–2021–29).

The Exchange's 2021 projected revenue from access fees is still less than, or similar to, the access fee revenues generated by access fees charged by other U.S. options exchanges. For example, the Cboe Exchange, Inc. (''Cboe'') reported $70,893,000 in ''access and capacity fee'' [44] revenue for 2020. Cboe C2 Exchange, Inc. (''C2'') reported $19,016,000 in ''access and capacity fee'' revenue for 2020.[45] Cboe BZX Exchange, Inc. (''BZX'') reported $38,387,000 in ''access and capacity fee'' revenue for 2020.[46] Cboe EDGX Exchange, Inc. (''EDGX'') reported $26,126,000 in ''access and capacity fee'' revenue for 2020.[47] PHLX reported $20,817,000 in ''Trade Management Services'' revenue for 2019.[48] The Exchange notes it is unable to compare ''access fee'' revenues with PHLX (or other affiliated NASDAQ exchanges) because after 2019, the ''Trade Management Services'' line item was bundled into a much larger line item in

[40] *See supra* note 17.

[41] *See id.*

[42] *See supra* notes 22 and 25.

[43] As described in the Exchange's Audited Financial Statements, fees for ''access services'' are assessed to exchange members for the opportunity to trade and use other related functions of the exchanges. *See https://www.sec.gov/Archives/edgar/vprr/2100/21000461.pdf.*

[44] According to Cboe, access and capacity fees represent fees assessed for the opportunity to trade, including fees for trading-related functionality. *See* Form 1 Amendment, at *https://www.sec.gov/Archives/edgar/vprr/2100/21000465.pdf.*

[45] *See id.*

[46] *See id.*

[47] *See id.*

[48] According to PHLX, ''Trade Management Services'' includes ''a wide variety of alternatives for connectivity to and accessing [the PHLX] markets for a fee. These participants are charged monthly fees for connectivity and support in accordance with [PHLX's] published fee schedules.'' *See* Form 1 Amendment, at *https://www.sec.gov/Archives/edgar/vprr/2001/20012246.pdf.*

PHLX's Form 1, simply titled ''Market services.'' [49]

The Exchange also believes that, based on the 2020 Audited Financial Statements of competing options exchanges, the Exchange's overall operating margin is in line with or less than the operating margins of competing options exchanges, including the revenue and expense associated with the Proposed Access Fees. For example, the 2020 operating margin for MIAX Emerald was −12%.[50] Based on competing exchanges' Form 1 Amendments, ISE's operating profit margin for 2020 was approximately 85%; PHLX's operating profit margin for 2020 was approximately 49%; NASDAQ's operating profit margin for 2020 was approximately 62%; Arca's operating profit margin for 2020 was approximately 55%; Amex's operating profit margin for 2020 was approximately 59%; Cboe Exchange, Inc.'s (''Cboe'') operating profit margin for 2020 was approximately 74%; and Cboe BZX Exchange, Inc.'s (''BZX'') operating profit margin for 2020 was approximately 52%.

The Exchange further believes its proposed fees are reasonable, equitably allocated and not unfairly discriminatory because the Exchange believes that it benefits overall competition in the marketplace to allow relatively new entrants like the Exchange and its affiliates, MIAX Pearl and MIAX, to propose fees that may help these new entrants recoup their substantial investment in building out costly infrastructure. The Exchange and its affiliates have historically set their fees purposefully low in order to attract business and market share. The Exchange notes that the concept of a tiered-pricing structure for ports is not new or novel.[51]

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees for services and products, in addition to order flow, to remain competitive with other exchanges. The Exchange believes that the proposed changes reflect this competitive environment.

The Exchange believes the proposal to move from a flat fee per month to a tiered-pricing structure is reasonable, equitably allocated and not unfairly discriminatory because the Exchange believes the proposed structure would encourage firms to be more economical and efficient in the number of Limited Service MEI Ports they purchase. The Exchange believes this will enable the Exchange to better monitor and provide access to the Exchange's network in order to ensure that the Exchange meets its obligations under the Act such that access to the Exchange is offered on terms that are not unfairly discriminatory, as well as to ensure sufficient capacity and headroom in the System.

There is also no regulatory requirement that any market participant access any one options exchange, that each Market Maker access the Exchange utilizing more than the two free Limited Service MEI Ports that the Exchange provides, access the Exchange in a particular capacity, or trade any particular product offered on the Exchange. Moreover, membership is not a requirement to participate on the Exchange. A market participant may submit orders to the Exchange via a Sponsored User.[52] Indeed, the Exchange is unaware of any one options exchange whose membership includes every registered broker-dealer. Based on a recent analysis conducted by Cboe, as of October 21, 2020, only three (3) of the broker-dealers, out of approximately 250 broker-dealers, were members of at least one exchange that lists options for trading and were members of all 16 options exchanges.[53] Additionally, the Cboe Fee Filing found that several broker-dealers were members of only a single exchange that lists options for trading and that the number of members at each exchange that trades options varies greatly.[54]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

With respect to intra-market competition, the Exchange does not believe that the proposed rule change would place certain market participants at the Exchange at a relative disadvantage compared to other market participants or affect the ability of such market participants to compete. As stated above, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that the proposed pricing structure for is associated with relative usage of the various market participants. Firms that are primarily order routers seeking best-execution do not utilize Limited Service MEI Ports on MIAX Emerald and therefore will not pay the fees associated with the tiered-pricing structure. Rather, the fees described in the proposed tiered-pricing structure will only be allocated to market making firms that engage in advanced trading strategies and typically request multiple Limited Service MEI Ports, beyond the two that are free. Accordingly, the firms engaged in market making business generate higher costs by utilizing more of the Exchange's resources. The market making firms that purchase higher amounts of Limited Service MEI Ports tend to have specific business oriented market making and trading strategies, as opposed to firms engaging solely in best-execution order routing business. Additionally, the use of such additional Limited Service MEI Ports is entirely voluntary.

The Exchange also does not believe that the proposed rule change will result in any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, options market participants are not forced to access all options exchanges. The Exchange operates in a highly competitive environment, and as discussed above, its ability to price access and ports is constrained by competition among exchanges and third parties. There are other options markets of which market participants may access

[49] *See* Form 1 Amendment, at *https://www.sec.gov/Archives/edgar/vprr/2100/21000475.pdf.*

[50] This information is provided in response to the SIG Comment Letter. *See supra* note 8.

[51] *See* Cboe BZX Exchange, Inc. (''BZX'') Options Fee Schedule, Options Logical Port Fees, Ports with Bulk Quoting Capabilities (charging $1,500/month for the 1st and 2nd port, $2,500/month for the 3rd port or more); Cboe Exchange, Inc. (''Cboe'') Fee Schedule, Logical Connectivity Fees (charging $750/month per port for BOE/FIX Logical Ports 1 to 5 and $800/month per port for BOE/FIX Logical Ports greater than 5; charging $1,500/month per port for BOE Bulk Logical Ports 1 to 5, $2,500/month per port for BOE Bulk Logical Ports 6 to 30, and $3,000/month per port for BOE Bulk Logical Ports greater than 30); The Nasdaq Stock Market LLC (''Nasdaq''), Options 7, Pricing Schedule, Section 3 Nasdaq Options Market—Ports and Other Services (charging $1,500/month per port for first 5 ports, $1,000/month per port for the next 15 ports, and $500/month per port for all ports over 20).

[52] *See* Exchange Rule 210. The Sponsored User is subject to the fees, if any, of the Sponsoring Member. The Exchange notes that the Sponsoring Member is not required to publicize, let alone justify or file with the Commission its fees, and as such could charge the Sponsored User any fees it deems appropriate, even if such fees would otherwise be considered supra-competitive, or otherwise potentially unreasonable or uncompetitive.

[53] *See* Securities Exchange Act Release No. 90333 (November 4, 2020), 85 FR 71666 (November 10, 2020) (SR–CBOE–2020–105) (the ''Cboe Fee Filing''). The Cboe Fee Filing cited to the October 2020 Active Broker Dealer Report, provided by the Commission's Office of Managing Executive, on October 8, 2020.

[54] *Id.*

in order to trade options. There is also a possible range of alternative strategies, including routing to the exchange through another participant or market center or accessing the Exchange indirectly. For example, there are 15 other U.S. options exchanges, which the Exchange must consider in its pricing discipline in order to compete for market participants. In this competitive environment, market participants are free to choose which competing exchange to use to satisfy their business needs. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Accordingly, the Exchange does not believe its proposed fee changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange received one comment on the proposed rule change.[55] The Exchange notes that the Exchange, and its affiliates, MIAX Pearl and MIAX, justified similar fee changes in the past with similar, if not identical, justifications in previous filings that have been noticed by the Commission for public comment and are currently in effect.[56] Nonetheless, the Exchange has sought to address the commenters concerns via the enhanced justification and additional information included in this proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[57] and Rule 19b–4(f)(2)[58] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EMERALD–2021–31 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–EMERALD–2021–31. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EMERALD–2021–31 and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[59]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21619 Filed 10–4–21; 8:45 am]

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[55] *See* the SIG Comment Letter, *supra* note 8.

[56] *See* Securities Exchange Act Release Nos. 90980 (January 25, 2021), 86 FR 7602 (January 29, 2021) (SR–MIAX–2021–02); 90981 (January 25, 2021), 86 FR 7582 (January 29, 2021) (SR–PEARL–2021–01); 91033 (February 1, 2021), 86 FR 8455 (February 5, 2021) (SR–EMERALD–2021–03); 91460 (April 2, 2021), 86 FR 18349 (April 8, 2021) (SR–EMERALD–2021–11).

[57] 15 U.S.C. 78s(b)(3)(A)(ii).

[58] 17 CFR 240.19b–4(f)(2).

[59] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93176; File No. SR–LCH SA–2021–002]

Self-Regulatory Organizations; LCH SA; Order Approving Proposed Rule Change Relating to Eligible Collateral and Liquidity Risk Management

September 29, 2021.

I. Introduction

On August 18, 2021, Banque Centrale de Compensation, which conducts business under the name LCH SA (''LCH SA''), filed with the Securities and Exchange Commission (''Commission'' or ''SEC''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4,[2] a proposed rule change to expand the non-cash collateral that a Clearing Member may post with LCH SA to meet margin requirements and make certain other changes as described further below.[3] The proposed rule change was published for comment in the **Federal Register** on August 27, 2021.[4] The Commission did not receive comments regarding the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

A. Additional Eligible Collateral

The proposed rule change would expand the list of non-cash collateral that a Clearing Member may post with LCH SA to meet margin requirements to include certain non-Euro government securities.[5] To carry out this change,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Capitalized terms used but not defined herein have the meanings specified in the CDS Clearing Rule Book, the CDS Clearing Procedures, the Clearing Notice, or the Liquidity Risk Modelling Framework the Clearing Regulations, as applicable.

[4] Self-Regulatory Organizations; LCH SA; Notice of Filing of Proposed Rule Change to Relating to Eligible Collateral and Liquidity Risk Management, Exchange Act Release No. 34–92723 (Aug. 23, 2021); 86 FR 48257 (Aug. 27, 2021) (SR–LCH SA–2021–002) (''Notice'').

[5] This description is substantially excerpted from the Notice, 86 FR 48257.

LCH SA would publish a new Clearing Notice, in accordance with Article 4.2.6.1 of the CDS Clearing Rule Book (the ''Rule Book''), specifying the additional acceptable non-Euro government securities.[6] The Clearing Notice would refer to the additional acceptable non-Euro government securities as the ''New Instruments.'' The Clearing Notice would further specify that only New Instruments with a minimum outstanding amount equivalent of 500 million Euros would be eligible.

Moreover, the Clearing Notice would specify that New Instruments transferred by a Clearing Member to LCH SA as Collateral shall be taken into account to satisfy the Clearing Member's Margin Requirements only up to 15% of the total Margin Requirements and New Instruments transferred by a Clearing Member to LCH SA as Collateral in excess of such 15% cap shall be ignored for the purposes of determining whether the Clearing Member's Margin Requirements are satisfied. LCH SA is including this particular limitation because the European Central Bank will not convert New Instruments to Euros and LCH SA currently does not otherwise have the operational capacity to convert New Instruments to Euros.[7]

Moreover, LCH SA has determined, at this time, not to treat New Instruments as Pledged Eligible Collateral. Pledged Eligible Collateral is that Eligible Collateral which a Clearing Member may pledge to LCH SA under a pledge agreement entered into between LCH SA and the Clearing Member. Under Article 3.2.3.2 of the Rule Book, Pledged Eligible Collateral is transferred to LCH SA using a Belgian law security interest with no title transfer pursuant to the applicable provisions of Belgian law. LCH SA determined that Clearing Member interest was not sufficient to justify the additional operational resources needed to allow the transfer of New Instruments as Pledged Eligible Collateral. Accordingly, the Clearing Notice would specify that New Instruments are not eligible as Pledged Eligible Collateral. Moreover, the proposed rule change would amend the definition of Pledged Eligible Collateral in Section 1.1.1 of the Rule Book to provide that the term means ''Eligible Collateral as described in a Clearing Notice which is pledged in accordance with a Pledge Agreement.'' Because the proposed Clearing Notice would specify that New Instruments are not Pledged Eligible Collateral, this proposed change would exclude New Instruments from the definition of Pledged Eligible Collateral in Section 1.1.1 of the Rule Book.

In furtherance with this change, the proposed rule change also would amend Section 3.13 of the CDS Clearing Procedures. Section 3.13 describes how Clearing Members may transfer Eligible Collateral pursuant to a Pledge Agreement under Article 3.2.3.2 of the Rule Book. The proposed rule change would clarify that the term Eligible Collateral, as used in Section 3.13, means Eligible Collateral as described in a Clearing Notice. Because the proposed Clearing Notice would specify that New Instruments are not Pledged Eligible Collateral, this proposed change would exclude New Instruments from amended Section 3.13 of the CDS Clearing Procedures.

The proposed rule change also would amend LCH SA's Liquidity Risk Modelling Framework (the ''Framework'') to take into account this expansion of Eligible Collateral. The Framework describes the Liquidity Stress Testing framework by which the Collateral and Liquidity Risk Management department of LCH Group Holdings Limited (''CaLM'') assures that LCH SA has enough cash available to meet any financial obligations, both expected and unexpected, that may arise over the liquidation period for each of the clearing services that LCH SA offers. The proposed rule change would amend Sections 4.1.3, 4.1.4, 5.2.1.1, 5.3.5, and 5.4.3 of the Framework to clarify that LCH SA will exclude New Instruments from the calculation of LCH SA's liquidity resources. The proposed rule change would further specify the reason for this exclusion: New Instruments are not European Central Bank eligible and currently not covered by CaLM's activities for transformation into Euros. In other words, the European Central Bank will not convert New Instruments to Euros and LCH SA currently does not otherwise have the operational capacity to convert them to Euros.[8] For this same reason, the proposed rule change would amend Section 5.5.1 of the Framework to clarify that Non-Euro, non-cash Collateral like the New Instruments are not European Central Bank eligible assets.

Finally, in accordance with these changes, the proposed rule change also would amend Section 3.9 of the CDS Clearing Procedures to update the link to the portion of LCH SA's website that contains a list of Eligible Collateral.

B. Other Changes

In addition to the expansion of Eligible Collateral, the proposed rule change would also expand the custodians at which Clearing Members may deposit Eligible Collateral by adding Clearstream Banking Luxembourg as a central securities depository for LCH SA. The proposed rule change would amend Section 3.4(d) of the CDS Clearing Procedures to include Clearing Banking Luxembourg in the list of entities through which securities may be transferred to LCH SA. Similarly, the proposed rule change would amend Sections 3.10 and 3.12 to include Clearing Banking Luxembourg in the list of central securities depositories in which LCH SA holds Eligible Collateral.

Moreover, unrelated to the expansion of Eligible Collateral, the proposed rule change also would amend the Framework to clarify certain sections, tables, and formula in response to model validations and other routine updates. Beginning in Section 4.1.1, Description of sources of liquidity, the proposed rule change would add description to clarify LCH SA's ability to use Collateral as a source of liquidity. Specifically, the proposed rule change would clarify that, with limited exceptions, LCH SA generally receives Collateral on a full title transfer basis, which permits LCH SA to use such collateral, to offset it with all related claims and to consider such Collateral available for liquidity purposes. As would be described, the two exceptions are: (i) Collateral deposited through a pledge and (ii) Collateral deposited through a central bank guarantee.

Next, in Sections 4.1.3 and 4.1.4, the proposed rule change would clarify that Collateral deposited through a pledge may be used for liquidity purposes only if the Clearing Member pledging such Collateral has defaulted.

The proposed rule change also would amend Section 4.1.4 regarding the use of non-Euro cash Collateral posted in full title by Clearing Members (*i.e.* Collateral that is not pledged). Section 4.1.4 currently describes how such Collateral may be used to raise liquidity and how CaLM has demonstrated its ability to raise Euro cash with non-Euro non-cash collateral. The proposed rule change would specify that the non-Euro non-cash collateral used by CaLM in that case was collateral in USD and GBP.

[6] The additional non-Euro Eligible Collateral would be: (i) Australian Treasury Bills and Government Bonds; (ii) Canadian Treasury Bills and Government Bonds; (iii) Danish Treasury Bills and Government Bonds; (iv) Japanese Treasury Bills, Treasury Discount Bills, and Government Bonds; (v) Norwegian Treasury Bills and Government Bonds; (vi) Swedish Treasury Bills and Government Bonds; and (vii) Swiss Treasury Bills and Government Bonds.

[7] Notice, 86 FR 48257.

[8] Notice, 86 FR 48257.

The proposed rule change also would add to Section 4.1.4 a short explanation of the overdraft facility in place with Citibank that allows LCH SA to source non-Euro currencies in case of liquidity needs.

In Section 4.2.1.4, the proposed rule change would update the table of figures of the liquidity injected in the settlement system to smooth settlement activity. LCH SA represents that these figures are updated periodically in line with the observed cash flows.[9]

In Section 5.1.1, the proposed rule change would clarify that LCH SA has a group policy that allows LCH SA to perform an extraordinary margin call if liquidity deteriorates.

Section 5.1.2 currently describes how LCH SA monitors liquidity risks potentially arising from operational issues at settlement platforms and how any warnings about such risks are escalated to senior management to provide colours. The proposed rule change would replace the word ''colours'' with ''justifications.''

Section 5.2.1.1 currently notes that investments maturing over the operational target are not factored as liquidity resources for certain purposes. The proposed rule change would replace the word ''over'' with ''beyond.''

In Section 5.3.1, which provides an overview of the Liquidity Coverage Ratio (''LCR''), the proposed rule change would add an explanation that the LCR is an internal ratio similar, but not equivalent, to the banking metric defined in the Basel III framework and is used to ensure compliance with EMIR. The proposed rule change would also correct two typographical errors in Section 5.3.1.

Section 5.3.1.1 currently describes the assessment of the market risk related to the volatility of the value of the securities arising from RepoClear settlement and pledged at the Banque de France. The proposed rule change would add further description of the formula and assumptions used in making that assessment.

Next, the proposed rule change would amend Section 5.3.1.3, to clarify the treatment of settlement risk to account for early exercise of American-style options. The proposed rule change would describe how the liquidity needs coming from American-style options are computed.

Section 5.3.1.4 currently specifies that the liquidity needs arising from variation margin are assessed consistent with the relevant listed derivatives stress scenario. The proposed rule change would specify that such scenario includes spread shifts and implied volatility shifts, thus clarifying the calculation of that particular LCR component. The proposed rule change would make similar updates to Sections 5.3.1.5 and 5.3.4.

In Section 5.5, the proposed rule change would delete a duplicated sentence.

Section 5.5.1 of the Framework describes the independent stress of various risk factors, and it includes a discussion of how many defaults LCH SA can sustain before generating a liquidity shortfall. The proposed rule change would add a clarification to this discussion that, when considering multiple defaults, the clearing members with the worst credit quality are assumed defaulting first.

Finally, the proposed rule change would update Appendix 3 and Appendix 5 to add description of the overdraft facility in place with Citibank that allows LCH SA to source non-Euro currencies in case of liquidity needs.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.[10] For the reasons given below, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act[11] and Rules 17Ad–22(e)(5), (e)(7), and (e)(7)(ix).[12]

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of LCH SA be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, as well as to assure the safeguarding of securities and funds which are in the custody or control of LCH SA or for which it is responsible.[13] As discussed in more detail below, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act.[14]

i. Additional Eligible Collateral

As discussed above, the proposed rule change would expand the list of non-cash collateral that a Clearing Member may post with LCH SA to meet margin requirements to include New Instruments, which would be certain non-Euro government securities. The proposed rule change would do so by issuing a new Clearing Notice to specify the New Instruments and amending Section 3.9 of the CDS Clearing Procedures to update the link to the portion of LCH SA's website that contains a list of Eligible Collateral. The Commission believes that by expanding the collateral that Clearing Members may post to satisfy margin requirements to include New Instruments and accordingly updating the link to the portion of LCH SA's website that contains a list of Eligible Collateral, these proposed changes would promote the ability of Clearing Members to meet margin requirements and therefore clear and settle transactions at LCH SA. Thus, the Commission believes these aspects of the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions.

Moreover, the Commission believes that the conditions placed upon New Instruments would promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of LCH SA or for which it is responsible. The Commission believes that, for example, limiting New Instruments to those with a minimum outstanding amount equivalent to 500 million Euros would help to ensure that LCH SA is able to liquidate posted New Instruments if necessary. Moreover, given that that the European Central Bank will not convert New Instruments to Euros and LCH SA currently does not otherwise have the operational capacity to convert New Instruments to Euros, the Commission believes that limiting the amount of additional Eligible Collateral to 15% of a Clearing Member's total Margin Requirements should help to ensure that LCH SA is able to maintain sufficient liquidity even while accepting New Instruments as Eligible Collateral. Similarly, the Commission believes that amending the Framework to clarify that LCH SA will exclude New Instruments from the calculation of LCH SA's liquidity resources and that non-Euro, non-cash Collateral like New Instruments are not European Central Bank eligible assets, should help to ensure that LCH SA is able to maintain sufficient liquidity. The Commission believes that maintaining sufficient liquidity should, in turn, help to ensure that LCH SA is able to

[9] Notice, 86 FR 48258.

[10] 15 U.S.C. 78s(b)(2)(C).

[11] 15 U.S.C. 78q–1(b)(3)(F).

[12] 17 CFR 240.17Ad–22(e)(5), (e)(7), and (e)(7)(ix).

[13] 15 U.S.C. 78q–1(b)(3)(F).

[14] 15 U.S.C. 78q–1(b)(3)(F).

continue clearing and settling securities transactions and safeguarding securities and funds in the face of a Clearing Member default or other liquidity need, and therefore the Commission believes these aspects of the proposed rule change would be consistent with Section 17A(b)(3)(F) of the Act.[15]

Finally, as discussed above, LCH SA has determined, at this time, not to treat New Instruments as Pledged Eligible Collateral due to a lack of Clearing Member interest and the additional operational resources required to allow such treatment. Accordingly, the proposed rule change would amend the Rule Book and the CDS Clearing Procedures to ensure that New Instruments are not treated as Pledged Eligible Collateral. The Commission believes these changes in particular should help to ensure that LCH SA is able to focus its operations and resources on clearing and settling securities transactions and assuring the safeguarding of securities and funds.

Therefore, for the reasons discussed above, the Commission finds that these aspects of the proposed rule change are consistent with the Section 17A(b)(3)(F) of the Act.[16]

ii. Other Changes

In addition to the expansion of Eligible Collateral, the Commission believes that the other changes discussed above would promote the prompt and accurate clearance and settlement of securities transactions and would assure the safeguarding of securities and funds which are in the custody or control of LCH SA or for which it is responsible. In particular, the Commission believes that amending Section 3 of the CDS Clearing Procedures to include Clearing Banking Luxembourg in the list of central securities depositories through which securities may be transferred to LCH SA would provide Clearing Members and LCH SA an additional option to use as a central securities depository, therefore increasing LCH SA's operational resiliency. The Commission believes that increasing operational resiliency, in turn, should promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of LCH SA or for which it is responsible by reducing the likelihood that Clearing Members would be unable to provide collateral to LCH SA.

Moreover, the Commission believes that the other clarifications, updates, and corrections to the Framework described in Section II.B above would be consistent with the Section 17A(b)(3)(F) of the Act.[17] As discussed above, these changes would, among other things, clarify LCH SA's ability to use Collateral, including Collateral that is pledged; describe the overdraft facility in place with Citibank that allows the LCH SA to source non-Euro currencies in case of liquidity needs; update the figures describing the liquidity injected in the settlement system to smooth settlement activity; clarify the treatment of settlement risk related to American-style options and other aspects of liquidity stress scenarios; and correct typographical and drafting errors. The Commission believes that all of the changes described in Section II.B above would improve the Framework by increasing its clarity and readability and helping to ensure that the Framework accurately describes how LCH SA considers and covers its liquidity needs. The Commission believes that increasing the clarity and readability of the Framework should help to avoid errors and inconsistencies in the application of the Framework and this should, in turn, improve LCH SA's ability to maintain sufficient liquidity using the Framework. Because the Commission believes that having sufficient liquidity should help to ensure that LCH SA is able to continue clearing and settling securities transactions and safeguarding securities and funds in the face of a Clearing Member default or other liquidity need, the Commission therefore finds these aspects of the proposed rule change are consistent with Section 17A(b)(3)(F) of the Act.[18]

B. Consistency With Rule 17Ad–22(e)(5)

Rule 17Ad–22(e)(5) requires that LCH SA establish, implement, maintain and enforce written policies and procedures reasonably designed to limit the assets it accepts as collateral to those with low credit, liquidity, and market risks, and set and enforce appropriately conservative haircuts and concentration limits if LCH SA requires collateral to manage its or its participants' credit exposure; and require a review of the sufficiency of its collateral haircuts and concentration limits to be performed not less than annually.[19] As discussed above, under the proposed new Clearing Notice, only those New Instruments with a minimum outstanding amount equivalent to 500 million Euros would be eligible for posting to LCH SA. The Commission believes that this aspect of the proposed rule change would help to ensure that New Instruments are limited to those assets with low liquidity risks, consistent with Rule 17Ad–22(e)(5),[20] by setting a reasonable condition that would help to ensure that LCH SA is able to liquidate the additional Eligible Collateral if necessary. Moreover, as discussed above, under the proposed new Clearing Notice, New Instruments transferred by a Clearing Member to LCH SA as Collateral shall be taken into account to satisfy the Clearing Member's Margin Requirements only up to 15% of the total Margin Requirements. The Commission believes this aspect of the proposed rule change would set an appropriate limit that should help to ensure that a Clearing Member's collateral is not overly concentrated in New Instruments. The Commission further believes this limit is important given that the European Central Bank will not convert New Instruments to Euros and LCH SA currently does not otherwise have the operational capacity to convert New Instruments to Euros.

Thus, the Commission finds that these aspects of the proposed rule change are consistent with Rule 17Ad–22(e)(5).[21]

C. Consistency With Rules17Ad–22(e)(7) and)(e)(7)(ix)

Rule 17Ad–22(e)(7) generally requires that LCH SA establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively measure, monitor, and manage the liquidity risk that arises in or is borne by LCH SA, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity.[22] As discussed in Part II.B above, the proposed rule change would add to the Framework description of Collateral as a source of liquidity—that LCH SA generally can use Collateral for liquidity purposes except (i) Collateral that is pledged (which could only be used for liquidity purposes if the Clearing Member pledging such Collateral has defaulted) and (ii) Collateral deposited through a central bank guarantee. The Commission believes that this additional description would help to clarify the sources of liquidity that LCH SA would use to, among other things, manage its liquidity risk. Moreover, the proposed rule change would clarify how CaLM has used collateral in USD and GBP to raise Euro cash and update the table of figures of the liquidity injected

[15] 15 U.S.C. 78q–1(b)(3)(F).

[16] 15 U.S.C. 78q–1(b)(3)(F).

[17] 15 U.S.C. 78q–1(b)(3)(F).

[18] 15 U.S.C. 78q–1(b)(3)(F).

[19] 17 CFR 240.17Ad–22(e)(5).

[20] 17 CFR 240.17Ad–22(e)(5).

[21] 17 CFR 240.17Ad–22(e)(5).

[22] 17 CFR 240.17Ad–22(e)(7).

in the settlement system to smooth settlement activity. Again, the Commission believes this additional description would help to clarify LCH SA's sources of liquidity and how it manages settlement and funding flows. Finally, the proposed rule change would add a general explanation of the LCR and how it relates to the Basel III framework. The proposed rule change similarly would add further explanations of some of the assumptions used in calculating the LCR, such as settlement risk associated with American-style options, liquidity needs arising from variation margin, and that when considering multiple defaults Clearing Members with the worst credit quality are assumed defaulting first. Because LCH SA uses the LCR to ensure that it has sufficient liquidity, the Commission believes that the additional description would help to clarify the LCR and therefore how LCH SA manages its liquidity risk. Thus, the Commission believes these aspects of the proposed rule change generally would be consistent with Rule 17Ad–22(e)(7).[23]

Rule 17Ad–22(e)(7)(ix), in particular, requires that LCH SA establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively measure, monitor, and manage the liquidity risk that arises in or is borne by LCH SA, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity by, at a minimum describing LCH SA's process to replenish any liquid resources that LCH SA may employ during a stress event.[24] As discussed in Part II.B above, the proposed rule change would add description to the Framework of LCH SA's group policy that allows LCH SA to perform an extraordinary margin call if liquidity deteriorates and description of the overdraft facility in place with Citibank that allows the LCH SA to source non-Euro currencies in case of liquidity needs. The Commission believes that these clarifications would help to describe LCH SA's process to replenish any liquid resources that LCH SA may employ during a stress event, consistent with Rule 17Ad–22(e)(7)(ix).[25]

Thus, the Commission finds that these aspects of the proposed rule change are consistent with Rule 17Ad–22(e)(7) generally and (e)(7)(ix) in particular.[26]

Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act, and in particular, with the requirements of Section 17A(b)(3)(F) of the Act[27] and Rules 17Ad–22(e)(5), (e)(7), and (e)(7)(ix).[28]

It is therefore ordered pursuant to Section 19(b)(2) of the Act[29] that the proposed rule change (SR–LCH SA–2021–002) be, and hereby is, approved.[30]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21614 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93173; File No. SR–CboeBZX–2021–024]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the WisdomTree Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

September 29, 2021.

On March 26, 2021, Cboe BZX Exchange, Inc. (''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the WisdomTree Bitcoin Trust under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on April 15, 2021.[3]

On May 26, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On July 13, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.[7]

Section 19(b)(2) of the Act[8] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on April 15, 2021.[9] The 180th day after publication of the proposed rule change is October 12, 2021. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days. The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised in the comment letters that have been submitted in connection therewith. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates December 11, 2021, as the date by which the Commission shall either approve or disapprove the proposed rule change (File Number SR–CboeBZX–2021–024).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21611 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

[23] 17 CFR 240.17Ad–22(e)(7).

[24] 17 CFR 240.17Ad–22(e)(7)(ix).

[25] 17 CFR 240.17Ad–22(e)(7)(ix).

[26] 17 CFR 240.17Ad–22(e)(7) and (e)(7)(ix).

[27] 15 U.S.C. 78q–1(b)(3)(F).

[28] 17 CFR 240.17Ad–22(e)(5), (e)(7), and (e)(7)(ix).

[29] 15 U.S.C. 78s(b)(2).

[30] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[31] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] *See* Securities Exchange Act Release No. 91521 (April 9, 2021), 86 FR 19917 (April 15, 2021). Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-cboebzx-2021024/srcboebzx2021024.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92032 (May 26, 2021), 86 FR 29611 (June 2, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 92392 (July 13, 2021), 86 FR 38154 (July 19, 2021).

[8] 15 U.S.C. 78s(b)(2).

[9] *See supra* note 3.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93212; File No. SR–NYSE–2021–40]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Adopt on a Permanent Basis the Pilot Program for Market-Wide Circuit Breakers in Rule 7.12

September 30, 2021.

I. Introduction

On July 2, 2021, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b–4 thereunder,[2] a proposal to make its rules governing the operation of the Market-Wide Circuit Breakers (''MWCB'') mechanism permanent. The proposed rule change was published for comment in the **Federal Register** on July 22, 2021.[3] On August 27, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to either approve the proposed rule changes, disapprove the proposed rule changes, or institute proceedings to determine whether to disapprove the proposed changes.[5] The Commission has received no comments on the proposed rule change.

This order institutes proceedings under Section 19(b)(2)(B) of the Exchange Act [6] to determine whether to approve or disapprove the proposed rule changes.

II. Description of the Proposed Rule Changes

MWCBs are coordinated, cross-market trading halts designed to operate during extreme market-wide declines to provide opportunities for markets and market participants to assess market conditions and systemic stress.[7] Each cash equity exchange and options exchange has rules that govern the operation of these MWCBs. These rules operate on a pilot basis. The current pilot period was recently extended from October 18, 2021 to March 18, 2022.[8]

The MWCB Pilot Rules provide for trading halts in all cash equity securities during a severe market decline as measured by a single-day decline in the S&P 500 Index (''SPX'').[9] Under the Pilot Rules, a market-wide trading halt will be triggered if SPX declines in price by specified percentages from the prior day's closing price of that index.[10] The triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3).[11] A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. and before 3:25 p.m. would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. would not halt market-wide trading.[12] Level 1 and Level 2 halts may occur only once a day. A market decline that triggers a Level 3 halt at any time during the trading day would halt market-wide trading for the remainder of the trading day.[13]

The NYSE's MWCB Pilot Rules also require all designated Regulation SCI firms to participate in at least one MWCB test each year.[14] Specifically, Regulation SCI Firms must attest that they are able to or have attempted to: (A) Receive and process MWCB halt messages from the securities information processors (''SIPs''); (B) receive and process resume messages from the SIPs following a MWCB halt; (C) receive and process market data from the SIPs relevant to MWCB halts; and (D) send orders following a Level 1 or Level 2 MWCB halt in a manner consistent with their usual trading behavior.[15]

The triggers provided for in the MWCB Pilot Rules were triggered for the first time in March 2020 when MWCB Level 1 halts occurred on March 9, 12, 16, and 18, 2020. In response to these events, a task force comprised of the SROs reviewed the events and concluded that the MWCBs had performed as expected and recommended that no changes be made to the MWCB rules.[16] Subsequently, at the request of the Director of the Commission's Division of Trading and Markets, the SROs and a ''Working Group'' composed of SRO representatives and industry advisers that included members of the advisory committees to both the LULD Plan and the NMS Plans prepared a study, which includes a timeline of the MWCB events in March 2020; a summary of the analysis and recommendations of the MWCB Task Force; an evaluation of the operation of the Pilot Rules during the March 2020 events; an evaluation of the design of the current MWCB system; and the Working Group's conclusions and recommendations.[17]

Based on the conclusions and recommendations reached by the Working Group after analyzing how the MWCBs performed in March 2020, the Exchange proposed to transition the Pilot Rules to operate on a permanent basis without substantive change.[18]

III. Proceedings To Determine Whether To Disapprove SR–NYSE–2021–40 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act to determine whether the proposal should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change, as discussed below. Institution of disapproval proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved.

Pursuant to Section 19(b)(2)(B) of the Act, the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis and input concerning the proposed rule change's consistency with the Act [19] and, in particular, with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchanges be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.[20]

Under the Commission's Rule of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization ['SRO'] that proposed the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 92428 (July 16, 2021), 86 FR 38776 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92785A, 86 FR 50202 (September 7, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Notice, *supra* note 3 at 38777.

[8] *See* Securities Exchange Act Release No. 93203 (September 30, 2021).

[9] *See* Notice, *supra* note 3 at 38777.

[10] *See id.*

[11] *See id.*

[12] *See id.*

[13] *See id.*

[14] *See id.* at 38786.

[15] *See id.*

[16] *See id.* at 38778.

[17] *See id.*

[18] *See id.*

[19] 15 U.S.C. 78s(b)(2)(B).

[20] 15 U.S.C. 78f(b)(5).

rule change.'' [21] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding.[22] Any failure of the SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and applicable rules and regulations.[23]

As discussed above, the Exchange is proposing to make the current MWCB Pilot Rules permanent, substantively without change, including the provision requiring systems testing by certain market participants. Specifically, the Exchange proposes to require Designated Market Makers and Supplemental Liquidity Providers that have been determined by the Exchange to contribute a meaningful percentage of the Exchange's overall volume, measured on a quarterly or monthly basis, to participate in MWCB testing, though the Exchange may consider other factors in determining the member organizations that will be required to participate in testing. These market participants would be required to participate in at least one MWCB test each year and attest that they can send and receive MWCB halt and resume messages, as well as receive and process market data from the SIPs relevant to MWCBs and send orders following a MWCB Level 1 or Level 2 event. The proposed testing requirement, however, does not contemplate an ongoing assessment of whether the MWCB design (*e.g.,* trigger thresholds, measurement criteria, and time of day application) remains appropriate over time, as the market structure evolves, and under various threat scenarios, nor does it require the Exchange to participate in testing. The Commission seeks comment on the following questions and asks commenters to submit data where appropriate to support their views:

1. Do commenters believe that an ongoing assessment of the MWCB design should be conducted as market structure evolves and under various threat scenarios? If so, how could such an assessment meaningfully be conducted, understanding that it is difficult to replicate or forecast how market participants would behave during an actual MWCB event? How frequently should such an assessment be done?

2. Are commenters aware of ongoing assessment methods in other contexts (*e.g.,* cybersecurity) that could inform how an ongoing assessment of the MWCB could be structured?

3. Should the Exchange be required to participate in a coordinated fashion in the operational test with the other SROs, report the results of their operational tests and periodic assessment of the MWCB design to the Commission and inform the Commission of any concerns or proposed modifications concerning the MWCBs?

For the reasons discussed above, the Commission believes it is appropriate to institute proceedings pursuant to Section 19(b)(2)(B) of the Act to determine whether the proposal should be approved or disapproved.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the concerns identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change is inconsistent with Section 6(b)(5) or any other provision of the Act, or the rules and regulation thereunder. Although there do not appear to be any issues relevant to approval or disapproval which would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request or an opportunity to make an oral presentation.[24]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by October 26, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by November 9, 2021. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed change.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2021–40 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2021–40. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–NYSE–2021–40 and should be submitted on or before October 26, 2021. Rebuttal comments should be submitted byNovember 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21750 Filed 10–4–21; 8:45 am]

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[21] 17 CFR 201.700(b)(3).

[22] *See id.*

[23] *See id.*

[24] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing and Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[25] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93183; File No. SR–NYSE–2021–56]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend NYSE Rule 7.2

September 30, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2021, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Rule 7.2 (Holidays) to make Juneteenth National Independence Day a holiday of the Exchange. Juneteenth National Independence Day was designated a legal public holiday in June 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Rule 7.2 (Holidays) to make Juneteenth National Independence Day a holiday of the Exchange.

On June 17, 2021, Juneteenth National Independence Day was designated a legal public holiday.[3] Consistent with broad industry sentiment [4] and the approach recommended by the Securities Industry and Financial Markets Association (''SIFMA''),[5] the Exchange proposes to add ''Juneteenth National Independence Day'' to the existing list of holidays in the first paragraph of NYSE Rule 7.2. As a result, the Exchange will not be open for business on Juneteenth National Independence Day, which falls on June 19 of each year. In accordance with the second paragraph of NYSE Rule 7.2, when the holiday falls on a Saturday, the Exchange will not be open for business on the preceding Friday, and when it falls on a Sunday, the Exchange will not be open for business on the succeeding Monday.[6]

The first paragraph of the revised rule would read as follows (proposed additions *italicized*):

The Exchange will not be open for business on New Year's Day, Martin Luther King Jr. Day, Presidents' Day, Good Friday, Memorial Day, *Juneteenth National Independence Day,* Independence Day, Labor Day, Thanksgiving Day and Christmas Day.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed amended rule would clearly state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The change would thereby promote clarity and transparency in the Exchange rules by updating the list of holidays of the Exchange.

The proposed change does not raise any new or novel issues.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[9] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather to amend the Exchange rule regarding holidays.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section

[3] Public Law 117–17.

[4] *See, e.g. https://www.bloomberg.com/news/articles/2021-06-18/bofa-makes-juneteenth-a-holiday-joining-jpmorgan-wells-fargo?sref=Hhue1scO.*

[5] SIFMA recommends a full market close in observance of Juneteenth National Independence Day. *See https://www.sifma.org/resources/general/holiday-schedule/. See also https://www.sifma.org/resources/news/sifma-revises-2022-fixed-income-market-close-recommendations-in-the-u-s-to-include-full-close-for-juneteenth-national-independence-day/.*

[6] NYSE Rule 7.2. There is an exception to the practice if unusual business conditions exist, such as the ending of a monthly or yearly accounting period. *Id.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(8).

19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6)[12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative prior to 30 days after the date of the filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because the proposed rule change, as described above, would state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The Exchange further states that the proposed change does not raise any new or novel issues. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2021–56 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2021–56. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2021–56, and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21742 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93187; File No. SR–NYSEAMER–2021–39]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend NYSE American Rule 7.2E

September 30, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2021, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE American Rule 7.2E (Holidays) to make Juneteenth National Independence Day a holiday of the Exchange. Juneteenth National Independence Day was designated a legal public holiday in June 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE American Rule 7.2E (Holidays) to make Juneteenth National Independence Day a holiday of the Exchange.

On June 17, 2021, Juneteenth National Independence Day was designated a legal public holiday.[3] Consistent with broad industry sentiment [4] and the approach recommended by the Securities Industry and Financial Markets Association (''SIFMA''),[5] the Exchange proposes to add ''Juneteenth National Independence Day'' to the existing list of holidays in the first paragraph of NYSE American Rule 7.2E. As a result, the Exchange will not be open for business on Juneteenth National Independence Day, which falls on June 19 of each year. In accordance with the second paragraph of NYSE American Rule 7.2E, when the holiday falls on a Saturday, the Exchange will not be open for business on the preceding Friday, and when it falls on a Sunday, the Exchange will not be open for business on the succeeding Monday.[6]

The first paragraph of the revised rule would read as follows (proposed additions *italicized*):

The Exchange will not be open for business on New Year's Day, Martin Luther King Jr. Day, Presidents' Day, Good Friday, Memorial Day, *Juneteenth National Independence Day,* Independence Day, Labor Day, Thanksgiving Day and Christmas Day.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed amended rule would clearly state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The change would thereby promote clarity and transparency in the Exchange rules by updating the list of holidays of the Exchange.

The proposed change does not raise any new or novel issues.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[9] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather to amend the Exchange rule regarding holidays.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) [12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative prior to 30 days after the date of the filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because the proposed rule change, as described above, would state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The Exchange further states that the proposed change does not raise any new or novel issues. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

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[3] Public Law 117–17.

[4] *See, e.g. https://www.bloomberg.com/news/articles/2021-06-18/bofa-makes-juneteenth-a-holiday-joining-jpmorgan-wells-fargo?sref=Hhue1scO.*

[5] SIFMA recommends a full market close in observance of Juneteenth National Independence Day. *See https://www.sifma.org/resources/general/holiday-schedule/. See also https://www.sifma.org/resources/news/sifma-revises-2022-fixed-income-market-close-recommendations-in-the-u-s-to-include-full-close-for-juneteenth-national-independence-day/.*

[6] NYSE American Rule 7.2E. There is an exception to the practice if unusual business conditions exist, such as the ending of a monthly or yearly accounting period. *Id.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(8).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2021–39 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2021–39. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2021–39, and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21744 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93172; File No. SR–Nasdaq–2021–066]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the Valkyrie XBTO Bitcoin Futures Fund Under Nasdaq Rule 5711(g)

September 29, 2021.

On August 23, 2021, The Nasdaq Stock Market LLC (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the Valkyrie XBTO Bitcoin Futures Fund under Nasdaq Rule 5711(g). On August 25, 2021, Nasdaq filed Amendment No. 1 to the proposed rule change. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on September 9, 2021.[3] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is October 24, 2021. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and any comments. Accordingly, pursuant to Section 19(b)(2) of the Act,[5] the Commission designates December 8, 2021, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change, as modified by Amendment No. 1 (File No. SR–Nasdaq–2021–066).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21610 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93192; File No. SR–NYSE–2021–53]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change To Amend the Shareholder Voting Requirement Set Forth in Section 312.07 of the NYSE Listed Company Manual

September 29, 2021.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on September 16, 2021, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt an amendment to the shareholder voting requirement set forth in Section 312.07 of the NYSE Listed Company Manual.

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 92865 (Sept. 2, 2021), 86 FR 50570 (Sept. 9, 2021).

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Section 312.07 of the NYSE Listed Company Manual (''Manual'') provides that, where shareholder approval is a prerequisite to the listing of any additional or new securities of a listed company, or where any matter requires shareholder approval, the minimum vote which will constitute shareholder approval for such purposes is defined as approval by a majority of votes cast on a proposal in a proxy bearing on the particular matter. Section 312.07 is currently applicable to shareholder approval of stock issuances under Sections 303A.08 (equity compensation) and 312.03 of the Manual.[4]

The text of Section 312.07 does not specifically address the treatment of abstentions. However, the Exchange has historically advised companies that abstentions should be treated as votes cast for purposes of Section 312.07. Under that approach, a proposal is deemed approved under Section 312.07 only if the votes in favor of the proposal exceed the aggregate of the votes cast against the proposal plus abstentions. The Exchange has observed that this approach has caused confusion among listed companies. The corporate laws of many states, including Delaware, allow companies to include in their governing documents that votes cast for purposes of a shareholder vote includes yes and no votes (but not abstentions), such that a proposal succeeds if the votes in favor exceed the votes cast against. The Exchange understands that, consistent with those state laws, many public companies have bylaws indicating that abstentions are not treated as votes cast.

The Exchange proposes to amend Section 312.07 to provide that a company must calculate the votes cast with respect to a proposal that is subject to Section 312.07 in accordance with its own governing documents and any applicable state law. The Exchange believes that this treatment of abstentions will avoid any complications engendered among issuers and shareholders when different voting standards are applied under the Exchange rule, a company's governing documents, and/or applicable state laws.

The Exchange notes that Nasdaq has a rule requiring that proposals receive a majority of ''the votes cast,'' [5] but is silent on the question as to whether abstentions should be treated as votes cast. Nasdaq has published an FAQ on its website that clearly states:

Nasdaq does not define the term ''votes cast''. As such, a company must calculate the ''votes cast'' in accordance with its governing documents and any applicable state law.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act'') generally.[6] Section 6(b)(5) [7] requires, among other things, that exchange rules are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect the public interest and the interests of investors, promote just and equitable principles of trade and that they are not designed to permit unfair discrimination between issuers, brokers or dealers.

The Exchange believes that the proposal is designed to protect the public interest and the interests of investors. The proposed approach to calculations of ''votes cast'' in Section 312.07 would not prescribe a particular interpretation under Exchange rules. Rather, a listed company would calculate votes cast in accordance with the company's governing documents and applicable state laws. In doing so, the proposal will reduce confusion among issuers and shareholders. The proposed amendment would also help ensure that shareholders properly understand the implications of choosing to abstain on a proposal subject to approval under Exchange rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal would impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. There would be no effect on the competition among issuers listed on the NYSE resulting from the proposed amendment, because all issuers would calculate votes cast in accordance with their own governing documents and applicable state laws. The proposed amendment is consistent with the existing interpretation of the comparable rule of the other primary listing exchange, so the proposed amendment would have no effect on the competition for listings among exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[4] Item 21(b) of Schedule 14A requires companies soliciting proxies to disclose the method by which votes will be counted, including the treatment and effect of abstentions and broker non-votes under applicable state law as well as the company's charter and bylaw provisions.

[5] *See* Nasdaq Marketplace Rule 5635(e)(4).

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2021–53 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2021–53. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2021–53, and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21623 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93171; File No. SR–NYSEArca–2021–67]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To List and Trade Shares of the One River Carbon Neutral Bitcoin Trust Under NYSE Arca Rule 8.201–E

September 29, 2021.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on September 20, 2021, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares of the One River Carbon Neutral Bitcoin Trust under NYSE Arca Rule 8.201–E. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade shares (''Shares'') of the One River Carbon Neutral Bitcoin Trust (the ''Trust'') pursuant to NYSE Arca Rule 8.201–E which governs the listing and trading of ''Commodity-Based Trust Shares.''[4]

Description of the Trust

The Shares will be issued by the Trust, a Delaware statutory trust.[5] The sponsor of the Trust is One River Digital Asset Management, LLC (''Sponsor''), a Delaware limited liability company. The Sponsor is a wholly-owned subsidiary of One River Asset Management, LLC. The trustee for the Trust is Delaware Trust Company (''Trustee''). The custodian for the Trust is Coinbase Custody Trust Company, LLC (''Custodian''). The Custodian will hold all of the Trust's bitcoin on the Trust's behalf. The marketing agent for the Trust is Foreside Global Services, LLC (the ''Marketing Agent''). The Bank of New York Mellon acts as the Trust's transfer agent (in such capacity, the ''Transfer Agent'') and its administrator (in such capacity, the ''Administrator'') to perform various administrative, accounting and recordkeeping functions on behalf of the Trust.

Operation of the Trust[6]

According to the Registration Statement, the Trust's investment objective is to seek to track the performance of bitcoin, as measured by the performance of the MVIS One River Carbon Neutral Bitcoin Index (the ''Index''), adjusted for the Trust's expenses and other liabilities. The Index is designed to reflect the performance of bitcoin in U.S. dollars on a carbon neutral basis. As described below, the Trust intends to offset the carbon footprint associated with bitcoin once a quarter by paying for the instantaneous retirement of carbon credits necessary to account for the daily estimated carbon emissions associated with the bitcoins

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Commodity-Based Trust Shares are securities issued by a trust that represent investors' discrete identifiable and undivided beneficial ownership interest in the commodities deposited into the Trust.

[5] The Trust is a Delaware statutory trust, formed on April 27, 2021, pursuant to the Delaware Statutory Trust Act. The Trust operates pursuant to the Trust Agreement dated April 26, 2021. On May 24, 2021, the Trust filed a registration statement on Form S–1 under the Securities Act of 1933 (15 U.S.C. 77a) (the ''Securities Act'') (File No. 333–256407) (the ''Registration Statement on Form S–1'' or ''Registration Statement''). The Trust intends to adopt an Amended and Restated Trust Agreement as described in the Registration Statement on Form S–1 prior to requesting accelerated effectiveness thereof.

[6] The description of the operation of the Trust, the Shares and the bitcoin market contained herein are based, in part, on the Registration Statement. *See* note 5, *supra.*

held by the Trust.[7] MVIS, with the assistance of its affiliates, is also the calculation agent for the Index and MVIS® CryptoCompare Bitcoin Benchmark Rate.

In seeking to achieve its investment objective, the Trust will hold bitcoin and will value its Shares based on the same methodology used to calculate the Index, as adjusted to reflect the expenses associated with offsetting carbon credits. The Trust aims to provide a cost-efficient, carbon neutral way for shareholders to implement strategic and tactical asset allocation strategies that use bitcoin by investing in the Trust's Shares rather than purchasing, holding, and trading bitcoin directly.

Under normal circumstances, the Trust will not purchase or sell bitcoin directly, although the Trust may direct the Custodian to sell or transfer bitcoin to pay certain expenses. The Trust will also not hold cash or cash equivalents. However, there may be situations where the Trust will hold cash on a temporary basis. The Trust has entered into a cash custody agreement with BNYM (in such capacity, the ''Cash Custodian'') under which BNYM acts as custodian of the Trust's cash and cash equivalents. The Fund will not hold futures, options or options on futures.

The Trust will process all creations and redemptions in-kind. Financial firms that are authorized to purchase or redeem Shares with the Trust (known as ''Authorized Participants'') will deliver, or facilitate the delivery of, bitcoin to the Bitcoin Account (as defined below) in exchange for Shares when they purchase Shares. The Trust, through the Custodian, will then deliver bitcoin to such Authorized Participants when they redeem Shares. All bitcoin will be held by the Custodian. The Transfer Agent will facilitate the processing of purchase and sale orders in ''Creation Baskets'' (defined below) from the Trust.

Although the Trust will create Baskets only upon the receipt of bitcoins, and will redeem Baskets only by distributing bitcoins, a separate cash exchange process will be made available to Authorized Participants, which can be used, for example, by Authorized Participants who cannot or do not wish to own a bitcoin digital wallet address. Under the cash exchange process, an Authorized Participant may deposit cash with the Administrator, which will facilitate the purchase or sale of bitcoins through a liquidity provider (each, a ''Liquidity Provider'') on behalf of an Authorized Participant. The bitcoin purchased (or sold) by the Liquidity Provider in connection with the cash exchange process will, in turn, be delivered to (or from, as appropriate) the Custodian, on behalf of the Trust, in exchange for Baskets. To the extent an Authorized Participant chooses to rely on this cash exchange process when submitting an order to create or redeem a Basket, that Authorized Participant will pay (or receive) a cash amount based on a firm quote calculated by the Liquidity Provider, which will be equal to the spot price of bitcoin, as reported by the BBR (as defined below), at the time at which the Administrator receives the appropriate cash collateral amount (or the time at which the Administrator notifies the Authorized Participant that the order has been accepted, in the case of redemptions), plus a proportional transaction fee that is intended to cover the Liquidity Provider's expenses in connection with the creation or redemption order. Regardless of whether an Authorized Participant chooses to rely on this cash exchange process in connection with a given creation or redemption order, the Trust will create (or redeem, as appropriate) Baskets only upon the receipt (or distribution, as appropriate) of bitcoin, and will not create or redeem any Baskets based on the receipt or distribution of cash alone.

The Index and Carbon Neutrality

The MVIS One River Carbon Neutral Bitcoin Index is designed to reflect the performance of bitcoin in U.S. dollars on a carbon neutral basis. The Index is constructed using bitcoin price feeds from eligible bitcoin spot markets and volume weighted median price average (''VWMP''), calculated over 20 intervals in rolling three-minute increments,[8] less the estimated cost of offsetting the daily carbon emissions attributable to each bitcoin in the network.

The Index methodology was developed by MV Index Solutions GmbH (the ''Index Provider'' or ''MVIS'') and is monitored by the One River Index Committee (the ''Committee''), an independent, third-party calculation agent for the Index. MVIS, with the assistance of its affiliates, is also the calculation agent for the MVIS® CryptoCompare Bitcoin Benchmark Rate, which measures the value of the underlying bitcoin represented by the Index. The Index and its public dissemination provide transparency to investors.

In establishing the Index, MVIS and the Sponsor created a robust, transparent process for quantifying the carbon footprint of bitcoin in a clear, repeatable manner. The cost of the carbon offset used in the Index is calculated in the following steps. First, electricity consumption for the bitcoin mining network is recorded daily. Second, geolocation of bitcoin miners identifies the location of electricity usage. Third, for each location, the average production of electricity by its source of production (*e.g.,* solar, coal) is recorded. This estimates the carbon emission intensity of electricity consumption in the Bitcoin network. Fourth, total electricity consumption is multiplied by the carbon intensity of the Bitcoin network to estimate total carbon emissions. These steps allow MVIS to obtain a daily estimate of the carbon emissions necessary to run the Bitcoin network. The total carbon emissions of the Bitcoin network are divided by the total number of bitcoins in circulation[9] to estimate the carbon emissions attributable to each bitcoin on each day. Finally, the carbon emission attributable to each bitcoin is multiplied by the MCO2-token market price of a carbon offset, thus, providing a daily account of the cost of carbon for each bitcoin.

The Trust intends to offset the carbon footprint associated with the bitcoin it holds by paying for the retirement of voluntary carbon credits—equal to the daily estimated carbon emissions associated with the bitcoins held by the Trust. Voluntary carbon credits are certified and standardized under the Verra Verified Carbon Standard (''Verra''), an organization that

[7] The instantaneous retirement of carbon credits means that the Trust does not hold an intangible asset and that the carbon credit is permanently removed from tradeable supply.

[8] Unlike previous proposed rule changes relating to the listing of bitcoin products on U.S. exchanges that the Commission has disapproved, *see, e.g.,* Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the Listing and Trading of Shares of the Bitwise Bitcoin ETF Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 87267 (Oct. 9, 2019), 84 FR 55382 (Oct. 16, 2019) (SR–NYSEArca–2019–01) (the ''Bitwise Order'') (measuring price over 6 consecutive five-minute segments) and Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) and to List and Trade Shares of the United States Bitcoin and Treasury Investment Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 88284 (February 26, 2020), 85 FR 12595 (March 3, 2020) (SR–NYSEArca–2019–39) (the ''Wilshire Phoenix Order'') (measuring price over 12 consecutive five-minute segments), the Sponsor believes that the use of 20 consecutive three-minute segments will better enable the Index to approximate a normal sampling distribution with respect to bitcoin prices and, thus, will result in overall more accurate pricing of bitcoin.

[9] Bitcoin in circulation is number of coins that are circulating in the market and are in public hands. It is analogous to the flowing shares in the stock market. Several third-party vendors provide verified data on at least a daily basis. *See https://coinmarketcap.com/currencies/bitcoin/.*

establishes and manages standards and programs in connection with voluntary carbon credits. The Trust will only utilize carbon credits that meet the Verra standards.

The Trust has entered into an agreement with LIRDES S.A. (doing business as Moss Earth) (''Moss''), a company located in Uruguay, to pay for carbon credit tokens created by Moss (''MCO2 tokens'') representing certified reductions in greenhouse gas emissions. The MCO2 token is a digital representation of a carbon credit that is stored on a registry by Verra and can be acquired in over the counter or publicly traded markets. The MCO2 tokens issued by Moss are carbon offsets encrypted and tokenized utilizing blockchain technology and are stored on a registry managed by Verra.

Moss purchases carbon credits from projects that are certified under Verra's Verified Carbon Standard. Each circulating MCO2 token is intended to represent a claim on a certified carbon credit held in an aggregated pool of carbon credits within the Moss account on the Verra Registry. Tokenized carbon credits are fungible and do not represent a claim on a specific underlying carbon credit issued to a specific carbon reduction project.

The Trust will purchase MCO2 tokens from Moss at the end of March, June, September, and December at pre-negotiated prices and Moss will instantaneously retire the tokens to the public blockchain.[10] The number of MCO2 tokens paid for by the Trust will equal the aggregated sum of offsets implied by the daily carbon emissions for a single bitcoin over the preceding quarter multiplied by the average number of bitcoins held in the Trust's portfolio during the quarter, with a view towards tracking the carbon footprint offset estimate calculated by the Index. Employing tokenized carbon credits provides investors with enhanced transparency as the blockchain serves as a public record of the Trust transactions in carbon offsets on the Verra registry.

The Index value is the benchmark value of the bitcoin less the estimated daily cost of offsetting the carbon emissions of a single bitcoin. The value of the carbon offset provides the marketplace with a tangible measurement of the implied market cost of carbon emissions. The daily accumulation of the carbon offset component of the Index measures the totality of the cost of the carbon offset required for holding a single bitcoin over the accumulation period.

The Trust does not hold the carbon offset MCO2 tokens as an asset. Instead, the Trust pays for the MCO2 tokenized carbon offsets from Moss, who then instantaneously retire the tokens to the public blockchain, to reduce global carbon emissions by the carbon dioxide tonnage (or tonnage of other similar greenhouse gases) corresponding to such tokens. In tokenized form, investors and the marketplace can validate the activity in carbon credit offsets through the public blockchain, enhancing transparency. The retirement of the carbon offset makes it unusable in the future and is the final step in offsetting emissions. Upon expiration of its agreement with Moss in April 2031, the Trust will either enter into a replacement agreement, or alternatively pay for the retirement of MCO2 tokens or similar carbon credits at then current spot prices for such instruments.

According to the Sponsor, the Index is the aggregation of executed trade data for major bitcoin spot exchanges. To be eligible for inclusion in the Index, a constituent bitcoin exchange (''Constituent Bitcoin Exchange'') must facilitate spot trading of bitcoin against the US Dollar and make trade data and order data available through an application programming interface (''API'') with sufficient reliability, relevant data, and appropriate speed. The volume for spot trading must meet a minimum threshold when compared to the total volume of all Constituent Bitcoin Exchanges included in the Index. To be considered, an exchange must also enforce policies to ensure fair and transparent market conditions and have processes in place to impede illegal, or manipulative trading practices. Additionally, to be included as a constituent in the Index, each Constituent Bitcoin Exchange must comply with applicable law and regulation, including proper AML/KYC procedures.

The MVIS® CryptoCompare Bitcoin Benchmark Rate (BBR), the bitcoin component of the Index, is the bitcoin benchmark used in the tracking of funds comprising $821.2 million in total capitalization as of June 29, 2021, including recently introduced exchange-traded products in Canada.[11] The constituent exchanges are based on the top five ranking CryptoCompare exchange benchmarks: Coinbase, Gemini, Bitstamp, Kraken, and itBit. BBR was first released in 2019 to improve upon systematic evaluation of exchange counterparties with no established framework for assessing various exchange risks. CryptoCompare assigns a grade from AA to F to each spot exchange, with the goal of helping markets assess the lowest-risk exchanges in the industry. Eligible spot markets include all U.S. digital asset exchanges and/or regulated digital asset exchanges selected by the Committee. Such markets will be evaluated semi-annually, and the final selections will be made on the third Friday of January and July or during market disruptions where a market review is warranted, as determined by the Committee.

Top-tier exchanges are in the AA–B bracket and meet the standard of acceptable risk. More than 160 global spot exchanges are evaluated monthly based on data transparency, KYC stringency and transaction monitoring. Operational standards have increased across the board. The Sponsor notes that after ascertaining API data from these exchanges, the information is aggregated from actual trade data in a manner specifically designed to resist manipulation. Partitions are utilized to ensure large individual trades have a limited effect on the price of the Index by only influencing the volume-weighted median for a particular partition. Use of volume-weighted medians, as opposed to volume-weighted means, verifies that transactions conducted at outlying prices do not have an excessive effect on the value of a partition. The Index weighs each partition equally and also weighs each exchange that is a part of the Index equally.

Bitcoin and the Bitcoin Network[12]

According to the Registration Statement, bitcoin is a digital asset that can be transferred among participants on the Bitcoin network on a peer-to-peer basis via the internet. Unlike other means of electronic payments, bitcoin can be transferred without the use of a central administrator or clearing agency. Because a central party is not necessary to administer bitcoin transactions or maintain the bitcoin ledger, the term decentralized is often used in descriptions of bitcoin.

The ''Bitcoin network'' is a decentralized, open-source protocol of a peer-to-peer network. No single entity owns or operates the Bitcoin network.

[10] MCO2 tokens are recorded on the Ethereum blockchain and is publicly available. *See https://www.blockchain.com/explorer?view=eth.*

[11] *See* MVIS Investible Indices, available at: *https://www.mvis-indices.com/indices/digital-assets/mvis-cryptocompare-bitcoin-benchmark-rate.*

[12] Bitcoin (with an uppercase ''B'') is used to describe the system as a whole that is involved in maintaining the ledger of bitcoin ownership and facilitating the transfer of bitcoin among parties. When referring to the digital asset within the Bitcoin network, bitcoin is written with a lower case ''b.''

Bitcoin is not issued by any government, by banks or similar organizations. The infrastructure of the Bitcoin network is collectively maintained by a decentralized user base. The Bitcoin network is accessed through software, and software governs the creation, movement, and ownership of ''bitcoin,'' the unit of account on the Bitcoin network ledger. The value of bitcoin is determined, in part, by the supply of, and demand for, bitcoin in the global markets for trading bitcoin, market expectations for the adoption of bitcoin as a decentralized store of value, the number of merchants and/or institutions that accept bitcoin as a form of payment and the volume of private end-user-to-end-user transactions.

The first step in using bitcoin for transactions is to download specialized software referred to as a ''bitcoin wallet.'' A user's bitcoin wallet can run on a computer or smartphone, and can be used both to send and to receive bitcoin. Within a bitcoin wallet, a user can generate one or more unique ''bitcoin addresses,'' which are conceptually similar to bank account numbers on the Bitcoin Blockchain and are associated with a pair of public and private keys. After establishing a bitcoin address, a user can send or receive bitcoin from his or her bitcoin address to another user's address using the public and private keys. Sending bitcoin from one bitcoin address to another is similar in concept to sending a bank wire from one person's bank account to another person's bank account.

The amount of bitcoin associated with each bitcoin address is listed in a public ledger, referred to as a ''blockchain.'' Copies of the Bitcoin Blockchain exist on thousands of computers on the Bitcoin network throughout the internet. A user's bitcoin wallet will either contain a copy of the Bitcoin Blockchain or be able to connect with another computer that holds a copy of the Bitcoin Blockchain.

When a bitcoin user wishes to transfer bitcoin to another user, the sender must first request a bitcoin address from the recipient. The sender then uses his or her bitcoin wallet software to create a data packet containing the proposed addition (often referred to as a ''transaction'') to the Bitcoin Blockchain. The proposed transaction would reduce the sender's address and increase the recipient's address by the amount of bitcoin desired to be transferred, and is sent on a peer-to-peer basis to other computers participating in the Bitcoin network.

Bitcoin transaction and ownership records are reflected on the ''Bitcoin Blockchain,'' which is a digital public record or ledger. Copies of this ledger are stored in a decentralized manner on the computers of each Bitcoin network node (a node is any user who maintains on their computer a full copy of all the bitcoin transaction records, the blockchain, as well as related software). Transaction data is permanently recorded in files called ''blocks,'' which reflect transactions that have been recorded and authenticated by Bitcoin network participants. The Bitcoin network software source code includes protocols that govern the creation of new bitcoin and the cryptographic system that secures and verifies bitcoin transactions.

Bitcoin Transactions

According to the Registration Statement, bitcoin transactions are similar to an irreversible digital check. The transaction contains the sender's bitcoin address, the recipient's bitcoin address, the amount of bitcoin to be sent, a transaction fee and the sender's digital signature. The sender's use of his or her digital signature enables participants on the Bitcoin network to verify the authenticity of the bitcoin transaction. A user's digital signature is generated via usage of the user's so-called ''private key,'' one of two numbers in a so-called cryptographic ''key pair.'' A key pair consists of a ''public key'' and its corresponding private key, both of which are lengthy alphanumeric codes, derived together and possessing a unique relationship. Public keys are associated with bitcoin addresses that are publicly known and can accept a bitcoin transfer. Private keys are used to sign transactions that initiate the transfer of bitcoin from a sender's bitcoin address to a recipient's bitcoin address. Only the holder of the private key associated with a particular bitcoin address can digitally sign a transaction proposing a transfer of bitcoin from that particular bitcoin address.

Bitcoin can be transferred in direct peer-to-peer transactions through the direct sending of bitcoin over the Bitcoin Blockchain from one bitcoin address to another. Among end-users, bitcoin can be used to pay other members of the Bitcoin network for goods and services under what resembles a barter system. Consumers can also pay merchants and other commercial businesses for goods or services through direct peer-to-peer transactions on the Bitcoin Blockchain or through third-party service providers. In addition, investors may purchase and sell bitcoin to speculate as to the value of bitcoin in the bitcoin market, or as a long-term investment to diversify their portfolio.

The value of bitcoin within the market is determined, in part, by the supply of and demand for bitcoin in the global bitcoin market, market expectations for the adoption of bitcoin as a store of value, the number of merchants that accept bitcoin as a form of payment, and the volume of peer-to-peer transactions, among other factors.

Custody of the Trust's Bitcoins

The Custodian will retain custody of the Trust's bitcoin in an account for the Trust (the ''Bitcoin Account''). The Custodian will keep a substantial portion of the private keys associated with the Trust's bitcoin in ''cold storage'' or similarly secure technology. Cold storage is a safeguarding method with multiple layers of protections and protocols, by which the private key(s) corresponding to the Trust's bitcoin is (are) generated and stored in an offline manner. Private keys are generated in offline computers that are not connected to the internet so that they are resistant to hacking.

Calculation of Net Asset Value

The NAV of the Trust will be equal to the median price of the bitcoin used in the calculation of the Index less the Trust's liabilities, including the cost of carbon measured in the Index, divided by the total number of outstanding Shares. The accumulation of the daily carbon offset costs calculated in the Index act as an expense to the Trust. The payment for the retirement of carbon offsets will occur once per quarter of the calendar year. The number of MCO2 tokens retired will equal the aggregated sum of offsets implied by the daily carbon footprint for each bitcoin during the quarter. The NAV will accrue the estimated carbon cost daily.

The Trust will not hold carbon offsets as assets; they are functionally equivalent to an expense of the Trust and will be retired by the Trust instantaneously upon payment. Furthermore, the creation of the Index and tokenization of the carbon offsets will provide additional transparency to investors with respect to the NAV of the Trust vis-à-vis the estimated carbon footprint of the bitcoin retired by the Trust, and will thus give investors an opportunity to independently monitor the Trust's efforts to offset the carbon emissions associated with its bitcoin holdings.

The Administrator will calculate the NAV of the Trust once each Exchange trading day. The NAV for a normal trading day will be released after 4:00

p.m. Eastern Time (''E.T.''). Trading during the core trading session on the Exchange typically closes at 4:00 p.m. E.T. However, NAVs are not officially struck until later in the day (often by 5:30 p.m. E.T. and almost always by 8:00 p.m. E.T.). The pause between 4:00 p.m. E.T. and 5:30 p.m. E.T. (or later) provides an opportunity to algorithmically detect, flag, investigate, and correct unusual pricing should it occur.

Intraday Indicative Value

In order to provide updated information relating to the Trust for use by Shareholders and market professionals, the Trust's website, as well as one or more major market data vendors, will disseminate an updated intraday indicative value (''IIV'') per Share updated every 15 seconds through the facilities of CTA/CQ High Speed Lines during the Exchange's Core Trading Session.[13] The IIV will be calculated by using the prior day's closing NAV per Share of the Trust as a base and updating that value throughout the trading day to reflect changes in the most recently reported price level of the Index as reported by Bloomberg, L.P. or another reporting service.

The IIV disseminated during the NYSE Arca Core Trading Session should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session by one or more major market data vendors. In addition, the IIV will be available through on-line information services.

Creation and Redemption of Shares

According to the Registration Statement, the Trust will issue Shares on an ongoing basis, but only in one or more Baskets. A Basket equals a block of 50,000 Shares. The Trust intends to redeem Shares in Baskets on an ongoing basis from Authorized Participants, according to the procedures described herein.

The creation and redemption of a Basket requires the delivery to the Trust, or the distribution by the Trust, of the number of whole and fractional bitcoins represented by each Basket being created or redeemed, the number of which is determined by dividing the number of bitcoins owned by the Trust at 4:00 p.m. E.T. on the trade date of a creation or redemption order, as adjusted for the number of whole and fractional bitcoins constituting accrued but unpaid fees and expenses of the Trust, by the number of Shares outstanding at such time (the quotient so obtained calculated to one one-hundred-millionth of one bitcoin), and multiplying such quotient by 50,000 (the ''Basket Bitcoin Amount''). The Basket Bitcoin Amount multiplied by the number of Baskets being created or redeemed is the ''Total Basket Bitcoin Amount.''

The MCO2 tokenized carbon offset is not a part of the Basket as it is not an asset to the Trust, nor does the Trust's payment for the retirement of such MCO2 tokens impact the process by which the Trust creates or redeems Baskets. The Trust will pay for the retirement of such carbon offsets at a quarterly frequency, thereby permanently offsetting carbon emissions.

According to the Registration Statement, Authorized Participants are the only persons that may place orders to create and redeem Creation Baskets. Authorized Participants must (1) be a registered broker-dealer, (2) enter into a Participant Agreement with the Sponsor, the Administrator, the Marketing Agent and the Liquidity Providers,[14] and (3) in the case of the creation or redemption of Baskets that do not use the Conversion Procedures,[15] own a bitcoin wallet address that is recognized by the Custodian as belonging to the Authorized Participant.

Creation Procedures

According to the Registration Statement, on any business day, an Authorized Participant may order one or more Creation Baskets from the Trust by placing a creation order with the Administrator. For purposes of processing both purchase and redemption orders, a ''business day'' means any day other than a day when the Exchange or the New York Stock Exchange is closed for regular trading.

As noted above, creation orders will be placed ''in-kind.'' Creation orders must be placed no later than 3:59:59 p.m. E.T. on each business day. Authorized Participants may only create Baskets and cannot create any Shares in an amount less than a Basket.

The Basket Bitcoin Amount required for a Creation Basket will be determined by dividing the number of bitcoins owned by the Trust at 4:00 p.m. E.T. on the trade date of a creation or redemption order, as adjusted for the number of whole and fractional bitcoins constituting accrued but unpaid fees and expenses of the Trust, by the number of Shares outstanding at such time (the quotient so obtained calculated to one one-hundred-millionth of one bitcoin), and multiplying such quotient by 50,000. All questions as to the composition of a Basket Bitcoin Amount will be conclusively determined by the Sponsor and will be final and binding on all persons interested in the Trust.

Redemption Procedures

According to the Registration Statement, the procedures by which an Authorized Participant can redeem one or more Creation Baskets mirror the procedures for the creation of Creation Baskets. On any business day, an Authorized Participant may place a redemption order specifying the number of Redemption Baskets to be redeemed. As noted above, redemption orders must be placed ''in-kind.'' Redemption orders must be placed no later than 3:59:59 p.m. E.T. on each Business Day. The Authorized Participants may only redeem Baskets and cannot redeem any Shares in an amount less than a Basket.

Bitcoin and Investor Protection

In prior orders relating to the listing of products on U.S. exchanges, the Commission Staff expressed its concern that the global market for bitcoin may be subject to potential manipulation.[16] In

[13] Several major market data vendors display and/or make widely available IIVs taken from the Consolidated Tape Association (''CTA'') or other data feeds. In addition, the IIV will be available through on-line information services such as Bloomberg and Reuters.

[14] Although the Trust will create Baskets only upon the receipt of bitcoins, and will redeem Baskets only by distributing bitcoins, an Authorized Participant may deposit cash with the Administrator, which will facilitate the purchase or sale of bitcoins through a Liquidity Provider on behalf of an Authorized Participant (the ''Conversion Procedures''). Liquidity Providers must (1) enter into a Participant Agreement with the Sponsor, the Administrator, the Marketing Agent and each Authorized Participant and (2) own a Liquidity Provider Account.

[15] The Conversion Procedures will be facilitated by a single Liquidity Provider. On an order-by-order basis, the Sponsor will select the Liquidity Provider that it believes will provide the best execution of the Conversion Procedures, and will base its decision on factors such as the Liquidity Provider's creditworthiness, financial stability, the timing and speed of execution, liquidity and the likelihood of, and capabilities in, execution, clearance and settlement. In the event that an order cannot be filled in its entirety by a single Liquidity Provider, additional Liquidity Provider(s) will be selected by the Sponsor to fill the remaining amount based on the criteria above.

[16] *See* Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To List and Trade Shares of the Winklevoss Bitcoin Trust, Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (Aug. 1, 2018) (SR–BatsBZX–2016–30) (the ''Winklevoss Order''); the Bitwise Order; Order the Wilshire Phoenix Order; Order Disapproving a Proposed Rule Change to List and Trade the Shares of the ProShares Bitcoin ETF

Continued

order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act.[17] In these disapproval orders, the Commission outlined that a proposal relating to a Bitcoin-based ETP could satisfy its concerns regarding potential for fraud and manipulation by demonstrating that (1) the underlying commodity market is inherently resistant to fraud and manipulation; (2) there are other means to prevent fraudulent and manipulative acts and practices that are sufficient; or (3) the listing exchange has entered into a surveillance sharing agreement with a regulated market of significant size relating to the underlying or reference assets.

According to the Sponsor,[18] bitcoin is dominant, accounting for more than 49% of the total market capitalization of cryptoassets.[19] As of June 2021, the market cap for Bitcoin is over $600 billion.[20] Bitcoin also has the longest history of any cryptoasset. Alongside the growth in users, active wallets and market capitalization, institutional ratings of various tokens have increased substantially. Ratings are based on factors such as core team, project, and ecosystem metrics. Bitcoin ranks as one of the most widely used, if not the most widely used, cryptoassets in the global token market. Within the Bitcoin network, there are more than 38 million unique bitcoin wallet addresses holding a positive balance, which shows a steady increase in the number of bitcoin owners and depth of ownership over the last four years. Holding periods for bitcoin are also relatively long, as 58% of owners maintain ownership for longer than a one-year period, and 70% of all holders are in profitable positions.[21]

The marketplace is maturing with increased institutional participation.[22] Twenty-eight public companies hold bitcoin, accounting for less than 1% of the total supply. More traditional financial market participants appear to be embracing cryptoassets: Large insurance companies,[23] asset managers,[24] university endowments,[25] pension funds,[26] and even historically bitcoin skeptical fund managers [27] are allocating to bitcoin. Established companies like Tesla, Inc.,[28] MicroStrategy Incorporated,[29] and Square, Inc.,[30] among others, have recently announced substantial investments in bitcoin in amounts as large as $1.5 billion (Tesla) and $425 million (MicroStrategy). MassMutual Insurance Company, one of the nation's oldest private companies and a historically conservative investor, has purchased over $100 million in bitcoin.

The rise in the digital economy has led to an increase in activity within the regulated banking system, reflecting increased institutional demand. Silvergate Bank, a commercial bank service provider in California, reported fee income from digital currency customers of $7.1 million in the first quarter of 2021, up from $1.7 million a year earlier. These are substantial developments since the Commission last reviewed a bitcoin ETF proposal. Additionally, licensed and regulated service providers have emerged to provide fund custodial services for digital assets, among other services. For example, in December 2020, the Commission adopted a conditional no-action position permitting certain special purpose broker-dealers to custody digital asset securities under Rule 15c3–3 under the Exchange Act; in September 2020, the Staff of the Commission released a no-action letter permitting certain broker-dealers to operate a non-custodial Alternative Trading System (''ATS'') for digital asset securities, subject to specified conditions.

Further, the U.S. Department of the Treasury's (the ''Treasury'') Financial Crimes Enforcement Network (''FinCEN''), which in 2013 and 2019 released guidance regarding the applicability of the Bank Secrecy Act (''BSA'') and its implementing regulations to exchangers and administrators of convertible virtual currency,[31] has recently proposed two separate rulemaking initiatives aimed at enhancing transparency, which would require certain financial institutions to collect, retain, share and report to FinCEN information related to certain transactions involving convertible virtual currency or certain digital assets,

and the ProShares Short Bitcoin ETF, Securities Exchange Act Release No. 83904 (Aug. 22, 2018), 83 FR 43934 (Aug. 28, 2018) (SR–NYSEArca–2017–139) (the ''ProShares Order''); Order Disapproving a Proposed Rule Change Relating to Listing and Trading of the Direxion Daily Bitcoin Bear 1X Shares, Direxion Daily Bitcoin 1.25X Bull Shares, Direxion Daily Bitcoin 1.5X Bull Shares, Direxion Daily Bitcoin 2X Bull Shares, and Direxion Daily Bitcoin 2X Bear Shares Under NYSE Arca Rule 8.200–E, Securities Exchange Act Release No. 83912 (Aug. 22, 2018), 83 FR 43912 (Aug. 28, 2018) (SR–NYSEArca–2018–02) (the ''Direxion Order''); Order Disapproving a Proposed Rule Change to List and Trade the Shares of the GraniteShares Bitcoin ETF and the GraniteShares Short Bitcoin ETF, Securities Exchange Act Release No. 83913 (Aug. 22, 2018), 83 FR 43923 (Aug. 28, 2018) (SR–CboeBZX–2018–01) (the ''GraniteShares Order'').

[17] 15 U.S.C. 78f(b)(5).

[18] *See* Registration Statement on Form S–1 at 42.

[19] *Coinmarketcap.com*, bitcoin price statistics are available at *https://coinmarketcap.com/currencies/bitcoin/*.

[20] *See id.*

[21] *See Coinmarketcap.com*, on-chain analysis of bitcoin available at *https://coinmarketcap.com/currencies/bitcoin/onchain-analysis/.*

[22] *See* Registration Statement on Form S–1 at 42.

[23] On December 10, 2020, Massachusetts Mutual Life Insurance Company (MassMutual) announced that it had purchased $100 million in bitcoin for its general investment account. *See* MassMutual Press Release ''Institutional Bitcoin provider NYDIG announces minority stake purchase by MassMutual'' (December 10, 2020), available at: *https://www.massmutual.com/about-us/news-and-press-releases/press-releases/2020/12/institutional-bitcoin-provider-nydig-announces-minority-stake-purchase-by-massmutual.*

[24] *See, e.g.,* ''BlackRock's Rick Rieder says the world's largest asset manager has 'started to dabble' in bitcoin' '' (February 17, 2021) available at: *https://www.cnbc.com/2021/02/17/blackrock-has-started-to-dabble-in-bitcoin-says-rick-rieder.html* and ''Guggenheim's Scott Minerd Says Bitcoin Should Be Worth $400,000'' (December 16, 2020), available at: *https://www.bloomberg.com/news/articles/2020-12-16/guggenheim-s-scott-minerd-says-bitcoin-should-be-worth-400-000.*

[25] *See, e.g.,* ''Harvard and Yale Endowments Among Those Reportedly Buying Crypto'' (January 25, 2021), available at: *https://www.bloomberg.com/news/articles/2021-01-26/harvard-and-yale-endowments-among-those-reportedly-buying-crypto.*

[26] *See, e.g.,* ''Virginia Police Department Reveals Why its Pension Fund is Betting on Bitcoin'' (February 14, 2019), available at: *https://finance.yahoo.com/news/virginia-police-department-reveals-why-194558505.html.*

[27] *See, e.g.,* ''Bridgewater: Our Thoughts on Bitcoin'' (January 28, 2021), available at: *https://www.bridgewater.com/research-and-insights/our-thoughts-on-bitcoin* and ''Paul Tudor Jones says he likes bitcoin even more now, rally still in the 'first inning' '' (October 22, 2020), available at: *https://www.cnbc.com/2020/10/22/-paul-tudor-jones-says-he-likes-bitcoin-even-more-now-rally-still-in-the-first-inning.html.*

[28] *See* Form 10–K submitted by Tesla, Inc., for the fiscal year ended December 31, 2020 at 23: *https://www.sec.gov/ix?doc=/Archives/edgar/data/1318605/000156459021004599/tsla-10k20201231.htm.*

[29] *See* Form 10–Q submitted by MicroStrategy Incorporated for the quarterly period ended September 30, 2020 at 8: *https://www.sec.gov/ix?doc=/Archives/edgar/data/1050446/000156459020047995/mstr-10q20200930.htm.*

[30] *See* Form 10–Q submitted by Square, Inc., for the quarterly period ended September 30, 2020 at 51: *https://www.sec.gov/ix?doc=/Archives/edgar/data/1512673/000151267320000012/sq-20200930.htm.*

[31] *See, e.g.,* FIN–2013–G001, *Application of FinCEN's Regulations to Persons Administering, Exchanging, or Using Virtual Currencies* (Mar. 18, 2013); FIN–2019–G001, *Application of FinCEN's Regulations to Certain Business Models Involving Convertible Virtual Currencies* (May 9, 2019) (consolidating existing FinCEN regulations, guidance and administrative rulings that relate to money transmission involving virtual currency and applying the same interpretive criteria to other common business models involving convertible virtual currencies). *See also* FIN–2019–A003, *Advisory on Illicit Activity Involving Convertible Virtual Currency* (May 9, 2019) (advising financial institutions in identifying and reporting suspicious activity related to criminal exploitation of convertible virtual currencies for money laundering, sanctions evasion, and other illicit financing purposes).

including identification information of persons engaged in such transactions.[32] Although FinCEN has not finalized these proposed rules, they signal an intention by FinCEN to close any regulatory gaps and require certain cryptoasset transactions to be subject to anti-money laundering compliance measures. Further to this point, in March 2021 the Financial Action Task Force (''FATF'') issued updated draft guidance that, when issued in final form, would significantly broaden the reach of certain anti-money laundering, including know-your-customer, compliance requirements applicable to transactions in virtual assets or involving virtual asset service providers.[33] Although FinCEN has not finalized its proposed rules yet, and the FATF guidance does not have the force of law, these actions signal a concerted effort among regulatory bodies to introduce requirements that would reduce anonymity of cryptoasset transactions and implement stronger anti-money laundering compliance measures among industry participants. In addition, the Treasury's Office of Foreign Assets Control (''OFAC'') has brought enforcement actions over apparent violations of the sanctions laws in connection with the provision of wallet management services for digital assets.[34] The proposed anti-money laundering rules are intended to reduce anonymity and promote transparency within the cryptoasset markets generally and of cryptoasset exchanges specifically, including the exchanges that compose the bitcoin component of the Index (as described below). These regulatory and enforcement actions acknowledge the increasing use of bitcoin and other cryptoassets within the broader global financial sector generally, and represent ongoing efforts to regularize the use of such cryptoassets within existing regulatory frameworks.

Technological advancements on the bitcoin protocol are also progressing and will broaden institutional adoption of the bitcoin protocol as a technology. The last major upgrade to the protocol occurred in 2017, when the technical feature known as ''segregated witness'' (''Segregated Witness'') was added. The Segregated Witness advancement allowed for the rise in block space and enabled the Lightning Network, a fast and inexpensive payment system that operates on the bitcoin protocol, to be safely employed. The Lightning network's capacity has risen from less than $200 thousand to more than $50 million since then.

Taproot is a technological innovation that will be implemented in November 2021. This innovation will allow for single-signature and multi-signature scripts and other complex transactions to become identical-looking commitments on the Bitcoin Blockchain. The Taproot innovation will accommodate complex transactions through smart contracts, which will have broader financial adoption. Institutional holdings of bitcoin reflect collateral that can benefit from these technological advancements.

There have also been advancements in regulatory frameworks, both on a global and national scale, on cryptoasset exposures since the Commission's last review. The Bank of International Settlements, the global bank for central banks who supports monetary and financial stability, provided consultation on prudential treatment of cryptoassets. The philosophy behind the guidance was ''same risk, same activity, same treatment,'' reinforcing the concept of ''technological neutrality.'' The design of the prudential treatment of cryptoassets is conservative, with a 1250% risk weight applied to the maximum of long and short exposures.[35]

Furthermore, within the United States, the Commodity Futures Trading Commission (''CFTC'') has exercised its regulatory jurisdiction in bringing a number of enforcement actions related to bitcoin and against trading platforms that offer cryptoasset trading,[36] including, in certain cases, against defendants for direct trading of cryptoassets.[37]

In *Gelfman,* the CFTC filed for injunctive relief against Gelfman Blueprint Inc., and its CEO, Nicholas Gelfman, concerning an alleged Ponzi scheme, asserting jurisdiction on the basis of Mr. Gelfman engaging in some Bitcoin trading and thereby engaging in manipulative trading in commodities. Similarly, in *CabbageTech,* CabbageTech, Corp. was found guilty of fraudulent behavior in another case brought by the CFTC for ''a deceptive and fraudulent virtual currency scheme.'' The CFTC has historically asserted jurisdiction over spot market commodities trading, where manipulative trading in the spot market can affect its derivatives market. The *Gelfman* case is unique in that the CFTC asserted jurisdiction over the spot market when there was little to no derivatives trading in the United States. Similarly, the *CabbageTech* case did not indicate that there was any derivatives trading conducted, yet the court rejected the defendant's claim that the CFTC had no jurisdiction in the matter. Courts have taken an expansive interpretation of the CFTC's jurisdiction over trading in particular virtual currency products on the basis that futures trading in such products as a class already occurs.[38] The CFTC's enforcement division has remained consistently active in the virtual currency space. On October 1, 2020, the CFTC filed a civil enforcement action against the owner/operators of the BitMEX trading platform, which was one of the largest bitcoin derivative exchanges.[39] On March 19, 2021, the CFTC ordered digital asset exchange

[32] Joint Notice of Proposed Rulemaking, Threshold for the Requirement To Collect, Retain, and Transmit Information on Funds Transfers and Transmittals of Funds That Begin or End Outside the United States, and Clarification of the Requirement to Collect, Retain, and Transmit Information on Transactions Involving Convertible Virtual Currencies and Digital Assets with Legal Tender Status, 85 FR 68005 (Oct. 27, 2020); Notice of Proposed Rulemaking, Requirements for Certain Transactions Involving Convertible Virtual Currency or Digital Assets, 85 FR 83840 (Dec. 23, 2020).

[33] *See* FATF Draft updated Guidance for a risk-based approach to virtual assets and VASPs (March 2021), available at *http://www.fatf-gafi.org/media/fatf/documents/recommendations/March%202021%20-%20VA%20Guidance%20update%20-%20Sixth%20draft%20-%20Public%20consultation.pdf.*

[34] *See* Enforcement Release, U.S. Dep't of the Treasury, ''OFAC Enters Into $507,375 Settlement with BitPay, Inc. for Apparent Violations of Multiple Sanctions Programs Related to Digital Currency Transactions'' (Feb. 18, 2021), available at *https://home.treasury.gov/system/files/126/20210218_bp.pdf* and Enforcement Release, U.S. Dep't of the Treasury, ''OFAC Enters Into $98,830 Settlement with BitGo, Inc. for Apparent Violations of Multiple Sanctions Programs Related to Digital Currency Transactions'' (Dec. 30, 2020), available at *https://home.treasury.gov/system/files/126/20201230_bitgo.pdf.*

[35] The Basel Committee on Banking Supervision has published a public consultation on preliminary proposals for the prudential treatment of banks' cryptoasset exposures. *See* Prudential Treatment of Cryptoasset Exposures available at: *https://www.bis.org/bcbs/publ/d519.htm.*

[36] The CFTC's annual report for Fiscal Year 2020 (which ended on September 30, 2020) noted that the CFTC ''continued to aggressively prosecute misconduct involving digital assets that fit within the CEA's definition of commodity'' and ''brought a record setting seven cases involving digital assets.'' *See* CFTC FY2020 Division of Enforcement Annual Report, available at: *https://www.cftc.gov/media/5321/DOE_FY2020_AnnualReport_120120/download.*

[37] *See CFTC* v. *Gelfman Blueprint,* No. 17–7181 (S.D.N.Y. Sept. 21, 2017) (''Gelfman'') and *CFTC* v. *Patrick K. McDonnell & Cabbagetech Corp., d/b/a Coin Drop Markets,* (No. 18–CV–0361) (E.D.N.Y. Aug. 24, 2018) (''CabbageTech'').

[38] *See Commodity Futures Trading Comm'n* v. *My Big Coin Pay, Inc.,* 334 F. Supp. 3d 492, 496–97 (D. Mass. 2018) (finding that defendants' virtual currency, ''My Big Coin,'' was a commodity subject to CFTC anti-fraud and anti-manipulation authority because contracts for future delivery of virtual currencies were already ''dealt in'' even if futures contracts for My Big Coin, specifically, were not).

[39] *See* CFTC Release No. 8270–20 (October 1, 2020), available at: *https://www.cftc.gov/PressRoom/PressReleases/8270-20.*

operator CoinBase Inc., to pay $6.5 million in monetary penalties and desist from further violations of Commodity Exchange Act and CFTC rules in connection with alleged reckless delivery of false, misleading, or inaccurate reports concerning transactions in digital assets, including bitcoin, on the Global Digital Asset Exchange (GDAX) electronic trading platform, as well as allegations of manipulative market activities by CoinBase Inc. employees.[40]

The U.S. Office of the Comptroller of the Currency (''OCC'') has also made clear that federally-chartered banks are able to provide custody services for cryptoassets and other digital assets.[41] In addition, the Board of Governors of the Federal Reserve System proposed guidelines to evaluate the requests for account services at Federal Reserve Banks in light of recent changes to the financial payments landscape.[42] The guidelines are in response to the rapidly-evolving technological progress and new financial services observed through cryptoassets, of which bitcoin is the dominant asset. The proposal is aimed at financial stability, protecting consumers, and promoting innovation in the payments system.

The Sponsor notes below the advancement of the application of the Index (as described below) over that same period of time, including how the Index articulates the potential remedy that it can be to sufficiently mitigate the pricing issues and various risks surrounding market manipulation.

Bitcoin and Market Integrity

The bitcoin market has evolved significantly as adoption pressure has broadened from both retail and institutional clients from a global perspective. There has been concern over whether cryptoasset exchanges have mechanisms in place to report and remediate price and ensure market integrity. As the industry has grown substantially and the number of marketplaces expands, it follows that the quality of these marketplaces will vary. This notion is amplified for exchanges that are unregulated or decentralized. Therefore, the Sponsor believes that there must be sufficiency of data inputs for the calculation of the spot price of bitcoin. In turn the data must be provided under licensing arrangements with each exchange, which in turn impose strict entry criteria. As described below, the design of the methodology and framework of the Index are sufficiently resistant to market manipulation while providing oversight managed by an independent committee.

Index Price Manipulation

According to the Sponsor, the use of the Index eliminates those bitcoin spot markets with indicia of suspicious, fake, or non-economic volume from the NAV calculation methodology pursuant to which the Trust prices its Shares. In addition, the use of multiple eligible bitcoin spot markets is designed to mitigate the potential for idiosyncratic market risk, as the failure of any individual bitcoin spot market should not materially impact pricing for the Trust.

The use of 20 rolling three-minute increments means a malicious actor would need to sustain efforts to manipulate the market over an extended period of time, or would need to replicate efforts multiple times, potentially triggering review from the spot market or regulators, or both. The use of a ''median'' price limits the ability of outlier prices, which may have been caused by attempts to manipulate the price on a particular market, to impact the NAV, as it systematically excludes those outlier prices from the NAV calculation. Any attempt to manipulate the NAV would require a substantial amount of capital distributed across a majority of the eligible spot markets, and potentially coordinated activity across those markets, making it more difficult to conduct, profit from, or avoid the detection of market manipulation.

The Sponsor further believes that because the Trust will, in all ordinary circumstances, not purchase or sell bitcoin, but instead process all creations and redemptions in-kind in transactions with Authorized Participants, the Trust is uniquely protected against potential attempts by bad actors to manipulate the price of bitcoin on spot markets contributing to the Index and thereby the Trust's NAV calculation.[43] This is true even with respect to transactions with Authorized Participants who rely on the cash exchange process, as regardless of whether an Authorized Participant chooses to rely on such process in connection with a given creation or redemption order, the Trust will create (or redeem, as appropriate) Baskets only upon the receipt (or distribution, as appropriate) of bitcoin, and will not create or redeem any Baskets based on the receipt or distribution of cash alone. Even if a bad actor were able to temporarily manipulate the price of bitcoin on a spot market or manipulate enough of the volume of the markets to overwhelm the protections designed into the Index and thereby the NAV, the fact that the Trust will create or redeem Baskets only upon receipt or distribution of bitcoin (in all circumstances barring a forced redemption) means that the amount of bitcoin per Share held by the Trust would not be impacted. Therefore, long-term Shareholders of the Trust would be protected in a way that shareholders of trusts processing creations or redemptions directly in cash would not be protected. In other words, because the Trust will generally not accept cash in order to create new Shares or, barring a forced redemption of the Trust or under other extraordinary circumstances, be forced to sell bitcoin to pay cash for redeemed Shares, the ratio of bitcoin per Share that Authorized Participants will tender (for creations) or receive (for distributions) will not change as a result of any changes in the price per Share, even if the Authorized Participant relies on the cash exchange process to facilitate such creation or redemption.

The Trust's NAV incorporates unpaid expenses, including costs of carbon offsets through the MCO2 token. If MCO2 tokens are unavailable for any reason, the carbon credit prices will be benchmarked to the average wholesale price as defined by IHS Markit survey for voluntary carbon credit wholesale prices, OPIS, plus the cost of tokenizing the credits. In addition, the Trust's performance will necessarily fall below that of similar bitcoin-focused investment vehicles due to the expenses associated with retiring MCO2 tokens as required to track the Index. Given the Trust's focus on carbon neutrality, its performance from a purely financial perspective will necessarily fall below other similar investment structures that do not seek to achieve a carbon neutral result from their portfolio investments. However, as discussed above, the Sponsor believes that the Trust's use of in-kind creations and distributions will tend to insulate Shareholders from any impact that these carbon neutrality-related expenses may have on the price of Shares by ensuring that Shareholders will pay (for creations) and receive (for

[40] *See* CFTC Release No. 8369–21 (March 19, 2021), available at: *https://www.cftc.gov/PressRoom/PressReleases/8369-21.*

[41] *See* OCC News Release 2021–2 (January 4, 2021), available at: *https://www.occ.gov/news-issuances/news-releases/2021/nr-occ-2021-2.html.*

[42] *See* Federal Reserve Docket No. OP–1747 (May 5, 2021), available at *https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20210505a1.pdf.*

[43] Except to pay certain expenses or in the case of a forced redemption or other ordinary circumstances, the Trust will not purchase or sell bitcoin directly.

redemptions) the same number of bitcoin regardless of Share price.

Availability of Information

Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. The IIV will be available through on-line information services.

Information about the Shares will be posted to the Trust's website *https://www.oneriveram.com/digital-strategies.* Information will include: (i) The NAV and NAV per Share for each Exchange trading day, posted at end of day; (ii) the daily holdings of the Trust, before 9:30 a.m. E.T. on each Exchange trading day; (iii) the Trust's effective prospectus, in a form available for download; and (v) the Shares' ticker and CUSIP information; and additional quantitative information updated on a daily basis for the Trust. The Trust's website will include: (i) The prior business day's trading volume, the prior business day's reported NAV and closing price, and a calculation of the premium and discount of the closing price or mid-point of the bid/ask spread at the time of NAV calculation (''Bid/Ask Price'') against the NAV and (ii) data in chart format displaying the frequency distribution of discounts and premiums of the daily closing price or Bid/Ask Price against the NAV, within appropriate ranges, for at least each of the four previous calendar quarters.

The Index value is available on Calculation Agent's website and from major market data vendors. Quotation and last sale information for bitcoin will be widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters. In addition, the complete real-time price (and volume) data for bitcoin is available by subscription from Reuters and Bloomberg. The spot price of bitcoin also is available on a 24-hour basis from major market data vendors, including Bloomberg and Reuters. Information relating to trading, including price and volume information, in bitcoin will be available from major market data vendors and from the exchanges on which bitcoin are traded. The normal trading hours for bitcoin exchanges are 24-hours per day, 365-days per year.

The Sponsor will publish the NAV per Share on the Trust's website as soon as practicable after its determination. The Trust will provide website disclosure of its NAV daily. The website disclosure of the Trust's NAV will occur at the same time as the disclosure by the Sponsor of the NAV to Authorized Participants so that all market participants are provided such information at the same time. Therefore, the same information will be provided on the public website as well as in electronic files provided to Authorized Participants. Accordingly, each investor will have access to the current NAV of the Trust through the Trust's website, as well as from one or more major market data vendors.

Trading

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4:00 to 8:00 p.m. E.T. in accordance with NYSE Arca Rule 7.34–E (Early, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00, for which the MPV for order entry is $0.0001.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Rule 8.201–E. Trading of the Shares will be subject to NYSE Arca Rule 8.201–E(g), which sets forth certain restrictions on Equity Trading Permit (''ETP'') holders (''ETP Holders'') acting as registered market makers in Commodity-Based Trust Shares to facilitate surveillance. The Exchange represents that, for initial and continued listing, the Trust will be in compliance with Rule 10A–3 [44] under the Act, as provided by NYSE Arca Rule 5.3–E. A minimum of 100,000 Shares of the Trust will be outstanding at the commencement of trading on the Exchange.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Trust.[45] Trading in Shares of the Trust will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

The Exchange may halt trading during the day in which an interruption to the dissemination of the IIV occurs.[46] If the interruption to the dissemination of the IIV persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants. The Exchange may also halt trading if the value of the Index is no longer calculated or available on at least a 15-second delayed basis from a source unaffiliated with the Sponsor, Trust, Custodian or the Exchange.

Surveillance

The Exchange represents that trading in the Shares of the Trust will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[47] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''), and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares from

[44] 17 CFR 240.10A–3.

[45] *See* NYSE Arca Rule 7.12–E.

[46] A limit up/limit down condition in the futures market would not be considered an interruption requiring the Trust to be halted.

[47] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement (''CSSA'').[48] The Exchange is also able to obtain information regarding trading in the Shares in connection with such ETP Holders' proprietary or customer trades which they effect through ETP Holders on any relevant market.

In addition, the Exchange also has a general policy prohibiting the improper distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (1) the description of the portfolios of the Trust, (2) limitations on portfolio holdings or reference assets, or (3) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange.

The Sponsor has represented to the Exchange that it will advise the Exchange of any failure by the Trust to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Trust is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[49] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.201–E. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets. In addition, the Exchange may obtain information regarding trading in the Shares from markets that are members of ISG or with which the Exchange has in place a CSSA. Also, pursuant to NYSE Arca Rule 8.201–E(g), the Exchange is able to obtain information regarding trading in the Shares and the underlying bitcoin or any bitcoin derivative through ETP Holders acting as registered market makers, in connection with such ETP Holders' proprietary or customer trades through ETP Holders which they effect on any relevant market.

The proposed rule change is designed to prevent fraudulent and manipulative acts and practices. The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws, and the Exchange may obtain information regarding trading in the Shares via the ISG, from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. Beyond the use of such surveillance agreements, the Exchange believes the significant liquidity in the spot market and resultant minimal impact of market orders on the overall price of bitcoin, in conjunction with the Trust's offering only in-kind creation and redemption of Shares with respect to Authorized Participants, further mitigates the risk associated with potential manipulation and financially disincentivizes manipulation of the Index.

To protect investors and the public interest, there is a considerable amount of bitcoin price and market information available on public websites and through professional and subscription services. Investors may obtain, on a 24-hour basis, bitcoin pricing information based on the spot price for bitcoin from various financial information service providers. The closing price and settlement prices of bitcoin are readily available from exchanges and other publicly available websites. In addition, such prices are published in public sources, or on-line information services such as Bloomberg and the Wall Street Journal. In addition to the price transparency of the Index and of bitcoin itself, the Trust will provide website disclosure of its bitcoin holdings daily, as well as additional information about the Trust. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session (normally 9:30 a.m. E.T. to 4:00 p.m. E.T.) by one or more major market data vendors. In addition, the IIV will be available through on-line information services. The Exchange represents that the Exchange may halt trading during the day in which an interruption to the dissemination of the IIV or the Index value occurs. If the interruption to the dissemination of the IIV or the Index value persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants.

The proposed rule change is also designed to promote just and equitable principles of trade and to protect investors and the public interest in that there is a considerable amount of bitcoin price and market information available on public websites and through professional and subscription services. Investors may obtain, on a 24-hour basis, bitcoin pricing information based on the spot price for bitcoin from various financial information service providers.

The Trust's website will also include a form of the prospectus for the Trust that may be downloaded. The website will include the Shares' ticker and CUSIP information, along with additional quantitative information updated on a daily basis for the Trust. The Trust's website will include (i) daily trading volume, the prior business day's reported NAV and closing price, and a calculation of the premium and discount of the closing price or mid-point of the Bid/Ask Price against the NAV; and (ii) data in chart format displaying the frequency distribution of discounts and premiums of the daily closing price or Bid/Ask Price against the NAV, within appropriate ranges, for at least each of the four previous calendar quarters. The Trust's website will be publicly available prior to the public offering of Shares and accessible at no charge.

The Index value is available on Calculation Agent's website and from major market data vendors. The spot

[48] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Trust may trade on markets that are members of ISG or with which the Exchange has in place a CSSA.

[49] 15 U.S.C. 78f(b)(5).

price of bitcoin also is available on a 24-hour basis from major market data vendors.

Trading in Shares of the Trust will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of a new type of exchange-traded product based on the price of bitcoin that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of exchange-traded product, and the first such product based on Bitcoin, which will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve or disapprove the proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2021–67 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2021–67. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2021–67 and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[50]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21609 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

[50] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93182; File No. SR–NYSECHX–2021–13]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend NYSE Chicago Rule 7.2

September 30, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2021, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Chicago Rule 7.2 (Holidays) to make Juneteenth National Independence Day a holiday of the Exchange. Juneteenth National Independence Day was designated a legal public holiday in June 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Chicago Rule 7.2 (Holidays) to make Juneteenth National Independence Day a holiday of the Exchange.

On June 17, 2021, Juneteenth National Independence Day was designated a legal public holiday.[3] Consistent with broad industry sentiment [4] and the approach recommended by the Securities Industry and Financial Markets Association (''SIFMA''),[5] the Exchange proposes to add ''Juneteenth National Independence Day'' to the existing list of holidays in the first paragraph of NYSE Chicago Rule 7.2. As a result, the Exchange will not be open for business on Juneteenth National Independence Day, which falls on June 19 of each year. In accordance with the second paragraph of NYSE Chicago Rule 7.2, when the holiday falls on a Saturday, the Exchange will not be open for business on the preceding Friday, and when it falls on a Sunday, the Exchange will not be open for business on the succeeding Monday.[6]

The first paragraph of the revised rule would read as follows (proposed additions *italicized*):

The Exchange will not be open for business on New Year's Day, Martin Luther King Jr. Day, Washington's Birthday, Good Friday, Memorial Day, *Juneteenth National Independence Day,* Independence Day, Labor Day, Thanksgiving Day and Christmas Day.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed amended rule would clearly state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The change would thereby promote clarity and transparency in the Exchange rules by updating the list of holidays of the Exchange.

The proposed change does not raise any new or novel issues.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[9] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather to amend the Exchange rule regarding holidays.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) [12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative prior to 30 days after the date of the filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because the proposed rule change, as described above, would state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The Exchange further states that the proposed change does not raise any new or novel issues. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

[3] Public Law 117–17.

[4] *See, e.g., https://www.bloomberg.com/news/articles/2021-06-18/bofa-makes-juneteenth-a-holiday-joining-jpmorgan-wells-fargo?sref=Hhue1scO.*

[5] SIFMA recommends a full market close in observance of Juneteenth National Independence Day. *See https://www.sifma.org/resources/general/holiday-schedule/. See also https://www.sifma.org/resources/news/sifma-revises-2022-fixed-income-market-close-recommendations-in-the-u-s-to-include-full-close-for-juneteenth-national-independence-day/.*

[6] NYSE Chicago Rule 7.2. There is an exception to the practice if unusual business conditions exist, such as the ending of a monthly or yearly accounting period. *Id.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(8).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSECHX–2021–13 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSECHX–2021–13. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSECHX–2021–13, and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21741 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93209; File No. SR–PEARL–2021–43]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by MIAX PEARL, LLC To Amend Exchange Rule 100, Definitions, Rule 402, Criteria for Underlying Securities, Rule 403, Withdrawal of Approval of Underlying Securities, Rule 404, Series of Option Contracts Open for Trading, Rule 404A, Select Provisions of Options Listing Procedures Plan, Rule 406, Long-Term Option Contracts, Rule 500, Access to and Conduct on the Exchange, Rule 503, Openings on the Exchange, Rule 515, Execution of Orders, and Rule 519, MIAX Pearl Order Monitor (''MOM'')

September 30, 2021.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 24, 2021, MIAX PEARL, LLC (''MIAX Pearl'') or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rules 100, Definitions, 402, Criteria for Underlying Securities, 403, Withdrawal of Approval of Underlying Securities, 404, Series of Option Contracts Open for Trading, 404A, Select Provisions of Options Listing Procedures Plan, 406, Long-Term Option Contracts, 500, Access to and Conduct on the Exchange, 503, Openings on the Exchange, 515, Execution of Orders, and 519, MIAX Pearl Order Monitor (''MOM''), to make minor, non-substantive edits and clarifying changes to the rule text.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/*pearl, at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 100, Definitions, to make minor non-substantive edits and clarifying changes. First, the Exchange proposes to amend Exchange Rule 100, Definitions, to make a minor, non-substantive clarifying change to the definition for ''PBBO.'' Currently, the definition for ''PBBO'' is as follows: ''The term 'PBBO' means the best bid or offer on the PEARL Exchange.'' Pursuant to Exchange Rule 100, when referring to the Exchange, the term ''MIAX Pearl'' is used. The Exchange proposes to amend the definition for ''PBBO'' in Exchange Rule 100 to insert the word ''MIAX'' in front of the words ''PEARL Exchange'' to align the name of the Exchange with how the term is defined and used throughout the Exchange's rulebook. Further, the Exchange proposes to delete the word ''the'' before the newly inserted word ''MIAX'' and delete the last word, ''Exchange,'' for clarity. With the proposed changes, the definition for ''PBBO'' will be as follows: ''The term 'PBBO' means the best bid or offer on MIAX Pearl.''

Next, the Exchange proposes to delete the period at the end of subparagraph (a)(1) of Exchange Rule 402(a) and add ''; and'' for purposes of clarity in the rule text that both conditions listed in Exchange Rule 402(a)(1)–(2) must be met.

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Next, the Exchange proposes to amend subparagraph (b) of Exchange Rule 402 to correctly spell the word ''foregoing'' in the last sentence before subparagraph (b)(1). The purpose of this change is for clarity in the rule text.

Next, the Exchange proposes to delete the period at the end of subparagraph (b)(6)(i) of Exchange Rule 402 and add ''; and'' for the sentence to be grammatically correct and for purposes of clarity in the rule text that both conditions listed in Exchange Rule 402(b)(6)(i)–(ii) must be met.

Next, the Exchange proposes to delete the period at the end of subparagraph (c)(2)(i)(A) of Exchange Rule 402 and add ''; and'' for the sentence to be grammatically correct and for purposes of clarity in the rule text.

Next, the Exchange proposes to delete the comma at the end of subparagraph (g)(1) of Exchange Rule 402 and add a semicolon for purposes of clarity in the rule text.

Next, the Exchange proposes to amend subparagraph (i) of Exchange Rule 402 to remove the word ''or'' after proposed renumbered subparagraphs (i)(1), (2) and (3). The Exchange also proposes to amend the hierarchical headings in Exchange Rule 402(i) as follows: Subparagraphs (i)(A)–(E) will be renumbered as (i)(1)–(5); subparagraph (i)(E)(1) will be renumbered as (i)(5)(i); subparagraphs (i)(E)(1)(i)–(iii) will be renumbered as (i)(5)(i)(A)–(C); subparagraph (i)(E)(2) will be renumbered as (i)(5)(ii); subparagraphs (i)(E)(2)(i)–(ii) will be renumbered as (i)(5)(ii)(A)–(B); and subparagraphs (i)(E)(2)(ii)(A)–(D) will be renumbered as (i)(5)(ii)(B)1.–4. The purpose of these proposed changes is to provide consistency and clarity throughout the rule text for the hierarchical subparagraph headings.

Next, the Exchange proposes to delete the semicolon at the end of subparagraph (k)(1)(vi) of Exchange Rule 402 and add a period for the sentence to be grammatically correct and for purposes of clarity in the rule text.

Next, the Exchange proposes to amend subparagraph (g) of Exchange Rule 403 to capitalize the word ''In'' that begins subparagraphs (g)(1) and (g)(2). The Exchange also proposes to amend subparagraph (g) of Exchange Rule 403 to replace certain internal cross reference to other rules in light of the changes described above. In particular, the Exchange proposes to amend the cross references contained in Exchange Rule 403(g)(1)–(2), that are to Exchange Rules 402(i)(E)(1)(i)–(ii), to now be to Exchange Rule 402(i)(5)(i)(A)–(B). These proposed rule changes are for clarity and consistency with the rule text.

Next, the Exchange proposes to amend Exchange Rule 403, Interpretation and Policy .02, to add a colon before an itemized list in the second sentence, which uses semicolons for the sentence to be grammatically correct.

Next, the Exchange proposes to amend Exchange Rule 404, Interpretation and Policy .02(a), to remove the word ''Pilot'' when referring to the Short Term Option Series Program. The purpose of this proposed change is to provide consistency and clarity throughout the rule text as the Short Term Options Series Program is not a pilot program.[3]

Next, the Exchange proposes to amend Exchange Rule 404, Interpretation and Policy .02(c), to add the word ''thirty'' before the number in parentheses in the first sentence for purposes of consistency and clarity in the rule text.

Next, the Exchange proposes to amend Exchange Rule 404, Interpretation and Policy .02(f), to add the number ''(21)'' after the word ''twenty-one'' for purposes of consistency and clarity in the rule text.

Next, the Exchange proposes to amend Exchange Rule 404, Interpretation and Policy .10, to update the name of one of the Exchange-Traded Funds (''ETF'') from ''PowerShares Trust (''QQQ'')'' to its updated name ''Invesco QQQ Trust (''QQQ'').'' [4] According to the most recent Prospectus for the QQQ ETF, the ETF Sponsor changed that ETF's name. Accordingly, the Exchange proposes to update the name of the QQQ ETF for consistency with the QQQ ETF's Prospectus.

Next, the Exchange proposes to amend Exchange Rule 404, Interpretation and Policy .11, to add the number ''(21)'' after the word ''twenty-one'' for purposes of consistency and clarity in the rule text.

Next, the Exchange proposes to amend subparagraph (b) of Exchange Rule 404A to add quotation marks around the phrase ''Exchange Traded Fund Shares'' for the sentence to be grammatically correct.

Next, the Exchange proposes to amend subparagraph (a) of Exchange Rule 406, Long-Term Option Contracts, to add the number ''(10)'' after the word ''ten'' for purposes of consistency and clarity in the rule text.

Next, the Exchange proposes to amend subparagraphs (b)(i)–(iv) of Exchange Rule 500, Access to and Conduct on the Exchange, to: (1) Replace periods with semicolons; and (2) add the word ''and'' to subparagraph (b)(iv) in the list for the sentence to be grammatically correct. The Exchange proposes to replace the periods in (i)–(iv) for the sentence to be grammatically correct and for purposes of clarity in the rule text.

Next, the Exchange proposes to amend subparagraph (b)(1)(ii)(A) to Exchange Rule 503, Openings on the Exchange, to remove the word ''or'' for purposes of clarity and consistency in the rule text.

Next, the Exchange proposes to amend Exchange Rule 515, Execution of Orders, to make minor, non-substantive edits and clarifying changes to the rule text in order to provide consistency and clarity within the rule text. Exchange Rule 515(g)(3)(iv) currently contains several references to the term ''Post-Only.'' However, there are two instances in subparagraph (g)(3)(iv) of Exchange Rule 515 where the term ''Post-Only'' is missing the hyphen connecting the two words. The Exchange now proposes to amend paragraph (g)(3)(iv) to amend all references to ''Post-Only'' to add the hyphen where it is missing. The purpose of these changes is to provide consistency and clarity throughout the rule text.

Next, the Exchange proposes to amend Exchange Rule 519, MIAX Pearl Order Monitor (''MOM''), to make minor, non-substantive edits and clarifying changes to the rule text. The Exchange proposes to amend the example in Exchange Rule 519(a)(3) to move the word ''not'' in clause ''(B)'' of that example. With the proposed change, clause ''(B)'' will state as follows: ''(B) if the NBO is $0.10 an incoming limit order to buy options for $0.15 will not be rejected; whereas if the NBO is $0.10 an incoming limit order to buy options for $0.35 will be rejected as the limit price of the order is $0.25 greater than the NBO.'' Similarly, the Exchange proposes to amend the example in Exchange Rule 519(a)(4) to delete the extra word ''be'' in the last part of clause ''(B'') of that example. With the proposed change, clause ''(B)'' will state as follows: ''(B) if the NBB is $0.30 an incoming limit order to sell options for $0.15 will be rejected; whereas if the NBB is $0.30 an incoming limit order to sell options for $0.20 will not be rejected as the limit price of the order is not less than 50% of the NBB price.'' The purpose of these changes is to provide clarity in the rule text.

[3] *See* Exchange Rule 404, Interpretation and Policy .02.

[4] *See* Invesco QQQ Trust, Series 1 Prospectus, dated January 31, 2021, *https://connect.rightprospectus.com/Invesco/TADF/46090E103/P?site=ETF.*

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act [5] in general, and furthers the objectives of Section 6(b)(5) of the Act [6] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes the proposed changes promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule changes will provide greater clarity to Members [7] and the public regarding the Exchange's Rules. It is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes the proposed changes will not impose any burden on intra-market competition as there is no functional change to the Exchange's System and because the rules of the Exchange apply to all MIAX Pearl participants equally. The proposed rule change will have no impact on competition as it is not designed to address any competitive issue but rather is designed to remedy minor non-substantive issues and provide added clarity to the rule text of Exchange Rules 100, 402, 403, 404, 404A, 406, 500, 503, 515, and 519. In addition, the Exchange does not believe the proposal will impose any burden on inter-market competition as the proposal does not address any competitive issues and is intended to protect investors by providing further transparency regarding the Exchange's functionality.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) [8] of the Act and Rule 19b–4(f)(6) thereunder.[9] Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act and subparagraph (f)(6) of Rule 19b–4 thereunder.[10]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PEARL–2021–43 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–PEARL–2021–43. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PEARL–2021–43, and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21747 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of these Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[8] 15 U.S.C. 78s(b)(3)(A)(iii).

[9] 17 CFR 240.19b–4(f)(6).

[10] In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93210; File No. SR–MIAX–2021–40]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by Miami International Securities Exchange, LLC To Amend Exchange Rule 402, Criteria for Underlying Securities, Rule 403, Withdrawal of Approval of Underlying Securities, Rule 404, Series of Option Contracts Open for Trading, Rule 404A, Select Provisions of Options Listing Procedures Plan, Rule 503, Openings on the Exchange, Rule 515A, MIAX Price Improvement Mechanism (''PRIME'') and PRIME Solicitation Mechanism, and Rule 518, Complex Orders

September 30, 2021.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 24, 2021, Miami International Securities Exchange, LLC (''MIAX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to make a number of minor, non-substantive edits to Exchange Rules 402, Criteria for Underlying Securities, 403, Withdrawal of Approval of Underlying Securities, 404, Series of Option Contracts Open for Trading, 404A, Select Provisions of Options Listing Procedures Plan, 503, Openings on the Exchange, 515A, MIAX Price Improvement Mechanism (''PRIME'') and PRIME Solicitation Mechanism, and 518, Complex Orders.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/,* at MIAX's principal office, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rules 402, 403, 404, 404A, 503, 515A, and 518 to make minor non-substantive edits and clarifying changes to provide consistency and clarity within the rule text.

First, the Exchange proposes to delete the period at the end of subparagraph (a)(1) of Exchange Rule 402 and add ''; and'' for purposes of clarity in the rule text that both conditions listed in Exchange Rule 402(a)(1)–(2) must be met.

Next, the Exchange proposes to amend subparagraph (b) of Exchange Rule 402 to correctly spell the word ''foregoing'' in the last sentence.

Next, the Exchange proposes to delete the period at the end of subparagraph (b)(6)(i) of Exchange Rule 402 and add ''; and'' for the sentence to be grammatically correct and for purposes of clarity in the rule text that both conditions listed in Exchange Rule 402(b)(6)(i)–(ii) must be met.

Next, the Exchange proposes to delete the period at the end of subparagraph (c)(2)(i)(A) of Exchange Rule 402 and add ''; and'' for the sentence to be grammatically correct and for purposes of clarity in the rule text.

Next, the Exchange proposes to delete the comma at the end of subparagraph (g)(1) of Exchange Rule 402 and add a semicolon for purposes of clarity in the rule text.

Next, the Exchange proposes to amend subparagraph (i) of Exchange Rule 402 to remove the word ''or'' after subparagraphs (i)(1), (2) and (3). The purpose of these proposed changes is to provide consistency and clarity throughout the rule text.

Next, the Exchange proposes to delete the semicolon at the end of subparagraph (k)(1)(vi) of Exchange Rule 402 and add a period for the sentence to be grammatically correct and for purposes of clarity in the rule text.

Next, the Exchange proposes to amend Exchange Rule 403, Interpretation and Policy .02, to add a colon before the list in the second sentence, which uses semicolons for the sentence to be grammatically correct.

Next, the Exchange proposes to amend Exchange Rule 404, Interpretation and Policy .02(a), to remove the word ''Pilot'' when referring to the Short Term Option Series Program. The purpose of this proposed change is to provide consistency and clarity throughout the rule text as the Short Term Options Series Program is not a pilot program.[3]

Next, the Exchange proposes to amend Exchange Rule 404, Interpretation and Policy .02(c), to add the word ''thirty'' before the number in parentheses in the first sentence for purposes of consistency and clarity in the rule text.

Next, the Exchange proposes to amend Exchange Rule 404, Interpretation and Policy .02(e), to capitalize the word ''rule'' in the last sentence of this subparagraph for purposes of consistency and clarity in the rule text.

Next, the Exchange proposes to amend Exchange Rule 404, Interpretation and Policy .02(f), to add the number ''(21)'' after the word ''twenty-one'' for purposes of consistency and clarity in the rule text.

Next, the Exchange proposes to amend Exchange Rule 404, Interpretation and Policy .10, to update the name of one of the Exchange-Traded Funds (''ETF'') from ''PowerShares Trust (''QQQ'')'' to its updated name ''Invesco QQQ Trust (''QQQ'').''[4] According to the most recent Prospectus for the QQQ ETF, the ETF Sponsor changed that ETF's name. Accordingly, the Exchange proposes to update the name of the QQQ ETF for consistency with the QQQ ETF's Prospectus.

Next, the Exchange proposes to amend Exchange Rule 404, Interpretations and Policies .11, to add the number ''(21)'' after the word ''twenty-one'' for purposes of consistency and clarity in the rule text.

Next, the Exchange proposes to amend subparagraph (b) of Exchange Rule 404A to add quotation marks around the phrase ''Exchange Traded

[3] *See* Exchange Rule 404, Interpretation and Policy .02.

[4] *See* Invesco QQQ Trust, Series 1 Prospectus, dated January 31, 2021, *https://connect.rightprospectus.com/Invesco/TADF/46090E103/P?site=ETF.*

Fund Shares'' for the sentence to be grammatically correct.

Next, the Exchange proposes to amend subparagraph (d) of Exchange Rule 503 to: (1) Change the word ''an'' to ''a'' immediately preceding the phrase ''class-by- class basis''; (2) remove the space in the middle of the hyphenated word ''class-by- class''; and (3) remove the word ''the'' before the phrase ''. . . Members through a Regulatory Circular.'' These proposed rule changes are to make the sentence grammatically correct and to provide clarity in the rule text.

Next, the Exchange proposes to amend subparagraph (e)(1) of Exchange Rule 503 to make two clarifying changes: (1) Deleting the space between the words ''market'' and ''place'' in the second sentence; and (2) capitalizing the word ''members'' in the third sentence. The purpose of these proposed changes is to provide consistency and clarity throughout the rule text as ''marketplace'' is supposed to be one word and the term ''Members'' [5] is a defined term in the Exchange's rulebook that should be capitalized.

Next, the Exchange proposes to amend subparagraph (f)(2)(vii)(B)5.a. of Exchange Rule 503 to make two clarifying changes. Subparagraph (f)(2)(vii)(B)5.a. currently has two references to Interpretations and Policies of Exchange Rule 503, stated as ''Policy .02'' and ''Policy .03.'' The Exchange now proposes to insert the words ''Interpretation and'' in front of both of those references to Interpretations and Policies in order to provide consistency and clarity throughout the rule text.

Next, the Exchange proposes to amend Exchange Rule 503, Interpretation and Policy .03(f)(1). Currently, Interpretation and Policy .03(f)(1) provides as follows: ''The System will broadcast a system imbalance broadcast message to all subscribers of the Exchange's relevant data feed and begin an SSIP Imbalance Timer, the duration of which shall be determined by the Exchange and announced via Regulatory Circular, however it shall not to exceed ten seconds.'' The Exchange now proposes to delete the word ''to'' at the end of that sentence in order for the sentence be grammatically correct and to provide clarity throughout the rule text.

Next, the Exchange proposes to amend subparagraph (a)(1) of Exchange Rule 515A to provide consistency and clarity to the rule text. Subparagraphs (a)(1)(i)–(iii) provide the three conditions that must be met in order for a Member (an ''Initiating Member'') to initiate a PRIME Auction.[6] The Exchange proposes to move the ''and'' from the end of subparagraph (a)(1)(i) to the end of subparagraph (a)(1)(ii), delete the period after subparagraph (a)(1)(ii), and lowercase the word ''with'' that begins subparagraph (a)(1)(iii). The purpose of these changes is to provide consistency and clarity to the rule text such that market participants know that in order to initiate a PRIME Auction, all three conditions of subparagraphs (a)(1)(i)–(iii) of Exchange Rule 515A must be met.

Finally, the Exchange proposes to amend subparagraph (b)(3) of Exchange Rule 518 to add a closing parenthesis around the phrase ''as defined in Rule 518(d)(4).'' The purpose of the proposed rule change is for the sentence to be grammatically correct and for clarity in the rule text.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act [7] in general, and furthers the objectives of Section 6(b)(5) of the Act [8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes the proposed changes promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule changes will provide greater clarity to Members and the public regarding the Exchange's Rules. It is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes the proposed changes will not impose any burden on intra-market competition as there is no functional change to the Exchange's System and because the rules of the Exchange apply to all MIAX participants equally. The proposed rule change will have no impact on competition as it is not designed to address any competitive issue but rather is designed to remedy minor non-substantive issues and provide added clarity to the rule text of Exchange Rules 402, 403, 404, 404A, 503, 515A, and 518. In addition, the Exchange does not believe the proposal will impose any burden on inter-market competition as the proposal does not address any competitive issues and is intended to protect investors by providing further transparency regarding the Exchange's functionality.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) [9] of the Act and Rule 19b–4(f)(6) thereunder.[10] Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act and subparagraph (f)(6) of Rule 19b–4 thereunder.[11]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the

[5] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[6] *See* Exchange Rule 515A(a)(1).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2021–40 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2021–40. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2021–40, and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21749 Filed 10–4–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93191; File No. SR–NYSEArca–2021–57]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the NYDIG Bitcoin ETF Under NYSE Arca Rule 8.201–E

September 29, 2021.

On June 30, 2021, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the NYDIG Bitcoin ETF (''Trust'') under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares). The proposed rule change was published for comment in the **Federal Register** on July 19, 2021.[3]

On August 23, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] This order institutes proceedings under Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.

I. Summary of the Proposal

As described in more detail in the Notice,[7] the Exchange proposes to list and trade the Shares of the Trust under NYSE Arca Rule 8.201–E, which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.

The investment objective of the Trust is to reflect the performance of the price of bitcoin less the expenses of the Trust's operations.[8] The Trust will not seek to reflect the performance of any benchmark or index. In seeking to achieve its investment objective, the Trust will only hold bitcoin.[9] The Trust generally does not intend to hold cash or cash equivalents. However, the Trust may hold cash and cash equivalents on a temporary basis to pay extraordinary expenses.[10]

The net asset value (''NAV'') of the Trust will be determined in accordance with Generally Accepted Accounting Principles (''GAAP'') as the total value of bitcoin held by the Trust, plus any cash or other assets, less any liabilities including accrued but unpaid expenses. The NAV of the Trust will typically be determined as of 4:00 p.m. E.T. on each day that the Exchange is open for regular trading (''Business Day''). The Administrator will calculate the NAV of the Trust once each Exchange trading day. The Exchange's Core Trading Session closes at 4:00 p.m. E.T. The Trust's daily activities will generally not be reflected in the NAV determined for the Business Day on which the transactions are effected (the trade date), but rather on the following Business Day. The NAV for the Trust's Shares will be disseminated daily to all market participants at the same time.[11]

The Trust will disseminate an intraday indicative value (''IIV'') per Share updated every 15 seconds. The IIV will be calculated by using the same methodology that the Trust uses to determine NAV, which is to follow GAAP. Generally, GAAP requires the fair value of an asset that is traded on a market to be measured by reference to orderly transactions on an active

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 92395 (July 13, 2021), 86 FR 38129 (July 19, 2021) (''Notice''). Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-nysearca-2021-57/srnysearca202157.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92722 (Aug. 23, 2021), 86 FR 48268 (Aug. 27, 2021). The Commission designated October 17, 2021, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Notice, *supra* note 3.

[8] *See id.* at 38129. NYDIG Asset Management LLC (''Sponsor'') is the sponsor of the Trust, and Delaware Trust Company is the trustee. U.S. Bancorp Fund Services, LLC (''Administrator'') is the transfer agent and the administrator of the Trust. The bitcoin custodian for the Trust is NYDIG Trust Company LLC (''Bitcoin Custodian''). The Bitcoin Custodian is chartered as a limited purpose trust company by the New York State Department of Financial Services (''NYDFS'') and is authorized by NYDFS to provide digital asset custody services. Both the Sponsor and the Bitcoin Custodian are indirect wholly-owned subsidiaries of New York Digital Investment Group LLC. *See id.*

[9] *See id.*

[10] *See id.* at 38130. The Trust will enter into a cash custody agreement with U.S. Bank N.A. under which U.S. Bank N.A. will act as custodian of the Trust's cash and cash equivalents. *See id.*

[11] *See id.* at 38130–32.

market. Among all active markets with orderly transactions, the market that is used to determine the fair value of an asset is the principal market. The Sponsor expects that the principal market will initially generally be the NYDFS-regulated trading venue with the highest trading volume and level of activity.[12]

The Trust will create and redeem Shares from time to time, but only in one or more blocks of 10,000 Shares (''Creation Baskets''). Creation Baskets will only be made in exchange for delivery to the Trust or the distribution by the Trust of the amount of bitcoin represented by the Shares being created or redeemed, the amount of which will be based on the quantity of bitcoin attributable to each Share of the Trust (net of accrued but unpaid Sponsor fees, extraordinary expenses or liabilities) being created or redeemed determined as of 4:00 p.m. E.T. on the day the order is properly received.[13]

II. Proceedings To Determine Whether To Approve or Disapprove SR–NYSEArca–2021–57 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [14] to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change, as discussed below. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[15] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices'' and ''to protect investors and the public interest.'' [16]

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice,[17] in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following questions and asks commenters to submit data where appropriate to support their views:

1. What are commenters' views on whether the proposed Trust and Shares would be susceptible to manipulation? What are commenters' views generally on whether the Exchange's proposal is designed to prevent fraudulent and manipulative acts and practices? What are commenters' views generally with respect to the liquidity and transparency of the bitcoin markets, the bitcoin markets' susceptibility to manipulation, and thus the suitability of bitcoin as an underlying asset for an exchange-traded product?

2. The Exchange asserts that the ''significant increase in trading volume and open interest in the bitcoin futures market, growth of liquidity in the spot market for bitcoin, and certain features of the Shares mitigate the manipulation concerns expressed by the Commission when it last reviewed exchange proposals to list a bitcoin exchange-traded product.'' [18] The Exchange concludes ''that, on the whole, the manipulation concerns previously articulated by the Commission have since been significantly mitigated, and do not exceed those that exist in the markets for other commodities that underly [sic] securities listed on U.S. national securities exchanges.'' [19] Do commenters agree or disagree? Are the changes that the Exchange identifies sufficient to support the determination that the proposal to list and trade the Shares is designed to protect investors and the public interest and is consistent with the other applicable requirements of Section 6(b)(5) of the Act?

3. The Exchange states that the ''Trust would provide investors with exposure to bitcoin in a manner that may be more efficient, more convenient and more regulated than the purchase of bitcoin or other investment products that provide exposure to bitcoin.'' [20] The Exchange asserts that ''investors in [over-the-counter] bitcoin funds . . . have historically borne significantly higher fees and expenses than those that would be borne by investors in the Trust'' and that investors holding bitcoin often face ''credit risk'' and ''risk of loss or theft of their bitcoin.'' [21] What are commenters' views regarding the Exchange's assertions? Do these reasons provide an appropriate basis for the determination that the proposal is consistent with the applicable requirements of Section 6(b)(5) of the Act?

4. The Exchange asserts that the Chicago Mercantile Exchange (''CME'') represents a regulated market of significant size relating to bitcoin.[22] The Exchange states that ''proprietary research, including lead-lag analyses, . . . demonstrates that prices in the CME bitcoin futures market . . . lead prices in the bitcoin spot market, including non-U.S. bitcoin spot markets.'' According to the Exchange, ''[t]his finding supports the thesis that a market participant attempting to manipulate the Shares would have to trade on that market.'' [23] The Exchange, however, does not provide any information regarding the proprietary research. What are commenters' views regarding these assertions?

5. According to the Exchange, ''the bitcoin futures market is one of the primary venues that market participants use to transact large exposures to bitcoin,'' and, ''[i]n contrast to the efficient leverage offered through the futures market, many bitcoin spot trading venues require full pre-funding of trading, which means it would be highly capital intensive to 'spoof' or 'layer' order books on spot trading venues.'' [24] The Exchange therefore concludes that if a market participant intended to manipulate the price of bitcoin, and thereby the Shares, the bitcoin futures market is the one that would be manipulated first.[25] Do commenters agree with the Exchange's analysis and conclusion?

6. What are commenters' views of the Exchange's assertion that (a) the significant volume in the bitcoin futures market; (b) the overall size of the bitcoin market; (c) the significant liquidity available in the bitcoin spot markets; and (d) the ability of market participants to buy or sell large amounts of bitcoin without significant market impact demonstrate that the Shares would not become the predominant force on pricing in either the bitcoin spot or futures markets? [26]

7. What are commenters' views on the Exchange's statements that ''the cost to buy or sell $5 million worth of bitcoin

[12] *See id.* at 38132.

[13] *See id.*

[14] 15 U.S.C. 78s(b)(2)(B).

[15] *Id.*

[16] 15 U.S.C. 78f(b)(5).

[17] *See* Notice, *supra* note 3.

[18] *See id.* at 38134.

[19] *See id.*

[20] *See id.*

[21] *See id.*

[22] *See id.*

[23] *See id.* at 38135.

[24] *See id.*

[25] *See id.*

[26] *See id.* at 38136.

averages roughly 20 basis points'' and that, ''[f]or a $10 million market order, the cost to buy or sell is roughly 40 basis points.'' [27] What are commenters' views of the Exchange's assertion that these metrics are comparable to the liquidity of existing commodity exchange-traded products? [28] What are commenters' views on the Exchange's assertion that the fact that ''the Trust receives and holds only bitcoin . . . substantially reduces the potential for manipulation of the number of Shares created or redeemed, which therefore substantially reduces the potential for shareholders to be harmed by manipulation.''? [29]

III. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[30]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by October 26, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by November 9, 2021.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2021–57 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2021–57. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2021–57 and should be submitted by October 26, 2021. Rebuttal comments should be submitted by November 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21622 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

[27] *See id.*

[28] *See id.*

[29] *See id.* at 38135.

[30] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[31] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93175; File No. SR–CboeBZX–2021–029]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the Kryptoin Bitcoin ETF Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

September 29, 2021.

On April 9, 2021, Cboe BZX Exchange, Inc. (''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the Kryptoin Bitcoin ETF Trust under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on April 28, 2021.[3]

On June 9, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On July 23, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.[7]

Section 19(b)(2) of the Act [8] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 91646 (April 22, 2021), 86 FR 22485 (April 28, 2021). Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-cboebzx-2021-029/srcboebzx2021029.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92131 (June 9, 2021), 86 FR 31772 (June 15, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 92476 (July 23, 2021), 86 FR 40883 (July 29, 2021).

[8] 15 U.S.C. 78s(b)(2).

determination. The proposed rule change was published for comment in the **Federal Register** on April 28, 2021.[9] The 180th day after publication of the proposed rule change is October 25, 2021. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised in the comment letters that have been submitted in connection therewith. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates December 24, 2021, as the date by which the Commission shall either approve or disapprove the proposed rule change (File Number SR–CboeBZX–2021–029).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93185; File No. SR–MIAX–2021–43]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule To Adopt a Tiered-Pricing Structure for Additional Limited Service MIAX Express Interface Ports

September 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2021, Miami International Securities Exchange LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Options Fee Schedule (the ''Fee Schedule'') to amend certain port fees.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to adopt a tiered-pricing structure for additional Limited Service MIAX Express Interface (''MEI'') Ports [3] available to Market Makers.[4] The Exchange believes a tiered-pricing structure will encourage Market Makers to be more efficient and economical when determining how to connect to the Exchange. This should also enable the Exchange to better monitor and provide access to the Exchange's network to ensure sufficient capacity and headroom in the System.[5]

The Exchange initially filed the proposed fee changes on August 2, 2021, with the changes being immediately effective.[6] The First Proposed Rule Change was published for comment in the **Federal Register** on August 19, 2021.[7] The Commission received one comment letter on the First Proposed Rule Change.[8] The Exchange has withdrawn the First Proposed Rule Change and now submits this proposal, which is immediately effective. This proposal provides additional justification for the proposed fee changes and addresses certain points raised in the single comment letter that was submitted on the First Proposed Rule Change.

Additional Limited Service MEI Port Tiered-Pricing Structure

The Exchange proposes to amend the fees for additional Limited Service MEI Ports. Currently, the Exchange allocates two (2) Full Service MEI Ports [9] and two (2) Limited Service MEI Ports [10] per matching engine [11] to which each Market Maker connects. Market Makers may also request additional Limited Service MEI Ports for each matching engine to which they connect. The Full Service MEI Ports, Limited Service MEI Ports and the additional Limited Service MEI Ports all include access to the Exchange's primary and secondary data centers and its disaster recovery center. Market Makers may request additional Limited Service MEI Ports for which they are assessed a $100 monthly fee for each additional Limited Service MEI

[9] *See supra* note 3.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] MIAX Express Interface is a connection to MIAX systems that enables Market Makers to submit simple and complex electronic quotes to MIAX. *See* Fee Schedule, note 26.

[4] The term ''Market Makers'' refers to Lead Market Makers (''LMMs''), Primary Lead Market Makers (''PLMMs''), and Registered Market Makers (''RMMs'') collectively. *See* Exchange Rule 100.

[5] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[6] *See* Securities Exchange Act Release No. 92661 (August 13, 2021), 86 FR 46737 (August 19, 2021) (SR–MIAX–2021–37) (the ''First Proposed Rule Change'').

[7] *Id.*

[8] *See* Letter from Richard J. McDonald, Susquehanna International Group, LLC (''SIG''), to Vanessa Countryman, Secretary, Commission, dated September 7, 2021 (''SIG Comment Letter'').

[9] Full Service MEI Ports provide Market Makers with the ability to send Market Maker quotes, eQuotes, and quote purge messages to the MIAX System. Full Service MEI Ports are also capable of receiving administrative information. Market Makers are limited to two Full Service MEI Ports per matching engine. *See* Fee Schedule, Section 5(d)(ii), note 27.

[10] Limited Service MEI Ports provide Market Makers with the ability to send eQuotes and quote purge messages only, but not Market Maker Quotes, to the MIAX System. Limited Service MEI Ports are also capable of receiving administrative information. Market Makers initially receive two Limited Service MEI Ports per matching engine. *See* Fee Schedule, Section 5(d)(ii), note 28.

[11] A ''matching engine'' is a part of the MIAX electronic system that processes options quotes and trades on a symbol-by-symbol basis. Some matching engines will process option classes with multiple root symbols, and other matching engines will be dedicated to one single option root symbol (for example, options on SPY will be processed by one single matching engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated matching engine. A particular root symbol may not be assigned to multiple matching engines. *See* Fee Schedule, Section 5(d)(ii), note 29.

Port for each matching engine. This fee has been unchanged since 2016.[12]

The Exchange now proposes to move from a flat monthly fee per additional Limited Service MEI Port for each matching engine to a tiered-pricing structure for additional Limited Service MEI Ports for each matching engine under which the monthly fee would vary depending on the number of additional Limited Service MEI Ports the Market Maker elects to purchase. Specifically, the Exchange will continue to provide the first and second additional Limited Service MEI Ports for each matching engine free of charge, as described above, per the initial allocation of Limited Service MEI Ports that Market Makers receive. The Exchange now proposes the following tiered-pricing structure: (i) The third and fourth additional Limited Service MEI Ports for each matching engine will increase from the current flat monthly fee of $100 to $150 per port; (ii) the fifth and sixth additional Limited Service MEI Ports for each matching engine will increase from the current flat monthly fee of $100 to $200 per port; and (iii) the seventh additional Limited Service MEI Port, and each Limited Service MEI Port for each matching engine purchased thereafter, will increase from the current monthly flat fee of $100 to $250 per port (collectively, the ''Proposed Access Fees'').

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [13] in general, and furthers the objectives of Section 6(b)(4) of the Act [14] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among Exchange Members and issuers and other persons using any facility or system which the Exchange operates or controls. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [15] in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees for services and products, in addition to order flow, to remain competitive with other exchanges. The Exchange believes that the proposed changes reflect this competitive environment.

The Exchange believes the proposal to move from a flat fee per month to a tiered-pricing structure is reasonable, equitably allocated and not unfairly discriminatory because the Exchange believes the proposed structure would encourage firms to be more economical and efficient in the number of additional Limited Service MEI Ports they purchase. The Exchange believes this will enable the Exchange to better monitor and provide access to the Exchange's network to ensure sufficient capacity and headroom in the System.

The Exchange notes that firms that are primarily order routers seeking best-execution do not utilize Limited Service MEI Ports on MIAX. Therefore, the fees described in the proposed tiered-pricing structure will only be allocated to market making firms that engage in advanced trading strategies and typically request multiple Limited Service MEI Ports, beyond the two per matching engine that are free. Accordingly, the firms engaged in market making business generate higher costs by utilizing more of the Exchange's resources. The market making firms that purchase higher amounts of Limited Service MEI Ports tend to have specific business oriented market making and trading strategies, as opposed to firms engaging solely in order routing as part of their best-execution obligations. The use of such additional Limited Service MEI Ports is a voluntary business decision of each market maker.

The Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the requirements of the Act that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among market participants. The Exchange believes this high standard is especially important when an exchange imposes various access fees for market participants to access an exchange's marketplace. The Exchange deems port fees to be access fees. It records these fees as part of its ''Access Fees'' revenue in its financial statements. The Exchange believes that it is important to demonstrate that these fees are based on its costs and reasonable business needs. The Exchange believes the Proposed Access Fees will allow the Exchange to offset expense the Exchange has and will incur, and that the Exchange is providing sufficient transparency (as described below) into how the Exchange determined to charge such fees. Accordingly, the Exchange is providing an analysis of its revenues, costs, and profitability associated with the Proposed Access Fees. This analysis includes information regarding its methodology for determining the costs and revenues associated with the Proposed Access Fees.

In order to determine the Exchange's costs to provide the access services associated with the Proposed Access Fees, the Exchange conducted an extensive cost review in which the Exchange analyzed nearly every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the Proposed Access Fees, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the access services. The sum of all such portions of expenses represents the total cost to the Exchange to provide the access services associated with the Proposed Access Fees. For the avoidance of doubt, no expense amount was allocated twice. The Exchange is also providing detailed information regarding the Exchange's cost allocation methodology—namely, information that explains the Exchange's rationale for determining that it was reasonable to allocate certain expenses described in this filing towards the cost to the Exchange to provide the access services associated with the Proposed Access Fees.

In order to determine the Exchange's projected revenues associated with the Proposed Access Fees, the Exchange analyzed the number of Market Makers currently utilizing Limited Service MEI Ports, and, utilizing a recent monthly billing cycle representative of 2021 monthly revenue, extrapolated annualized revenue on a going-forward basis. The Exchange does not believe it is appropriate to factor into its analysis future revenue growth or decline into its projections for purposes of these calculations, given the uncertainty of such projections due to the continually changing access needs of market participants, discounts that can be achieved due to lower trading volume and vice versa, market participant consolidation, etc. Additionally, the Exchange similarly does not factor into its analysis future cost growth or decline. The Exchange is presenting its

[12] *See* Securities Exchange Act Release No. 79666 (December 22, 2016), 81 FR 96133 (December 29, 2016) (SR–MIAX–2016–47).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78f(b)(5).

revenue and expense associated with the Proposed Access Fees in this filing in a manner that is consistent with how the Exchange presents its revenue and expense in its Audited Unconsolidated Financial Statements. The Exchange's most recent Audited Unconsolidated Financial Statement is for 2020. However, since the revenue and expense associated with the Proposed Access Fees were not in place in 2020 or for the first seven months of 2021, the Exchange believes its 2020 Audited Unconsolidated Financial Statement is not representative of its current total annualized revenue and costs associated with the Proposed Access Fees. Accordingly, the Exchange believes it is more appropriate to analyze the Proposed Access Fees utilizing its 2021 revenue and costs, as described herein, which utilize the same presentation methodology as set forth in the Exchange's previously-issued Audited Unconsolidated Financial Statements. Based on this analysis, the Exchange believes that the Proposed Access Fees are fair and reasonable because they will not result in excessive pricing or supra-competitive profit when comparing the Exchange's total annual expense associated with providing the services associated with the Proposed Access Fees versus the total projected annual revenue the Exchange will collect for providing those services.

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On March 29, 2019, the Commission issued its Order Disapproving Proposed Rule Changes to Amend the Fee Schedule on the BOX Market LLC Options Facility to Establish BOX Connectivity Fees for Participants and Non-Participants Who Connect to the BOX Network (the ''BOX Order'').[16] On May 21, 2019, the Commission issued the Staff Guidance on SRO Rule Filings Relating to Fees.[17] Accordingly, the Exchange believes that the Proposed Access Fees are consistent with the Act because they (i) are reasonable, equitably allocated, not unfairly discriminatory, and not an undue burden on competition; (ii) comply with the BOX Order and the Guidance; (iii) are supported by evidence (including comprehensive revenue and cost data and analysis) that they are fair and reasonable because they will not result in excessive pricing or supra-competitive profit; and (iv) utilize a cost-based justification framework that is substantially similar to a framework previously used by the Exchange, and its affiliates MIAX PEARL, LLC (''MIAX Pearl'') and MIAX Emerald, LLC (''MIAX Emerald''), to establish or increase other non-transaction fees.[18] Accordingly, the Exchange believes that the Commission should find that the Proposed Access Fees are consistent with the Act.

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As of September 27, 2021, the Exchange had a market share of only 5.80% of the U.S. equity options industry for the month of September 2021.[19] The Exchange is not aware of any evidence that a market share of approximately 5–6% provides the Exchange with anti-competitive pricing power. If the Exchange were to attempt to establish unreasonable pricing for any of its means provided to access the Exchange, market participants may look to access the Exchange via other means such as through a third party service provider, or look to connect to the Exchange via a competing exchange with cheaper access alternatives that also provides routing services to the Exchange. In addition, existing market participants that are connected to the Exchange may choose to disconnect from the Exchange or reduce their number of connections to the Exchange as a means to reduce their overall costs.

The proposed tiered-pricing structure and proposed fees for additional Limited Service MEI Ports are less than or similar to fees charged by competing options exchanges for similar access on those exchanges. The Exchange believes that it provides a better value through its enhanced network monitoring, customer reporting, and superior network infrastructure than markets with higher market shares and more expensive access alternatives. For example, NYSE American, LLC (''Amex'') (equity options market share of 7.86% as of September 23, 2021 for the month of September)[20] and NYSE Arca, Inc. (''Arca'') (equity options market share of 12.58% as of September 23, 2021 for the month of September)[21] both charge $450 per port for order/quote entry ports 1–40 and $150 per port for ports 41 and greater,[22] all on a per matching engine basis, with Amex and Arca having 17 match engines and 19 match engines, respectively.[23] Similarly, The Nasdaq Stock Market LLC (''NASDAQ'') (equity options market share of 7.81% as of September 23, 2021 for the month of September)[24] charges $1,500 per port for SQF ports 1–5, $1,000 per SQF port for ports 6–20, and $500 per SQF port for ports 21 and greater,[25] all on a per matching engine basis, with NASDAQ having multiple matching engines.[26] The NASDAQ SQF Interface Specification provides that PHLX/NOM/BX Options trading infrastructures may consist of multiple matching engines with each matching engine trading only a range of option underlyings. Further, the SQF infrastructure is such that the firms connect to one or more servers residing directly on the matching engine infrastructure. Since there may be multiple matching engines, firms will need to connect to each engine's infrastructure in order to establish the ability to quote the symbols handled by that engine.[27]

In the each of the above cases, the Exchange's highest tier in the proposed tiered-pricing structure is lower than that of competing options exchanges. Further, as described in more detail below, those exchanges generate higher operating profit margins and higher ''access fees'' than the Exchange, even with the proposed fee change. Despite proposing lower or similar fees to that of competing options exchanges with similar market share, the Exchange believes that it provides a better overall value to its Members and non-Members via a highly deterministic System, enhanced network monitoring and customer reporting, and a superior network infrastructure than markets with higher market shares and more expensive access alternatives. Each of the port rates in place at competing

[16] *See* Securities Exchange Act Release No. 85459 (March 29, 2019), 84 FR 13363 (April 4, 2019) (SR–BOX–2018–24, SR–BOX–2018–37, and SR–BOX–2019–04).

[17] *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019), at *https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees* (the ''Guidance'').

[18] See Securities Exchange Act Release Nos. 90981 (January 25, 2021), 86 FR 7582 (January 29, 2021) (SR–PEARL–2021–01) (proposal to increase connectivity fees); 91460 (April 2, 2021), 86 FR 18349 (SR–EMERALD–2021–11) (proposal to adopt port fees, increase connectivity fees, and increase additional limited service ports); 91033 (February 1, 2021), 86 FR 8455 (February 5, 2021) (SR–EMERALD–2021–03) (proposal to adopt trading permit fees).

[19] *See* ''The market at a glance,'' *available at https://www.miaxoptions.com/* (last visited September 27, 2021).

[20] *See* ''The market at a glance,'' *available at https://www.miaxoptions.com/* (last visited September 23, 2021).

[21] *See id.*

[22] *See* NYSE American Options Fee Schedule, Section V.A., Port Fees; NYSE Arca Options Fee Schedule, Port Fees.

[23] *See* NYSE Technology FAQ and Best Practices: Options, Section 5.1 (How many matching engines are used by each exchange?) (September 2020) (providing a link to an Excel file detailing the number of matching engines per options exchange).

[24] *See supra* note 20.

[25] *See* Nasdaq Stock Market, Nasdaq Options 7 Pricing Schedule, Section 3, Nasdaq Options Market—Ports and Other Services.

[26] *See* Nasdaq Specialized Quote Interface (SQF) Specification, Version 6.4 (October 2017), Section 2, Architecture (the ''NASDAQ SQF Interface Specification'').

[27] *See id.*

options exchanges were filed with the Commission for immediate effectiveness and remain in place today.

Separately, the Exchange is not aware of any reason why market participants could not simply drop their access (or not initially access an exchange) if an exchange were to establish prices for its non-transaction fees that, in the determination of such market participant, did not make business or economic sense for such market participant to access such exchange. No options market participant is required by rule, regulation, or competitive forces to be a Member of the Exchange. As evidence of the fact that market participants can and do drop their access to exchanges based on non-transaction fee pricing, R2G Services LLC (''R2G'') filed a comment letter after BOX's proposed rule changes to increase its connectivity fees (SR–BOX–2018–24, SR–BOX–2018–37, and SR–BOX–2019–04). The R2G Letter stated, ''[w]hen BOX instituted a $10,000/month price increase for connectivity; we had no choice but to terminate connectivity into them as well as terminate our market data relationship. The cost benefit analysis just didn't make any sense for us at those new levels.'' Similarly, the Exchange's affiliate, MIAX Emerald, noted in a recent filing that once MIAX Emerald issued a notice that it was instituting MEI Port fees, among other non-transaction fees, one MIAX Emerald Member dropped its access to MIAX Emerald as a result of those fees.[28] Accordingly, these examples show that if a market participant believes, based on its business model, that an exchange charges too high of a fee for ports and/or other non-transaction fees, including other access fees for its relevant marketplace, market participants can choose to drop their access to such exchange.

In order to provide more detail and to quantify the Exchange's costs associated with providing access to the Exchange in general, the Exchange notes that there are material costs associated with providing the infrastructure and headcount to fully-support access to the Exchange. The Exchange incurs technology expense related to establishing and maintaining Information Security services, enhanced network monitoring and customer reporting, as well as Regulation SCI mandated processes, associated with its network technology. While some of the expense is fixed, much of the expense is not fixed, and thus increases as the services associated with the Proposed Access Fees increase. For example, new Members to the Exchange may require the purchase of additional hardware to support those Members as well as enhanced monitoring and reporting of customer performance that the Exchange and its affiliates provide. Further, as the total number Members increases, the Exchange and its affiliates may need to increase their data center footprint and consume more power, resulting in increased costs charged by their third-party data center provider. Accordingly, the cost to the Exchange and its affiliates to provide access to its System for market participants is not fixed. The Exchange believes the Proposed Access Fees are a reasonable attempt to offset a portion of the costs to the Exchange associated with providing access to its network infrastructure.

The Exchange only has four primary sources of revenue: Transaction fees, access fees (which includes the Proposed Access Fees), regulatory fees, and market data fees. Accordingly, the Exchange must cover all of its expenses from these four primary sources of revenue.

The Exchange believes that the Proposed Access Fees are fair and reasonable because they will not result in excessive pricing or supra-competitive profit, when comparing the total annual expense that the Exchange projects to incur in connection with providing these access services versus the total annual revenue that the Exchange projects to collect in connection with services associated with the Proposed Access Fees. For 2021,[29] the total annual expense for providing the access services associated with the Proposed Access Fees is projected to be approximately $1.32 million. The approximately $1.32 million in projected total annual expense is comprised of the following, all of which are directly related to the access services associated with the Proposed Access Fees: (1) Third-party expense, relating to fees paid by the Exchange to third-parties for certain products and services; and (2) internal expense, relating to the internal costs of the Exchange to provide the services associated with the Proposed Access Fees.[30] As noted above, the Exchange believes it is more appropriate to analyze the Proposed Access Fees utilizing its 2021 revenue and costs, which utilize the same presentation methodology as set forth in the Exchange's previously-issued Audited Unconsolidated Financial Statements.[31] The $1.32 million in projected total annual expense is directly related to the access services associated with the Proposed Access Fees, and not any other product or service offered by the Exchange. It does not include general costs of operating matching systems and other trading technology, and no expense amount was allocated twice.

As discussed, the Exchange conducted an extensive cost review in which the Exchange analyzed nearly every expense item in the Exchange's general expense ledger (this includes over 150 separate and distinct expense items) to determine whether each such expense relates to the access services associated with the Proposed Access Fees, and, if such expense did so relate, what portion (or percentage) of such expense actually supports those services, and thus bears a relationship that is, ''in nature and closeness,'' directly related to those services. The sum of all such portions of expenses represents the total cost of the Exchange to provide access services associated with the Proposed Access Fees.

For 2021, total third-party expense, relating to fees paid by the Exchange to third-parties for certain products and services for the Exchange to be able to provide the access services associated with the Proposed Access Fees, is projected to be $0.16 million. This includes, but is not limited to, a portion of the fees paid to: (1) Equinix, for data center services, for the primary, secondary, and disaster recovery locations of the Exchange's trading system infrastructure; (2) Zayo Group Holdings, Inc. (''Zayo'') for network services (fiber and bandwidth products

[28] *See* Securities Exchange Act Release No. 91460 (April 2, 2021), 86 FR 18349 (April 8, 2021) (SR–EMERALD–2021–11) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule To Adopt Port Fees, Increase Certain Network Connectivity Fees, and Increase the Number of Additional Limited Service MIAX Emerald Express Interface Ports Available to Market Makers) (adopting tiered MEI Port fee structure ranging from $5,000 to $20,500 per month).

[29] The Exchange has not yet finalized its 2021 year end results.

[30] The percentage allocations used in this proposed rule change may differ from past filings from the Exchange or its affiliates due to, among other things, changes in expenses charged by third-parties, adjustments to internal resource allocations, and different system architecture of the Exchange as compared to its affiliates.

[31] For example, the Exchange previously noted that all third-party expense described in its prior fee filing was contained in the information technology and communication costs line item under the section titled ''Operating Expenses Incurred Directly or Allocated From Parent,'' in the Exchange's 2019 Form 1 Amendment containing its financial statements for 2018. *See* Securities Exchange Act Release No. 87875 (December 31, 2019), 85 FR 770 (January 7, 2020) (SR–MIAX–2019–51). Accordingly, the third-party expense described in this filing is attributed to the same line item for the Exchange's 2021 Form 1 Amendment, which will be filed in 2022.

and services) linking the Exchange's office locations in Princeton, New Jersey and Miami, Florida, to all data center locations; (3) Secure Financial Transaction Infrastructure (''SFTI''),[32] which supports connectivity and feeds for the entire U.S. options industry; (4) various other services providers (including Thompson Reuters, NYSE, Nasdaq, and Internap), which provide content, connectivity services, and infrastructure services for critical components of options connectivity and network services; and (5) various other hardware and software providers (including Dell and Cisco, which support the production environment in which Members connect to the network to trade, receive market data, etc.). For clarity, only a portion of all fees paid to such third-parties is included in the third-party expense herein, and no expense amount is allocated twice. Accordingly, the Exchange does not allocate its entire information technology and communication costs to the access services associated with the Proposed Access Fees.

For clarity, only a portion of all fees paid to such third-parties is included in the third-party expense herein, and no expense amount is allocated twice. Accordingly, the Exchange does not allocate its entire information technology and communication costs to the access services associated with the Proposed Access Fees. Further, the Exchange notes that, with respect to the expenses included herein, those expenses only cover the MIAX market; expenses associated with MIAX Pearl for its options and equities markets and MIAX Emerald, are accounted for separately and are not included within the scope of this filing. As noted above, the percentage allocations used in this proposed rule change may differ from past filings from the Exchange or its affiliates due to, among other things, changes in expenses charged by third-parties, adjustments to internal resource allocations, and different system architecture of the Exchange as compared to its affiliates. Further, as part its ongoing assessment of costs and expenses, the Exchange recently conducted a periodic thorough review of its expenses and resource allocations which, in turn, resulted in a revised percentage allocations in this filing.

The Exchange believes it is reasonable to allocate such third-party expense described above towards the total cost to the Exchange to provide the access services associated with the Proposed Access Fees. In particular, the Exchange believes it is reasonable to allocate the identified portion of the Equinix expense because Equinix operates the data centers (primary, secondary, and disaster recovery) that host the Exchange's network infrastructure. This includes, among other things, the necessary storage space, which continues to expand and increase in cost, power to operate the network infrastructure, and cooling apparatuses to ensure the Exchange's network infrastructure maintains stability. Without these services from Equinix, the Exchange would not be able to operate and support the network and provide the access services associated with the Proposed Access Fees to its Members and their customers. The Exchange did not allocate all of the Equinix expense toward the cost of providing the access services associated with the Proposed Access Fees, only that portion which the Exchange identified as being specifically mapped to providing the access services associated with the Proposed Access Fees, approximately 4.95% of the total applicable Equinix expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees, and not any other service, as supported by its cost review.[33]

The Exchange believes it is reasonable to allocate the identified portion of the Zayo expense because Zayo provides the internet, fiber and bandwidth connections with respect to the network, linking the Exchange with its affiliates, MIAX Pearl and MIAX Emerald, as well as the data center and disaster recovery locations. As such, all of the trade data, including the billions of messages each day per exchange, flow through Zayo's infrastructure over the Exchange's network. Without these services from Zayo, the Exchange would not be able to operate and support the network and provide the access services associated with the Proposed Access Fees. The Exchange did not allocate all of the Zayo expense toward the cost of providing the access services associated with the Proposed Access Fees, only the portion which the Exchange identified as being specifically mapped to providing the Proposed Access Fees, approximately 2.64% of the total applicable Zayo expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees, and not any other service, as supported by its cost review.[34]

The Exchange believes it is reasonable to allocate the identified portions of the SFTI expense and various other service providers' (including Thompson Reuters, NYSE, Nasdaq, and Internap) expense because those entities provide connectivity and feeds for the entire U.S. options industry, as well as the content, connectivity services, and infrastructure services for critical components of the network. Without these services from SFTI and various other service providers, the Exchange would not be able to operate and support the network and provide access to its Members and their customers. The Exchange did not allocate all of the SFTI and other service providers' expense toward the cost of providing the access services associated with the Proposed Access Fees, only the portions which the Exchange identified as being specifically mapped to providing the access services associated with the Proposed Access Fees, approximately 4.95% of the total applicable SFTI and other service providers' expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees.[35]

The Exchange believes it is reasonable to allocate the identified portion of the other hardware and software provider expense because this includes costs for dedicated hardware licenses for switches and servers, as well as dedicated software licenses for security monitoring and reporting across the network. Without this hardware and software, the Exchange would not be able to operate and support the network and provide access to its Members and their customers. The Exchange did not allocate all of the hardware and software provider expense toward the cost of

[32] In fact, on October 22, 2019, the Exchange was notified by SFTI that it is again raising its fees charged to the Exchange by approximately 11%, without having to show that such fee change complies with the Act by being reasonable, equitably allocated, and not unfairly discriminatory. It is unfathomable to the Exchange that, given the critical nature of the infrastructure services provided by SFTI, that its fees are not required to be rule-filed with the Commission pursuant to Section 19(b)(1) of the Act and Rule 19b–4 thereunder. *See* 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4, respectively.

[33] As noted above, the percentage allocations used in this proposed rule change may differ from past filings from the Exchange or its affiliates due to, among other things, changes in expenses charged by third-parties, adjustments to internal resource allocations, and different system architecture of the Exchange as compared to its affiliates. Again, as part its ongoing assessment of costs and expenses, the Exchange recently conducted a periodic thorough review of its expenses and resource allocations which, in turn, resulted in a revised percentage allocations in this filing.

[34] *Id.*

[35] *Id.*

providing the access services associated with the Proposed Access Fees, only the portions which the Exchange identified as being specifically mapped to providing the access services associated with the Proposed Access Fees, approximately 4.95% of the total applicable hardware and software provider expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees.[36]

For 2021, total projected internal expense, relating to the internal costs of the Exchange to provide the access services associated with the Proposed Access Fees, is projected to be $1.16 million. This includes, but is not limited to, costs associated with: (1) Employee compensation and benefits for full-time employees that support the access services associated with the Proposed Access Fees, including staff in network operations, trading operations, development, system operations, and business that support those employees and functions (including an increase as a result of the higher determinism project); (2) depreciation and amortization of hardware and software used to provide the access services associated with the Proposed Access Fees, including equipment, servers, cabling, purchased software and internally developed software used in the production environment to support the network for trading; and (3) occupancy costs for leased office space for staff that provide the access services associated with the Proposed Access Fees. The breakdown of these costs is more fully-described below. For clarity, only a portion of all such internal expenses are included in the internal expense herein, and no expense amount is allocated twice. Accordingly, the Exchange does not allocate its entire costs contained in those items to the access services associated with the Proposed Access Fees.

The Exchange believes it is reasonable to allocate such internal expense described above towards the total cost to the Exchange to provide the access services associated with the Proposed Access Fees. In particular, the Exchange's employee compensation and benefits expense relating to providing the access services associated with the Proposed Access Fees is projected to be approximately $0.91 million, which is only a portion of the $12.6 million total projected expense for employee compensation and benefits. The Exchange believes it is reasonable to allocate the identified portion of such expense because this includes the time spent by employees of several departments, including Technology, Back Office, Systems Operations, Networking, Business Strategy Development (who create the business requirement documents that the Technology staff use to develop network features and enhancements), and Trade Operations. As part of the extensive cost review conducted by the Exchange, the Exchange reviewed the amount of time spent by each employee on matters relating to the provision of access services associated with the Proposed Access Fees. Without these employees, the Exchange would not be able to provide the access services associated with the Proposed Access Fees to its Members and their customers. The Exchange did not allocate all of the employee compensation and benefits expense toward the cost of the access services associated with the Proposed Access Fees, only the portions which the Exchange identified as being specifically mapped to providing the access services associated with the Proposed Access Fees, approximately 7.24% of the total applicable employee compensation and benefits expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees, and not any other service, as supported by its cost review.[37]

The Exchange's depreciation and amortization expense relating to providing the services associated with the Proposed Access Fees is projected to be $0.22 million, which is only a portion of the $4.8 million total projected expense for depreciation and amortization. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network and provide the access services associated with the Proposed Access Fees. Without this equipment, the Exchange would not be able to operate the network and provide the access services associated with the Proposed Access Fees to its Members and their customers. The Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing the access services associated with the Proposed Access Fees, only the portion which the Exchange identified as being specifically mapped to providing the access services associated with the Proposed Access Fees, approximately 4.60% of the total applicable depreciation and amortization expense, as these access services would not be possible without relying on such. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the access services associated with the Proposed Access Fees, and not any other service, as supported by its cost review.[38]

The Exchange's occupancy expense relating to providing the services associated with the Proposed Access Fees is projected to be $0.03 million, which is only a portion of the $0.6 million total projected expense for occupancy. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense represents the portion of the Exchange's cost to rent and maintain a physical location for the Exchange's staff who operate and support the network, including providing the access services associated with the Proposed Access Fees. This amount consists primarily of rent for the Exchange's Princeton, NJ office, as well as various related costs, such as physical security, property management fees, property taxes, and utilities. The Exchange operates its Network Operations Center (''NOC'') and Security Operations Center (''SOC'') from its Princeton, New Jersey office location. A centralized office space is required to house the staff that operates and supports the network. The Exchange currently has approximately 150 employees. Approximately two-thirds of the Exchange's staff are in the Technology department, and the majority of those staff have some role in the operation and performance of the access services associated with the Proposed Access Fees. Without this office space, the Exchange would not be able to operate and support the network and provide the access services associated with the Proposed Access Fees to its Members and their customers. Accordingly, the Exchange believes it is reasonable to allocate the identified portion of its occupancy expense because such amount represents the Exchange's actual cost to house the equipment and personnel who operate and support the Exchange's network infrastructure and the access services associated with the Proposed Access Fees. The Exchange

[36] *Id.*

[37] *Id.*

[38] *Id.*

did not allocate all of the occupancy expense toward the cost of providing the access services associated with the Proposed Access Fees, only the portion which the Exchange identified as being specifically mapped to operating and supporting the network, approximately 4.69% of the total applicable occupancy expense. The Exchange believes this allocation is reasonable because it represents the Exchange's cost to provide the access services associated with the Proposed Access Fees, and not any other service, as supported by its cost review.[39]

The Exchange notes that a material portion of its total overall expense is allocated to the provision of access services (including connectivity, ports, and trading permits). The Exchange believes this is reasonable and in line, as the Exchange operates a technology-based business that differentiates itself from its competitors based on its trading systems that rely on access to a high performance network, resulting in significant technology expense. Over two-thirds of Exchange staff are technology-related employees. The majority of the Exchange's expense is technology-based. As described above, the Exchange has only four primary sources of fees to recover their costs; thus, the Exchange believes it is reasonable to allocate a material portion of their total overall expense towards access fees.

Accordingly, based on the facts and circumstances presented, the Exchange believes that its provision of the access services associated with the Proposed Access Fees will not result in excessive pricing or supra-competitive profit. To illustrate, on a going-forward, fully-annualized basis, the Exchange projects that annualized revenue for providing the access services associated with the Proposed Access Fees would be approximately $3.21 million per annum, based on a recent billing cycle. This revenue number includes the revenue the Exchange projects to collect only from the fees the Exchange will charge for additional Limited Service MEI Ports after the first two Limited Service MEI Ports that Market Makers receive for free. The Exchange projects that its annualized expense for providing the services associated with the Proposed Access Fees will be approximately $1.32 million per annum. This expense includes the costs related to all Limited Service MEI Ports, including the two Limited Service MEI Ports that Market Makers receive for free. Accordingly, on a fully-annualized basis, the Exchange believes its total projected revenue for providing the access services associated with the Proposed Access Fees will not result in excessive pricing or supra-competitive profit, as the Exchange will make a profit margin of approximately 59% ($3.21 million in total revenue minus $1.32 million in expense = $1.89 million in profit per annum). Additionally, this profit margin does not take into account the cost of capital expenditures (''CapEx'') the Exchange projects to spend each year on CapEx going forward.

For the avoidance of doubt, none of the expenses included herein relating to the access services associated with the Proposed Access Fees relate to the provision of any other services offered by the Exchange or its affiliates. Stated differently, no expense amount of the Exchange is allocated twice. The Exchange notes that, with respect to expenses associated with the Exchange's affiliates, MIAX Pearl and MIAX Emerald, those expenses are accounted for separately and are not included within the scope of this filing. Stated differently, no expense amount of the Exchange is also allocated to MIAX Pearl or MIAX Emerald.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to allocate the respective percentages of each expense category described above towards the total cost to the Exchange of operating and supporting the network, including providing the access services associated with the Proposed Access Fees because the Exchange performed a line-by-line item analysis of nearly every expense of the Exchange, and has determined the expenses that directly relate to providing access to the Exchange. Further, the Exchange notes that, without the specific third-party and internal items listed above, the Exchange would not be able to provide the access services associated with the Proposed Access Fees to its Members and their customers. Each of these expense items, including physical hardware, software, employee compensation and benefits, occupancy costs, and the depreciation and amortization of equipment, have been identified through a line-by-line item analysis to be integral to providing access services. The Proposed Access Fees are intended to recover the Exchange's costs of providing access to its System. Accordingly, the Exchange believes that the Proposed Access Fees are fair and reasonable because they do not result in excessive pricing or supra-competitive profit, when comparing the actual costs to the Exchange versus the projected annual revenue from the Proposed Access Fees.

The Exchange believes the proposed changes are reasonable, equitably allocated and not unfairly discriminatory, and do not result in a ''supra-competitive'' [40] profit. Of note, the Guidance defines ''supra-competitive profit'' as profits that exceed the profits that can be obtained in a competitive market.[41] With the proposed changes, the Exchange anticipates that its profit margin will be approximately 59%, inclusive of the Proposed Access Fees. In order to achieve a consistent, premium network performance, the Exchange must build out and continue to maintain a network that has the capacity to handle the message rate requirements of not only firms that consume minimal ports resources of the Exchange, but also those firms that most heavily consume port resources of the Exchange, network consumers, and purchasers of numerous Limited Service MEI Ports, which handle billions of messages per day across the Exchange's network. These billions of messages per day consume the Exchange's resources and significantly contribute to the overall network port expense for storage and network transport capabilities. Given that purchasers of the greatest amount of Limited Service MEI Ports utilize the most resources across the network, the Exchange believes that it is reasonable to operate at a profit margin of approximately 59% for these ports, inclusive of the Proposed Access Fees. Such profit margin should enable the Exchange to continue to invest in its network and systems, maintain its current infrastructure, support future enhancements to ports and network connectivity, and continue to offer enhanced customer reporting and monitoring services.

While the proposed fees are similar or less than that of other options exchanges,[42] as discussed above, the incremental increase in revenue generated from the 59% profit margin for Limited Service MEI Ports will allow the Exchange to further invest in its System architecture and matching engine functionality to the benefit of all market participants. The ability to continue to invest in technology and systems will also enable the Exchange to improve the determinism and overall performance of not only its logical ports, but overall performance including the resiliency and efficiency of its matching engines. The revenue generated under the proposed rule change would also provide the Exchange with the resources

[39] *Id.*

[40] *See supra* note 17.

[41] *See id.*

[42] *See supra* notes 22 and 25.

necessary to further innovate and enhance its systems and seek additional improvements or functionality to offer market participants generally. The Exchange believes that these investments, in turn, will benefit all investors by encouraging other exchanges to further invest, innovate, and improve their own systems in response.

Based on the 2020 Audited Financial Statements of competing options exchanges (since the 2021 Audited Financial Statements will likely not become publicly available until early July 2022, after the Exchange has submitted this filing), the Exchange's revenue that is derived from its access fees is in line with the revenue that is derived from access fees of competing exchanges. For example, the total revenue from ''access fees'' [43] for 2020 for MIAX was $15,805,000. MIAX projects that the total revenue from ''access fees'' for 2021 for MIAX will be $21,727,396, inclusive of the Proposed Access Fees described herein. The Exchanges notes that the projected 2021 ''access fee'' revenue also includes projected revenue due to the Exchange's recent proposal to move to a tiered-pricing structure for its 10Gb ULL connectivity (SR–MIAX–2021–41).

The Exchange's 2021 projected revenue from access fees is still less than, or similar to, the access fee revenues generated by other U.S. options exchanges. For example, the Cboe Exchange, Inc. (''Cboe'') reported $70,893,000 in ''access and capacity fee'' [44] revenue for 2020. Cboe C2 Exchange, Inc. (''C2'') reported $19,016,000 in ''access and capacity fee'' revenue for 2020.[45] Cboe BZX Exchange, Inc. (''BZX'') reported $38,387,000 in ''access and capacity fee'' revenue for 2020.[46] Cboe EDGX Exchange, Inc. (''EDGX'') reported $26,126,000 in ''access and capacity fee'' revenue for 2020.[47] PHLX reported $20,817,000 in ''Trade Management Services'' revenue for 2019.[48] The Exchange notes it is unable to compare ''access fee'' revenues with PHLX (or other affiliated NASDAQ exchanges) because after 2019, the ''Trade Management Services'' line item was bundled into a much larger line item in PHLX's Form 1, simply titled ''Market services.'' [49]

The Exchange also believes that, based on the 2020 Audited Financial Statements of competing options exchanges, the Exchange's overall operating margin is in line with or less than the operating margins of competing options exchanges, including the revenue and expense associated with the Proposed Access Fees. For example, the 2020 operating margin for MIAX was 46%.[50] Based on competing exchanges' Form 1 Amendments, ISE's operating profit margin for 2020 was approximately 85%; PHLX's operating profit margin for 2020 was approximately 49%; NASDAQ's operating profit margin for 2020 was approximately 62%; Arca's operating profit margin for 2020 was approximately 55%; Amex's operating profit margin for 2020 was approximately 59%; Cboe Exchange, Inc.'s (''Cboe'') operating profit margin for 2020 was approximately 74%; and Cboe BZX Exchange, Inc.'s (''BZX'') operating profit margin for 2020 was approximately 52%. The Exchange's anticipated operating margin, inclusive of this proposed fee change, would remain lower than or comparable to that of the competing U.S. options exchanges.

The Exchange further believes its proposed fees are reasonable, equitably allocated and not unfairly discriminatory because the Exchange believes that it benefits overall competition in the marketplace to allow relatively new entrants like the Exchange and its affiliates, MIAX Pearl and MIAX Emerald, to propose fees that may help these new entrants recoup their substantial investment in building out costly infrastructure. The Exchange and its affiliates have historically set their fees purposefully low in order to attract business and market share. The Exchange notes that the concept of a tiered-pricing structure for ports is not new or novel.[51]

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees for services and products, in addition to order flow, to remain competitive with other exchanges. The Exchange believes that the proposed changes reflect this competitive environment.

The Exchange believes the proposal to move from a flat fee per month to a tiered-pricing structure is reasonable, equitably allocated and not unfairly discriminatory because the Exchange believes the proposed structure would encourage firms to be more economical and efficient in the number of Limited Service MEI Ports they purchase. The Exchange believes this will enable the Exchange to better monitor and provide access to the Exchange's network in order to ensure that the Exchange meets its obligations under the Act such that access to the Exchange is offered on terms that are not unfairly discriminatory, as well as to ensure sufficient capacity and headroom in the System.

There is also no regulatory requirement that any market participant access any one options exchange, that each Market Maker access the Exchange utilizing more than the two free Limited Service MEI Ports that the Exchange provides, access the Exchange in a particular capacity, or trade any particular product offered on the Exchange. Moreover, membership is not a requirement to participate on the Exchange. A market participant may submit orders to the Exchange via a Sponsored User.[52] Indeed, the Exchange is unaware of any one options exchange

[43] As described in the Exchange's Audited Financial Statements, fees for ''access services'' are assessed to exchange members for the opportunity to trade and use other related functions of the exchanges. *See https://www.sec.gov/Archives/edgar/vprr/2100/21000461.pdf.*

[44] According to Cboe, access and capacity fees represent fees assessed for the opportunity to trade, including fees for trading-related functionality. *See* Form 1 Amendment, at *https://www.sec.gov/Archives/edgar/vprr/2100/21000465.pdf.*

[45] *See id.*

[46] *See id.*

[47] *See id.*

[48] According to PHLX, ''Trade Management Services'' includes ''a wide variety of alternatives for connectivity to and accessing [the PHLX] markets for a fee. These participants are charged monthly fees for connectivity and support in accordance with [PHLX's] published fee schedules.'' *See* Form 1 Amendment, at *https://www.sec.gov/Archives/edgar/vprr/2001/20012246.pdf.*

[49] *See* Form 1 Amendment, at *https://www.sec.gov/Archives/edgar/vprr/2100/21000475.pdf.*

[50] This information is provided in response to the SIG Comment Letter. *See supra* note 8.

[51] *See* Cboe BZX Exchange, Inc. (''BZX'') Options Fee Schedule, Options Logical Port Fees, Ports with Bulk Quoting Capabilities (charging $1,500/month for the 1st and 2nd port, $2,500/month for the 3rd port or more); Cboe Exchange, Inc. (''Cboe'') Fee Schedule, Logical Connectivity Fees (charging $750/month per port for BOE/FIX Logical Ports 1 to 5 and $800/month per port for BOE/FIX Logical Ports greater than 5; charging $1,500/month per port for BOE Bulk Logical Ports 1 to 5, $2,500/month per port for BOE Bulk Logical Ports 6 to 30, and $3,000/month per port for BOE Bulk Logical Ports greater than 30); The Nasdaq Stock Market LLC (''Nasdaq''), Options 7, Pricing Schedule, Section 3 Nasdaq Options Market—Ports and Other Services (charging $1,500/month per port for first 5 ports, $1,000/month per port for the next 15 ports, and $500/month per port for all ports over 20).

[52] *See* Exchange Rule 210. The Sponsored User is subject to the fees, if any, of the Sponsoring Member. The Exchange notes that the Sponsoring Member is not required to publicize, let alone justify or file with the Commission its fees, and as such could charge the Sponsored User any fees it deems appropriate, even if such fees would otherwise be considered supra-competitive, or otherwise potentially unreasonable or uncompetitive.

whose membership includes every registered broker-dealer. Based on a recent analysis conducted by Cboe, as of October 21, 2020, only three (3) of the broker-dealers, out of approximately 250 broker-dealers, were members of at least one exchange that lists options for trading and were members of all 16 options exchanges.[53] Additionally, the Cboe Fee Filing found that several broker-dealers were members of only a single exchange that lists options for trading and that the number of members at each exchange that trades options varies greatly.[54]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

With respect to intra-market competition, the Exchange does not believe that the proposed rule change would place certain market participants at the Exchange at a relative disadvantage compared to other market participants or affect the ability of such market participants to compete. As stated above, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that the proposed pricing structure for is associated with relative usage of the various market participants. Firms that are primarily order routers seeking best-execution do not utilize Limited Service MEI Ports on MIAX and therefore will not pay the fees associated with the tiered-pricing structure. Rather, the fees described in the proposed tiered-pricing structure will only be allocated to market making firms that engage in advanced trading strategies and typically request multiple Limited Service MEI Ports. Accordingly, the firms engaged in market making business generate higher costs by utilizing more of the Exchange's resources. The market making firms that purchase higher amounts of Limited Service MEI Ports tend to have specific business oriented market making and trading strategies, as opposed to firms engaging solely in best-execution order routing business. Additionally, the use of such additional Limited Service MEI Ports is entirely voluntary.

The Exchange also does not believe that the proposed rule change will result in any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, options market participants are not forced to access all options exchanges. The Exchange operates in a highly competitive environment, and as discussed above, its ability to price access and ports is constrained by competition among exchanges and third parties. There are other options markets of which market participants may access in order to trade options. There is also a possible range of alternative strategies, including routing to the exchange through another participant or market center or accessing the Exchange indirectly. For example, there are 15 other U.S. options exchanges, which the Exchange must consider in its pricing discipline in order to compete for market participants. In this competitive environment, market participants are free to choose which competing exchange to use to satisfy their business needs. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Accordingly, the Exchange does not believe its proposed fee changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange received one comment on the proposed rule change.[55] The Exchange notes that the Exchange, and its affiliates, MIAX Pearl and MIAX Emerald, justified similar fee changes in the past with similar, if not identical, justifications in previous filings that have been noticed by the Commission for public comment and are currently in effect.[56] Nonetheless, the Exchange has sought to address the commenters concerns via the enhanced justification and additional information included in this proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[57] and Rule 19b–4(f)(2)[58] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2021–43 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2021–43. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public

[53] *See* Securities Exchange Act Release No. 90333 (November 4, 2020), 85 FR 71666 (November 10, 2020) (SR–CBOE–2020–105) (the ''Cboe Fee Filing''). The Cboe Fee Filing cited to the October 2020 Active Broker Dealer Report, provided by the Commission's Office of Managing Executive, on October 8, 2020.

[54] *Id.*

[55] *See* the SIG Comment Letter, *supra* note 8.

[56] *See* Securities Exchange Act Release Nos. 90980 (January 25, 2021), 86 FR 7602 (January 29, 2021) (SR–MIAX–2021–02); 90981 (January 25, 2021), 86 FR 7582 (January 29, 2021) (SR–PEARL–2021–01); 91033 (February 1, 2021), 86 FR 8455 (February 5, 2021) (SR–EMERALD–2021–03); 91460 (April 2, 2021), 86 FR 18349 (April 8, 2021) (SR–EMERALD–2021–11).

[57] 15 U.S.C. 78s(b)(3)(A)(ii).

[58] 17 CFR 240.19b–4(f)(2).

Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2021–43 and should be submitted on or before October 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[59]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21618 Filed 10–4–21; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[License No. 02/02–0687]

Saratoga Investment Corp SBIC II; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Saratoga Investment Fund II, L.P. 535 Madison Ave, 4th Floor, New York, NY, 10022 a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concerns, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration Saratoga Investment Corp SBIC II is proposing to provide financing to Teachers of Tomorrow, 5599 San Felipe Street, Suite 1425, Houston, TX 77056, to support the company's growth.

The proposed transaction is brought within the purview of § 107.730 of the Regulations because Saratoga Investment Funding LLC, an Associate of Saratoga Investment Corp SBIC II, L.P., by virtue of Common Control as defined at § 107.50, holds a term loan in Teachers of Tomorrow and the proposed transaction would refinance such obligation to an Associate. Both Saratoga Investment Corp SBIC II, and Saratoga Investment Funding LLC are wholly owned by Saratoga Investment Corp, which holds an equity investment in Teachers of Tomorrow which will also be redeemed through the transaction.

Therefore, the proposed transaction is considered self-deal pursuant to 13 CFR 107.730 and requires a regulatory exemption. Notice is hereby given that any interested person may submit written comments on the transaction within fifteen days of the date of this publication to Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

Bailey DeVries,

Associate Administrator, Office of Investment and Innovation.

[FR Doc. 2021–21630 Filed 10–4–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17204 and #17205; VERMONT Disaster Number VT–00044]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Vermont

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Vermont (FEMA–4621–DR), dated 09/29/2021. Incident: Severe Storm and Flooding. Incident Period: 07/29/2021 through 07/30/2021.

DATES: Issued on 09/29/2021. Physical Loan Application Deadline Date: 11/29/2021. Economic Injury (EIDL) Loan Application Deadline Date: 06/29/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 09/29/2021, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Bennington, Windham.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.000
Non-Profit Organizations without Credit Available Elsewhere	2.000
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17204 6 and for economic injury is 17205 0.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021–21715 Filed 10–4–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

National Women's Business Council Meeting

AGENCY: Small Business Administration.

ACTION: Notice of open public meeting and listening session.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the National Women's Business Council (NWBC) announces its first public meeting of Fiscal Year 2022. The 1988 Women's Business Ownership Act established NWBC to serve as an independent source of advice and policy recommendations to the President, Congress, and the Administrator of the U.S. Small Business Administration (SBA) on issues of importance to women entrepreneurs. This meeting will allow the Council to recap its activity and engagement over the course of Fiscal Year 2021. Each of the Council's three subcommittees (Access to Capital & Opportunity, Women in STEM and Rural Women's Entrepreneurship) will present their policy recommendations and current projects to the full body for deliberation. The public will have the opportunity to provide feedback.

DATES: The public meeting will be held on Monday, October 25, 2021, from 1:00 p.m. to 3:00 p.m. EDT.

ADDRESSES: Due to the coronavirus pandemic, this meeting will be held via Microsoft Teams, a web conferencing platform. The access link will be provided to attendees upon registration.

FOR FURTHER INFORMATION CONTACT: For more information, please visit the

[59] 17 CFR 200.30–3(a)(12).

NWBC website at *www.nwbc.gov,* email *info@nwbc.gov* or call 202–205–3850.

SUPPLEMENTARY INFORMATION: The meeting is open to the public; however, advance notice of attendance is requested. To RSVP, please visit the NWBC website at *www.nwbc.gov*. The ''2022 Public Meetings'' section will feature a link to register on Eventbrite.

NWBC strongly encourages that public comments and questions be submitted in advance by October 19th. The Eventbrite registration page will include an opportunity to do so, but individuals may also email *info@nwbc.gov* with subject line—''[Name/Organization] Comment for 10/25/21 Public Meeting.'' NWBC staff will read the first five submitted statements during the final 20 minutes of the program.

During the live event, attendees will be in listen-only mode and may submit additional questions via the Q&A Chat feature. For technical assistance, please visit the Microsoft Teams Support Page. All public comments will be included in the meeting record, which will be made available on *www.nwbc.gov* under the ''2022 Public Meetings'' section.

Andrienne Johnson,

Committee Management Officer.

[FR Doc. 2021–21739 Filed 10–4–21; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 11551]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Whistler to Cassatt: American Painters in France'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Whistler to Cassatt: American Painters in France'' at the Denver Art Museum, Denver, Colorado; the Virginia Museum of Fine Arts, Richmond, Virginia; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Matthew R. Lussenhop,

Acting Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2021–21708 Filed 10–4–21; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11550]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''The Hare with Amber Eyes'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''The Hare with Amber Eyes'' at The Jewish Museum, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Matthew R. Lussenhop,

Acting Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2021–21712 Filed 10–4–21; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11554]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Wealth & Beauty: Pier Francesco Foschi and Painting in Renaissance Florence'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Wealth & Beauty: Pier Francesco Foschi and Painting in Renaissance Florence'' at the Georgia Museum of Art, Athens, Georgia, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Matthew R. Lussenhop,

Acting Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2021–21711 Filed 10–4–21; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11552]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Modern Architecture in South Asia: The Project of Decolonization (1947–1985)'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Modern Architecture in South Asia: The Project of Decolonization (1947–1985)'' at The Museum of Modern Art, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Matthew R. Lussenhop,

Acting Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2021–21709 Filed 10–4–21; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11553]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Staging Injustice. Italian Art 1880–1917'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Staging Injustice. Italian Art 1880–1917'' at the Center for Italian Modern Art, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Matthew R. Lussenhop,

Acting Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2021–21710 Filed 10–4–21; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. –2021–0005]

Petition for Exemption; Summary of Petition Received; Insitu, Inc.

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before October 25, 2021.

ADDRESSES: Send comments identified by docket number FAA–2021–0746 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Timothy R. Adams,

Acting Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2021–0746.
Petitioner: Insitu, Inc.
Section(s) of 14 CFR Affected: § 61.3(a)(1)(i).

Description of Relief Sought: Insitu, Inc. proposes to operate the ScanEagle3, a fixed-wing unmanned aircraft system (UAS), with a maximum takeoff weight of 85 pounds (lbs.), for Durability & Reliability flight test hours to show compliance towards type certification in the United States. Relief is requested from the requirement that a person acting as a required flight crewmember or a pilot of a civil aircraft must hold a pilot certificate issued under part 61. Insitu proposes the use of remote certificated pilots who have undergone platform-specific training based on part 61, rather than part 61 certificated pilots, during the controlled flight test operations within a FAA UAS test site, over low population density areas, operating with a special airworthiness certificate in the experimental category and a civil Certificate of Waiver or Authorization.

[FR Doc. 2021–21640 Filed 10–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Release Certain Properties From All Terms, Conditions, Reservations and Restrictions of a Release Agreement Between the City of Fernandina Beach and the United States of America for a Parcel Previously Included in the Fernandina Beach Municipal Airport Property, Fernandina, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for public comment.

SUMMARY: The FAA hereby provides notice of intent to release 2.63 acres near the Fernandina Beach Municipal Airport, Fernandina Beach, FL from the restrictions and reservations as contained in a Release Agreement between the United States of America and the City of Fernandina Beach, dated Novermber 24, 1954. The subject parcel is located on the Northwest Corner of Amelia Island Parkway and Amelia Road, north of the Fernandina Beach Municipal Airport in Nassau County. The subject parcel is defined as Nassau County, Florida, Parcel #06–2N–28–0000–0001–0010.

DATES: Comments are due on or before November 4, 2021.

ADDRESSES: Documents are available for review at Fernandina Beach Municipal Airport, and the FAA Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, FL 32819. Written comments on the Sponsor's request must be delivered or mailed to: Hilary Maull, Program Manager, Orlando Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, FL 32819.

FOR FURTHER INFORMATION CONTACT: Hilary Maull, Program Manager, Orlando Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, FL 32819.

SUPPLEMENTARY INFORMATION: The subject parcel was originally owned by the City of Fernandina Beach, Florida. On May 26, 1943, a ground lease was entered between the Federal Government and City of Fernandina Beach providing property for use as an airfield to be operated by the United States Navy. On July 9, 1947 a Cancellation of Lease and Quitclaim returned airport-owned property to the City of Fernandina Beach for the purposes of being operated as a public airport. On November 24, 1954 the United States of America, acting by and through the Administrator of Civil Aeronautics, and the City of Fernandina Beach approved a 'Release of the property with Restrictions and Reservations' (Restrictions). The Restrictions were established under Paragraphs 1C, 1D, and 1E of said Release, for a portion of airport property which included the subject parcel. The Restictions were obligated to carry forward with the deed of the property. In 1954, the subject parcel was sold from the City of Fernandina Beach to a private entity, with Restrictions. Since the initial sale, the subject parcel has changed ownership multiple times.

The Restrictions implemented in 1954 are outdated compared to current FAA airport protection surface restrictions, and are no longer deemed necessary or relevant to the subject parcel. The release of Restrictions will allow the current property owner to re-sell the subject parcel for future development. Future use of the subject parcel must comply with all City of Fernandina Beach Zoning and land use regulations as established by the City of Fernandina Beach. Any proposed development of the subject parcel will require submittal of an Obstruction Evaluation/Airport Airspace Analysis (OE/AAA) for review by the Federal Aviation Administration.

Documents reflecting the Sponsor's request are available, by appointment only, for inspection at the Fernandina Beach Municipal Airport and the FAA Airports District Office.

Section 125 of The Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR–21) requires the FAA to provide an opportunity for public notice and comment prior to the ''waiver'' or ''modification'' of a sponsor's Federal obligation to use certain airport land for non-aeronautical purposes.

Bartholomew Vernace,

Manager, Orlando Airports District Office, Southern Region.

[FR Doc. 2021–21621 Filed 10–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2021–01]

Petition for Exemption; Summary of Petition Received; Merck & Co., Inc.

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before October 25, 2021.

ADDRESSES: Send comments identified by docket number FAA–2021–0709 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to

http://www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Alphonso Pendergrass, *alphonso.pendergrass@faa.gov,* Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Timothy R. Adams,

Acting Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2021–0709.

Petitioner: Merck & Co., Inc.

Section(s) of 14 CFR Affected: § 91.211(b)(1)(ii).

Description of Relief Sought: Merck seeks an alternative means of compliance for 14 CFR 91.211(b)(1)(ii) that will permit it to fly above FL 410 without one pilot wearing an oxygen mask. This request is based on additional conditions and limitations as well as the design features of the Gulfstream G550/650 aircraft designed to reduce the likelihood of decompression and provide for an automated emergency descent in the event of a decompression.

[FR Doc. 2021–21641 Filed 10–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Indiana and Kentucky

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by FHWA and other federal agencies.

SUMMARY: This notice announces actions taken by the FHWA and the USFWS that are final pursuant to the statute. The actions relate to the proposed I–69 Ohio River Crossing (ORX) project in Evansville, Indiana and Henderson, Kentucky and grant licenses, permits, and approvals for the project.

DATES: By this notice, FHWA is advising the public that FHWA and other Federal agencies have made decisions that are subject to 23 U.S.C. 139(l)(1) and are final within the meaning of that law. A claim seeking judicial review of those Federal agency decisions on the proposed highway project will be barred unless the claim is filed on or before March 4, 2022. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then the shorter time period applies.

FOR FURTHER INFORMATION CONTACT: For the FHWA: Ms. Michelle Allen, Federal Highway Administration, Indiana Division, 575 North Pennsylvania Street, Room 254, Indianapolis, IN 46204–1576; telephone: (317) 226–7344; email: *Michelle.Allen@dot.gov.* The FHWA Indiana Division Office's normal business hours are 7:30 a.m. to 4:00 p.m., EST. For the USFWS: Mr. Scott Pruitt, Field Supervisor, Indiana Field Office, USFWS, 620 South Walker Street, Bloomington, IN 47403–2121; telephone: (812) 334–4261; email: *Scott_Pruitt@fws.gov.* Normal business hours for the USFWS Indiana Field Office are: 8 a.m. to 4:30 p.m., EST. For the Indiana Department of Transportation (INDOT), you may contact Laura Hilden, Director—Environmental Services, 100 North Senate Avenue, Room N758–ES, Indianapolis, IN 46204; telephone: (317) 552–9692; email: *lhilden@indot.in.gov.* Normal business hours for INDOT are: 8:00 a.m. to 4:30 p.m., EST. For the Kentucky Transportation Cabinet (KYTC), you may contact Danny Peake, Director—Division of Environmental Analysis, 200 Mero Street, Frankfort, KY 40622; telephone: (502) 564–7250; email: *Danny.Peake@ky.gov.* Normal business hours for KYTC are: 8:00 a.m. to 4:30 p.m., EST.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA has approved the Final Environmental Impact Statement (FEIS) for the I–69 ORX project in Evansville, Indiana and Henderson, Kentucky and issued a Record of Decision (ROD) on September 16, 2021.

The FEIS and ROD identified Central Alternative 1B Modified as the Selected Alternative. Decisions in the FEIS and ROD that were cited in the **Federal Register** included, but were not limited to, the following:

1. Purpose and need for the project.
2. Range of alternatives for analysis.
3. Screening of alternatives and the identification of alternatives to be carried forward for more detailed analysis in the Draft Environmental Impact Statement (DEIS).
4. Identification of Central Alternatives 1A and 1B as the Preferred Alternatives in the DEIS and the decision to prepare a combined FEIS and ROD.
5. Development and identification of Central Alternative 1B Modified as the Single Preferred Alternative.
6. Identification of Central Alternative 1B Modified as the Selected Alternative in the combined FEIS and ROD.

Interested parties may consult the FEIS and ROD for details about each of the decisions described above and for information on other issues decided. The FEIS and ROD can be viewed and downloaded from the project website at *https://i69ohiorivercrossing.com/.* People unable to access the website may contact FHWA, INDOT, or KYTC at the addresses listed above. Decisions in the I–69 ORX FEIS and ROD that have final approval include, but are not limited to, the following:

1. National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351].
2. Endangered Species Act [16 U.S.C. 1531–1544]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667d]; Migratory Bird Treaty Act [16 U.S.C. 703–712]; Bald and Golden Eagle Protection Act [16 U.S.C. 688–688d].
3. Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].
4. Clean Air Act, 42 U.S.C. 7401–7671(q).
5. Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303].
6. Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa–470(ll)]; Archeological and Historic Preservation Act [16 U.S.C. 469–469c]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].
7. Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j)(6)].
8. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601–9675]; Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].
9. Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; Uniform Relocation Assistance and Real Property Acquisition Act [42 U.S.C. 61].
10. Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

11. Executive Order (E.O.) 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

Notice is hereby given that the USFWS has taken the final agency actions within the meaning of 23 U.S.C. 139(l)(1) by issuing the following:

1. A letter dated September 3, 2020, concurring with the effects determinations in the Biological Assessment (BA) and that no further coordination with the USFWS is needed for the species that received a ''may affect, not likely to adversely affect'' determination and for the northern long-eared bat, which received a ''may affect, is likely to adversely affect'' determination. The adverse effects for the northern long-eared bat will be addressed through Section 4(d) of the Endangered Species Act.

2. A Biological Opinion (BO) dated December 17, 2020, that the I–69 ORX project is not likely to jeopardize the continued existence of the fat pocketbook and sheepnose mussels.

3. A Conference Opinion dated December 17, 2020, that the I–69 ORX project is not likely to jeopardize the continued existence of the longsolid mussel.

As part of the BA, the Indiana bat received an effect determination of ''may affect, is likely to adversely affect.'' The adverse effects for the Indiana bat will be addressed through Kentucky's latest Statewide Bat Programmatic Agreement. However, additional coordination with the USFWS Indiana Field Office is required during final design to determine the appropriate amount and/or type of conservation to offset the effects of incidental take.

The BA and BO and other project records relating to the USFWS actions, taken pursuant to the Endangered Species Act, 16 U.S.C. 1531–1544, are available by contacting the FHWA, INDOT, KYTC, or USFWS at the addresses provided above. The BA and BO can be viewed in Appendices K–4 and K–5 of the I–69 ORX FEIS.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Jermaine R. Hannon,

Division Administrator, FHWA, Indianapolis, Indiana.

[FR Doc. 2021–21452 Filed 10–4–21; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT)

ACTION: Notice of limitation on claims for judicial review of actions by the California Department of Transportation (Caltrans).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to a proposed highway project, Interstate 10/Jackson Street Interchange between Monroe Street and 0.4 miles west of Golf Center Parkway at PM R54.9/R56.5 in the City of Indio, in Riverside County, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before March 4, 2022. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Renetta Cloud, Chief, Environmental Studies ''A'', Caltrans District 8, 464 W 4th Street, 6th Floor, MS–823, San Bernardino, CA 92401–1400, Office Hours: 9:00 a.m. to 4:00 p.m., Office Phone: (909) 383–6323, Email: *Renetta.Cloud@dot.ca.gov.* For FHWA, contact David Tedrick at (916) 498–5024 or email *David.tedrick@dot.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, FHWA assigned, and Caltrans assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans has taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: Caltrans proposes to reconstruct and widen Jackson Street at Interstate 10 (I–10) to improve the operational performance of the existing I–10/Jackson Street Interchange within the city limits. The I–10/Jackson Street interchange is located on I–10 between Monroe Street and Gold Center Parkway. The project limits extend from approximately Post Mile (PM) R54.9 to PM R56.6 along I–10 and from Kenner Avenue (south of I–10) to Atlantic Avenue (north of I–10) along Jackson Street. The project site is centrally located within the City of Indio at the crossroads of I–10 and Jackson Street in Riverside County, California. The current I–10/Jackson interchange configuration is a diamond interchange, with signal control at the ramp termini. The interchange is a major access point for existing residential and retail sites. The project proposes to reconstruct and widen Jackson Street at I–10 from one to two lanes in the southbound direction, to construct two new access ramps to the CV Link recreational facility, and to realign and widen the existing I–10 eastbound (EB) and I–10 westbound (WB) on- and off-ramps. The project would also include the construction of a WB auxiliary lane preceding the Jackson Street WB off-ramp, the installation of planned ramp meters on the I–10 EB and WB on-ramps, and construction of the Whitewater River Bridge Structure to accommodate two through lanes, a shoulder, and a sidewalk in each direction.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (EA)/Finding of No Significant Impact (FONSI) for the project, approved on August 27, 2021, and in other documents in the FHWA project records. The EA/FONSI, and other project records are available by contacting Caltrans at the address provided above.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. Council on Environmental Quality regulations;
2. National Environmental Policy Act (NEPA);
3. Moving Ahead for Progress in the 21st Century Act (MAP–21);
4. Americans with Disabilities Act;
5. Department of Transportation Act of 1966;
6. Federal Aid Highway Act of 1970;

7. Federal Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970;
8. Clean Air Act Amendments of 1990;
9. Noise Control Act of 1970;
10. 23 CFR part 772 FHWA Noise Standards, Policies and Procedures;
11. Department of Transportation Act of 1966, Section 4(f);
12. Clean Water Act of 1977 and 1987;
13. Safe Drinking Water Act;
14. Executive Order 12088, Federal Compliance with Pollution Control;
15. Flood Disaster Protection Act;
16. Executive Order 11988, Floodplain Management;
17. Federal Endangered Species Act of 1973;
18. Migratory Bird Treaty Act;
19. Fish and Wildlife Coordination Act;
20. Executive Order 11990, Protection of Wetlands;
21. Executive Order 13112, Invasive Species;
22. Antiquities Act of 1906;
23. National Historic Preservation Act of 1966, as amended;
24. Historic Sites Act of 1935;
25. Farmland Protection Policy Act;
26. Resource Conservation and Recovery Act of 1976;
27. Comprehensive Environmental Response, Compensation and Liability Act of 1980;
28. Toxic Substances Control Act;
29. Community Environmental Response Facilitation Act of 1992;
30. Occupational Safety and Health Act;
31. Executive Order 12898, Federal Actions to Address Environmental Justice and Low-Income Populations; and
32. Title VI of the Civil Rights Act of 1964.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

(Authority: 23 U.S.C. 139(l)(1))

Issued on: September 30, 2021.

Rodney Whitfield,

Director, Financial Services, Federal Highway Administration, California Division.

[FR Doc. 2021–21722 Filed 10–4–21; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0104]

Denial of Motor Vehicle Defect Petition

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Denial of petition for a defect investigation.

SUMMARY: This notice sets forth the reasons for the denial of a petition submitted on September 17, 2019, by Mr. Edward Chen (the petitioner), requesting that the Agency ''initiate a Defect Investigation into the recent set of software updates, including software updates 2019.16.1 and 2019.16.2 and all subsequent updates issued by Tesla, Inc. to its Model S and Model X vehicles, which have been alleged to be issued by Tesla in response to the alarming number of car fires that have occurred worldwide.'' On October 1, 2019, ODI opened Defect Petition DP19–005 to evaluate the petitioner's request. After reviewing the information provided by the petitioner, information provided by Tesla in response to an information request letter from NHTSA, and field data regarding non-crash vehicle fires in model year (MY) 2012 through 2019 Tesla Model S and Model X vehicles, NHTSA has concluded that the issues raised by the petition do not warrant a defect investigation at this time. Accordingly, the Agency has denied the petition.

FOR FURTHER INFORMATION CONTACT: Mr. Kareem Habib, 202–366–8703, Vehicle Defects Division—D, Office of Defects Investigation, NHTSA, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

1.0 Introduction

Pursuant to 49 CFR 552.1, interested persons may petition NHTSA requesting that the Agency initiate an investigation to determine whether a motor vehicle or an item of replacement equipment fails to comply with applicable motor vehicle safety standards or contains a defect that relates to motor vehicle safety. Upon receipt of a properly filed petition, the Agency conducts a technical review (49 CFR 552.6) of the petition, material submitted with the petition, and any appropriate additional information. After the technical review and considering appropriate factors, which may include, among others, Agency priorities, and the likelihood of success in litigation that might arise from a determination of noncompliance or a defect related to motor vehicle safety, the Agency will grant or deny the petition (49 CFR 552.8).

2.0 The Petition

In a September 17, 2019 letter, the petitioner requested that the Agency ''initiate a Defect Investigation into the recent set of software updates, including software updates 2019.16.1 and 2019.16.2 and all subsequent updates issued by Tesla, Inc. to its Model S and Model X vehicles, which have been alleged to be issued by Tesla in response to the alarming number of car fires that have occurred worldwide.'' The petitioner's letter alleges that Tesla ''is using over-the-air software updates to mask and cover-up a potentially widespread and dangerous issue with the batteries in their vehicles.'' He associated the updates with a loss of range and requested that the investigation include model year (MY) 2012 through 2019 Tesla Model S and Model X vehicles:

''*The fact pattern for most, if not all, of the affected owners is the same and begin in or around late May 2019, where Tesla issued its 2019.16.1. and 2019.16.2 software updates. For most owners, it was shortly discovered after updating their cars that the cars had suffered from a sudden and significant decrease in the amount of rated miles available. On average, affected owners have reported losing anywhere between 25–30 miles, with 50 miles of range loss at the higher end of the spectrum.*''

''*There is evidence to suggest that Tesla issued these updates in response to an increasing number of battery fires that have occurred worldwide. Tesla has taken the position and made statements to the public regarding the same, that the updates were issued in order to promote the health and longevity of their batteries. Additionally, despite some media coverage and news outlets having covered the issue and taking interest in the litigation, it is clear that there is widespread confusion and uncertainty regarding the true purpose of the software updates in question and the safety of the affected vehicles.*[1] [2] [3]''

In a class action lawsuit complaint submitted as an attachment to the petition, the petitioner cited five non-crash fires in Tesla vehicles summarized in Table 1.[4]

[1] *https://www.reuters.com/article/tesla-battery/tesla-hit-by-lawsuit-claiming-thousands-of-owners-lost-battery-capacity-after-software-update-idUSL2N25418A.*

[2] *https://electrek.co/2019/08/08/tesla-owner-range-slashed-software-update-class-action-lawsuit/.*

[3] *https://insideevs.com/news/364347/tesla-model-s-update-lawsuit/.*

[4] *Rasmussen* v. *Tesla,* 5:19–cv–04596, United States District Court for the Northern District of California, filed August 7, 2019.

TABLE 1—FIRES CITED BY PETITIONER

Date	Vehicle	Location
June 15, 2018	2012 Model S 85	West Hollywood, California.
April 21, 2019	2014 Model S P85	Shanghai, China (Xuhui District).
May 3, 2019	2014 Model S 85	San Francisco, California.
May 12, 2019	2015 Model S 85D	Hong Kong, China.
July 30, 2019	2015 Model S 85D	Ratingen, Germany.

3.0 Analysis

On October 1, 2019, ODI opened Defect Petition DP19–005 to evaluate the petitioner's request. On October 24, 2019, ODI sent an information request (IR) letter to Tesla to gather information to assist the Office in its evaluation of DP19–005. The letter included requests for production data, over-the-air (OTA) firmware updates, non-crash fire incidents, and Tesla's investigations related to the fires. In evaluating the petition, ODI:

1. Analyzed the scope of the petition and the alleged defect;
2. Analyzed the non-crash fire incidents cited by the petitioner;
3. Reviewed over-the-air updates to the Battery Management System (BMS) released by Tesla from May 2019 to date; and
4. Reviewed all relevant Vehicle Owner Questionnaires (VOQs) received through August 2021.

3.1 Subject Vehicles

Tesla sold approximately 225,000 MY 2012 through 2019 Model S and Model X vehicles in the United States. This petition evaluation will focus on vehicles receiving the firmware update that could limit maximum brick voltage.

TABLE 2—PETITION SCOPE AND SUBJECT VEHICLE POPULATION

Voltage limiting firmware installed	Model years	Model		Total
		Model S	Model X	
Yes	2012–2016	61,781	0	61,781
No	2016–2019	93,163	69,801	162,964
Total	2012–2019	154,944	69,801	224,745

The subject firmware was installed in certain MY 2012 through 2016 Model S vehicles that were equipped with the first two generations of the Panasonic 18650 battery cell (subject vehicles). Tesla sold approximately 62,000 subject vehicles in the United States (Table 2). The firmware update limiting maximum brick (defined below) voltage is a dynamic algorithm that is enabled in vehicles with high Supercharging use histories.[5] [6] Through August 20, 2021, that firmware had been enabled in approximately 2,062 vehicles, or about 3.5 percent of the subject vehicles.

3.2 Subject System

The subject vehicles are equipped with high voltage (HV) battery packs containing first- and second-generation nickel cobalt aluminum (NCA) Panasonic 18650 form factor cells. The packs contain up to 16 modules, with each module containing 6 series elements (bricks) comprising 74 cells connected in parallel.[7] Each module in the battery pack has a battery monitoring board (BMB) to monitor module brick parameters. The battery cooling system distributes ethylene glycol/water coolant to each module through front, left and right manifolds. Coolant enters and exits the battery pack through connections at the front of the pack. Each module has a single ribbon-shaped cooling tube that snakes through the rows of battery cells, placing the tube in contact with each cell in the module. The cooling tubes for all modules are connected in parallel.

The BMS monitors system voltages, currents and temperatures to control the HV battery within safe operating limits and maximize battery capacity. The BMS receives information from sensors at the brick and module levels, including voltage signals from each of the BMBs and temperature signals from two sensors in each module. The BMS controls a system of switches and resistors to manage current ''bleed'' from each brick to maintain the bricks in balance and maximize the capacity the battery pack can provide.

The BMS in the subject vehicles has hundreds of diagnostic routines to monitor for anomalies in the HV battery, including diagnostics for state-of-charge (SOC) brick-to-brick imbalances.[8] When anomalies are detected, the BMS may initiate an internal compensation (*e.g.,* to balance brick voltages), trigger mitigations (*e.g.,* range reduction or limits on vehicle restart or charging), or trigger warnings, such as, ''Car needs service; Contact Tesla Service'' or, for the most serious conditions, ''Car shutting down; PULL OVER IMMEDIATELY.''

At the cell level, the subject vehicles contain design features that may disable the cells in response to certain short conditions, including separator shutdown, Current Interrupt Device (CID) activation, and cell interconnect fusing. Should single cell runaway occur, the subject battery packs are designed to prevent propagation to surrounding cells (Passive Propagation Resistance) by releasing the hot gasses through the top of the initiating cell and venting them away from the module.

3.3 China Fires

On April 21, 2019, a 2014 Model S experienced a battery fire in a parking garage in the Xuhui District of Shanghai, China, shortly after recharging the HV battery. Tesla's investigation of the fire identified several factors in common

[5] When the firmware is ''enabled,'' the maximum cell voltage is limited.

[6] ''Supercharger'' is Tesla's name for its DC fast charging network. The terms Supercharging and fast charging are used interchangeably in this report.

[7] The battery packs in the subject vehicles contain up to 7,104 cells.

[8] These diagnostics were part of the BMS prior to the release of the subject firmware updates that are the focus of this defect petition and have continued to be updated through Tesla's standard practices in the months since the subject updates (see Section 3.5 ''Tesla Updates'').

with other non-crash battery fires in China, including a fire in a 2015 Model S in Hong Kong, referenced by the petitioner, that occurred three weeks later. First, each of the fires occurred shortly after completing a Supercharging session to a high SOC. Second, the fires occurred when the vehicles were parked with the cooling systems off and the HV batteries remaining at high SOCs. Third, the vehicle histories showed high percentages of fast charging, average depth of discharge (DoD), and other stress factors for the HV battery packs (*e.g.,* ''top off'' charging [9] above 90 percent SOC).[10] Lastly, the vehicles were equipped with battery packs using first or second-generation battery cells. Reviews of the Shanghai-Xuhui and Hong Kong fire investigations are provided in the following summaries:

Shanghai–Xuhui Fire. On April 21, 2019, a 2014 Tesla Model S P85 caught fire in a parking garage approximately 75 minutes after completing a Supercharging session to 96 percent SOC.[11] The vehicle had a high percentage of fast charging use (78 percent). Tesla's investigation, conducted in conjunction with China's safety regulators, did not find a root cause. However, the company believed the fire likely resulted from a combination of factors, including charging history and thermal conditions following a Supercharging session. Battery charging histories that include high stress conditions such as Supercharging increase the likelihood of developing internal cell failures that can lead to ''weak short'' conditions.[12] Thermal conditions following the Supercharging session may create conditions in which a single cell failure may propagate to neighboring cells, resulting in thermal runaway of the affected module.

Hong Kong Fire. On May 12, 2019, a 2015 Tesla Model S 85D caught fire in a parking garage approximately 74 minutes after completing a Supercharging session to 96 percent SOC. The vehicle's charging history was almost exclusively fast charging (94 percent). The vehicle had previously been repaired as part of a unique process in China and Hong Kong in which a vehicle's battery pack is removed, remanufactured and reinstalled.[13] The vehicle had triggered a warning ''car needs service'' and a voltage fault was confirmed at a Tesla service center. However, the issue was not considered urgent and the repair was scheduled for the week after the fire occurred. The incident vehicles' battery charging history and recent Supercharging session increase the likelihood that it may have shared characteristics with the Shanghai-Xuhui fire.

3.4 Other Non-Crash Vehicle Fires Cited by Petitioner

Apart from the incidents in China, Tesla stated that it is not aware of any non-crash HV battery fires associated with fast charging in the United States or any other country. The three incidents cited by the petitioner that did not occur in China include one HV battery fire that was not related to fast charging and two that were external to the HV battery. Reviews of the investigations of each of those incidents and a fourth non-crash fire incident that occurred in December 2018 [14] are provided in the following summaries:

West Hollywood Fire. On June 15, 2018, a 2012 Tesla Model S 85 experienced thermal runaway in Module 14 while driving on Santa Monica Boulevard in West Hollywood, California.[15] Unlike the China fire incidents reviewed by ODI, there was no fast charging event prior to this fire, the vehicle was driving with the cooling system in operation when the fire occurred, and the vehicle had no fast charging in its service history.[16] Tesla's investigation evaluated multiple potential causal factors in the affected module, but was unable to determine a root cause. Tesla has advised the Agency that it has not seen another similar fire. Because there was no fast charging prior to the incident and no history of fast charging, this incident is not believed to be related to the 2019 fires investigated in China.

Los Gatos Fire. On December 18, 2018, a 2018 Tesla Model S experienced runaway in Modules 13–16 after being towed to a tire repair shop in Los Gatos, California.[17] The vehicle was not at a high SOC when the incident occurred and the vehicle had a low frequency of fast charging in its history (13 percent). In addition, the incident vehicle was equipped with a battery pack using later generation cells, putting it outside the scope of the subject vehicles for this petition evaluation. Tesla's investigation was unable to identify a root cause, but could not rule out physical damage. This incident is not relevant to this petition because it used different cells than what is at issue in this petition.

San Francisco Fire. On May 3, 2019, a 2014 Tesla Model S 85 caught fire while parked in a residential garage.[18] Tesla's investigation determined the that the fire originated in the rear drive unit. The fire did not originate in the HV battery and is not relevant to this petition.

Ratingen, Germany Fire. On July 30, 2019, a 2015 Tesla Model S 85D caught fire in Ratingen, Germany while parked in a parking lot. The vehicle was at a low SOC (approximately 40 percent) and had been parked for at least 14 hours when the fire occurred. The cause of the fire is undetermined, but Tesla has determined that the origin of the fire was external to the HV battery pack.

3.5 Tesla Updates

As background, Tesla provides regular OTA updates to add new features or enhance existing functions to systems throughout the vehicle, including updates to optimize charging rate, charging capacity, and thermal management of the HV battery.[19] The updates are numbered by the year and week of release and wave.[20]

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[9] ''Top off'' charging refers to the practice of re-initiating charging from a very high SOC after the system has completed the initial charge.

[10] Tesla also noted other unique factors in the China non-crash fires, including a broken AC compressor in one vehicle and a remanufactured battery pack with a recent fault detection in another.

[11] Tesla provided ODI with a technical review of its investigation of the China fires on June 12, 2019.

[12] Frequent fast charging, high SOC, large swings in SOC (*e.g.,* going from a high depth of discharge to a high SOC), specific patterns of rest intervals at low SOCs, and ''top-off'' charging all result in high stress to the HV battery.

[13] This process is not used in the United States.

[14] *https://electrek.co/2018/12/19/tesla-model-s-fire-towing/.*

[15] Tesla provided ODI with a technical review of its investigation of the West Hollywood fire on September 6, 2018.

[16] The vehicle had completed a slow AC charge at the owner's residence earlier in the day and then driven to a SOC of less than 89 percent at the time of the fire incident.

[17] Tesla provided ODI with a technical review of its investigation of the Los Gatos fire on June 12, 2019.

[18] Tesla provided ODI with a technical review of its investigation of the San Francisco fire on June 12, 2019.

[19] *https://www.tesla.com/support/software-updates.*

[20] The Safety Act imposes an obligation on manufacturers of motor vehicles and motor vehicle equipment to notify NHTSA when they determine vehicles or equipment they produced contain defects related to motor vehicle safety or do not comply with an applicable motor vehicle safety standard. *See* 49 U.S.C. 30118. This notice, referred to as a Safety Recall Report, must be filed no more than five working days after the manufacturer knew or should have known of the defect or noncompliance. *See* 49 CFR 573.6(b); *see also United States* v. *General Motors Corp.,* 656 F. Supp. 1555, 1559 n.5 (D.D.C. 1987). NHTSA recognizes that over-the-air updates are issued for a variety of reasons including to offer new product features, fix software bugs, and to optimize vehicle performance. NHTSA, however, expects any manufacturer issuing an over-the-air update that mitigates a defect that poses an unreasonable risk to motor vehicle safety to file an accompanying Safety Recall Report pursuant to 49 CFR part 573.

In May 2019, while continuing its investigation of the Shanghai-Xuhui fire, Tesla issued OTA firmware updates 2019.16.x revising fast charging and thermal management strategies at high SOCs for all Model S vehicles. Tesla has indicated that these changes were implemented as improvements to battery health, longevity and safety. In addition, OTA 2019.16.1, released May 15, 2019, included a dynamic algorithm that enables a limit on maximum brick voltage if the vehicle has a high ratio of DC fast charging in its history. This update was limited to vehicles equipped with first and second-generation battery cells. Tesla stated that the cell voltage limit was implemented as a precaution while Tesla continued to investigate the causes of the fires in China. A subsequent update, released in August 2019, restored some of the voltage capacity to affected vehicles.[21]

Staggered updates, released to targeted sub-populations of subject vehicles in November 2019 and December 2019, activated a new ''weak short'' detection algorithm designed to identify shorts months before they could potentially result in cell runaway. Vehicles in which the voltage limiting firmware had been enabled have received further incremental restoration of maximum-allowed brick voltage after receiving the ''weak short'' detection update.

3.6 VOQ Analysis

Through August 2021, ODI identified 67 complaints from consumers alleging reductions in battery capacity or charging speed in Model S and Model X vehicles, all but 4 of which were received after DP19–005 was opened.[22] Six of the complaints involved Model S or Model X vehicles that are not in the scope of the subject vehicles (*i.e.,* vehicles equipped with battery packs using later generation battery cells that were not affected by the firmware update with the algorithm that could limit maximum brick voltage). Of the 59 complaints involving subject vehicles through December 2020, 52 alleged reductions in battery capacity and driving range after receiving the subject OTA updates and 7 alleged reduced DC fast charging speeds.

Data provided by Tesla indicate that the maximum brick voltage firmware had been enabled in 30 of the 52 vehicles alleging reduced charging capacity. Of those vehicles, by the end of August 2021, Three had received a new battery under warranty, 26 had received full restoration of maximum brick voltage, and 4 continued to have maximum brick voltage limited at approximately 93 percent.[23] None of the vehicles have reported any thermal incidents or other safety hazards related to the HV battery.

4.0 Manufacturer Position

Tesla's investigation of the non-crash fires in China did not identify a root cause or positively link the incidents to any design or manufacturing defect conditions.[24] The company identified a potential concern with internal cell shorts that may occur within a narrow range of resistance values that were below BMS diagnostic thresholds. Tesla stated that while such shorts occur very rarely, they can be caused by multiple factors and high-stress use can contribute to their formation and growth. Internal cell shorts usually result in cell failure without leading to a thermal incident, but can progress to cell runaway. According to Tesla, under certain thermal conditions most likely to occur shortly after completion of a Supercharging session, cell runaway may overcome the passive propagation of the system and lead to module runaway. Tesla indicated that the latter has only been observed in China.

Tesla released several OTA firmware updates to improve the thermal management, fast charging strategy, and BMS diagnostics to detect early signs of internal cell shorts. Per the company, the updates will improve the durability and health of batteries subjected to high-stress use conditions, as well as providing an added margin of safety.

5.0 Observations

ODI's analysis of the petition allegations, information provided by Tesla, and information contained in consumer complaints finds the following:

- The voltage limiting firmware that is the focus of the petition was installed in just 27 percent of the vehicles cited by the petitioner and enabled in less than 1 percent.
- The subject OTA firmware is a dynamic algorithm that may limit maximum brick voltage based on battery usage stress. The voltage limit is based on fast charging history. Frequent fast charging is recognized as a stress factor that can adversely affect battery health, longevity, durability, lithium plating aging conditions and overall safety of lithium-ion batteries.[25]
- Approximately 80 percent of the vehicles in which the firmware limiting maximum brick voltage was enabled have had the maximum voltage restored by August 2021 and almost all the remaining vehicle population had the maximum voltage partially restored to 93 percent or higher.
- A small number of vehicles have received new battery packs after receiving alerts triggered by the new ''weak short'' detection algorithm.[26]
- There are many potential causes of non-crash battery fires in vehicles equipped with lithium ion batteries.[27] [28] ODI looks for indications of a common cause or pattern of incidents when assessing evidence of a potential defect that may warrant investigation. While a pattern of fires occurring shortly after completing Supercharging sessions was observed in China, no similar fire incidents have been identified in the United States.
- The available data indicate that non-crash battery fires in Tesla vehicles are rare events. The fires occurring in vehicles parked at high SOCs shortly after completing Supercharging sessions have only been observed in China. High stress use factors appear to be more common in China. For example, the population of subject vehicles in China is approximately 6 percent that of the United States, but China has 51 percent more vehicles with fast charging histories of 80 percent or greater.
- The three fires cited by the petitioner that occurred outside China include two that did not originate in the battery (San Francisco and Ratingen) and a third that is unrelated to a fast charging event.
- No fires related to the subject condition have been observed globally

[21] OTA 2019.28.x.

[22] The three complaints received before DP19–005 was opened were submitted by the petitioner or his client (see NHTSA complaint ID's 11240787, 11246770 and 11246771).

[23] No data was available for two vehicles due to a lack of recent communication with Tesla's remote diagnostics.

[24] Tesla's investigation included forensic analysis of battery packs from incident vehicles and reviews of cell manufacturing process issues that may affect intercalation kinetics during fast charging.

[25] A. Tomaszewska, Z. Chu, X. Feng, S. O'Kane, X. Liu, J. Chen, et al. (2019). *Lithium-Ion Battery Fast Charging: A Review*. eTransportation. 100011. 10.1016/j.etran.2019.100011.

[26] The weak short alert algorithm is independent of charging history. HV battery pack replacements have occurred in vehicles with the brick voltage limiting firmware enabled and in vehicles where it had not been enabled. The likelihood of receiving an alert was higher in the vehicles with the maximum brick voltage firmware enabled.

[27] Brewer, J., Nasser, A., Hommes, Q.V.E., Najm, W., Pollard, J., & Jackson, C. (2018, November). *Safety management of automotive rechargeable energy storage systems: The application of functional safety principles to generic rechargeable energy storage systems* (Report No. DOT HS 812 556). Washington, DC: National Highway Traffic Safety Administration.

[28] Stephens, D., Shawcross, P., Stout, G., Sullivan, E., Saunders, J., Risser, S., & Sayre, J. (2017, October). *Lithium-ion battery safety issues for electric and plug-in hybrid vehicles* (Report No. DOT HS 812 418). Washington, DC: National Highway Traffic Safety Administration.

since three fires in China and Hong Kong over a 48-day period from late-March to mid-May 2019.

- There have been no fires in the United States related to the subject condition.
- ODI will continue to monitor the battery performance of the subject vehicles.

6.0 Conclusion

NHTSA is authorized to issue an order requiring notification and remedy of a defect if the Agency's investigation shows a defect in the design, construction, or performance of a motor vehicle that presents an unreasonable risk to safety. 49 U.S.C. 30102(a)(9), 30118. Given the absence of any incidents in the United States related to fast charging, and the absence of any such incidents globally since May 2019, it is unlikely that an order concerning the notification and remedy of a safety-related defect would be issued due to any investigation opened as a result of granting this petition. Therefore, upon full consideration of the information presented in the petition, and the potential risks to safety, the petition is denied. The denial of this petition does not foreclose the Agency from taking further action if warranted, or the potential for a future finding that a safety-related defect exists based upon additional information the Agency may receive.

Authority: 49 U.S.C. 30162(d); delegations of authority at CFR 1.95 and 501.8.

Joseph Kolly,

Acting Associate Administrator for Enforcement.

[FR Doc. 2021–21416 Filed 10–4–21; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On September 29, 2021, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals

1. AL BANAI, Ali Reda Hassan (Arabic: علي رضا حسن البناى) (a.k.a. AL-BANAI, Ali Reda H; a.k.a. AL-BANAI, 'Ali Ridha' Hasan; a.k.a. ALBANAI, 'Ali Ridha Hassan; a.k.a. AL-BANAI, 'Ali Ridha Hassan; a.k.a. AL-BANAY, Ali Ridha; a.k.a. AL-BANI, Ali Reda H; a.k.a. AL-BANNAY, 'Ali Ridha Hassan), Al Hilal Area, Ibn Abad Street, District 41, Villa Number 7, P.O. Box 1676, Doha, Qatar; 25 Highfield Drive, Ickenham, Uxbridge UB10 8AW, United Kingdom; DOB 28 Mar 1975; nationality Qatar; Gender Male; Passport 01226090 (Qatar) expires 09 Jun 2020; alt. Passport 00968564 (Qatar) expires 07 Mar 2016; National ID No. 27563400027 (Qatar) expires 12 Mar 2018 (individual) [SDGT] (Linked To: HIZBALLAH).

Designated pursuant to section 1(a)(iii)(C) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism,'' 66 FR 49079, as amended by Executive Order 13886 of September 9, 2019, ''Modernizing Sanctions To Combat Terrorism,'' 84 FR 48041 (E.O. 13224, as amended), for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, HIZBALLAH, a person whose property and interests in property are blocked pursuant to E.O. 13224.

2. AL-'ABD–AL–MUHSIN, Yahya Muhammad (a.k.a. AL–ABDULMOHSEN, Yahya Mohamad; a.k.a. ALABDULMOHSEN, Yahya Mohammed Y; a.k.a. AL–ABU HAYDAR, Yahya Muhammad; a.k.a. ''YAHYA, Sayyid''), Saudi Arabia; DOB 16 Dec 1979; citizen Saudi Arabia; Gender Male; Passport P045620 (Saudi Arabia) expires 22 Mar 2019; National ID No. 1003159462 (Saudi Arabia) (individual) [SDGT] (Linked To: AL BANAI, Ali Reda Hassan).

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, ALI REDA HASSAN AL–BANAI, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

3. AL–BANAI, Abd al-Muayyid (a.k.a. AL BANAI, A Moayied Rida H; a.k.a. AL–BANAI, 'Abd al-Muwid Rada Hasn; a.k.a. AL–BANAI, Abd-al-Mu'ayyid Ridha Hassan), Qatar; DOB 1959; POB Qatar; nationality Qatar; Gender Male; Passport 265643 (Qatar) (individual) [SDGT] (Linked To: HIZBALLAH).

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, HIZBALLAH, a person whose property

and interests in property are blocked pursuant to E.O. 13224.

4. AL-BANAI, Sulaiman (a.k.a. AL BANAI, Sulaiman Abdulkaliq; a.k.a. AL-BANAI, Sulayman ‘Abd-al-Khaliq; a.k.a. AL-BANI, Sulaiman Abdulkhaliq RH (Arabic: سليمان عبد الخالق رضا حسن البناى)), Qatar; DOB 16 Feb 1979; nationality Qatar; Gender Male; Passport 01072130 (Qatar) expires 27 Nov 2017; Identification Number 27963401809 (Qatar); alt. Identification Number Y4431029R (Spain) (individual) [SDGT] (Linked To: AL BANAI, Ali Reda Hassan).

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, ALI REDA HASSAN AL–BANAI, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

5. AL-USTADZ, Majdi Fa’iz (a.k.a. AL-USTAD, Majdi Fayiz Hasan (Arabic: مجدي فايز حسن الاستاذ); a.k.a. AL-‘USTADZ, Majid Fayiz), Istanbul, Turkey; DOB 27 Feb 1966; nationality Palestinian; Gender Male; Identification Number 26699900002 (Palestinian) (individual) [SDGT] (Linked To: AL BANAI, Ali Reda Hassan).

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, ALI REDA HASSAN AL–BANAI, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

6. LARI, ‘Ali Ridha Qasabi (a.k.a. LARI, ‘Ali Ridha Qassabi; a.k.a. QASSABI, Alireda Bashi M R), Qatar; DOB 1959; nationality Qatar; Gender Male; Passport 1001546 (individual) [SDGT] (Linked To: HIZBALLAH).

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, HIZBALLAH, a person whose property and interests in property are blocked pursuant to E.O. 13224.

7. SHAMS, ‘Abd Al-Rahman ‘Abd Al-Nabi (a.k.a. SHAMS, Abdulrahman; a.k.a. SHAMS, Abdulrahman Abdulrahim Abdulnab), Bahrain; DOB 31 Jan 1989; citizen Bahrain; Gender Male; Passport 2026337 (Bahrain) expires 01 Jun 2021 (individual) [SDGT] (Linked To: AL BANAI, Ali Reda Hassan).

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, ALI REDA HASSAN AL–BANAI, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

Entity

1. ALDAR PROPERTIES, Al Jazira Street, Bin Mahmoud, Doha, Qatar; website *http://www.aldarproperties.qa;* Organization Type: Real estate activities with own or leased property [SDGT] (Linked To: AL–BANAI, Sulaiman).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, SULAIMAN AL–BANAI, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

Dated: September 29, 2021.

Bradley T. Smith,

Acting Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2021–21657 Filed 10–4–21; 8:45 am]

BILLING CODE 4810–AL–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meeting

TIME AND DATE: October 7, 2021, 12:00 p.m. to 2:00 p.m., Eastern time.

PLACE: This meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (U.S. Toll) or 1–669–900–6833 (U.S. Toll) or (ii) 1–877–853–5247 (U.S. Toll Free) or 1–888–788–0099 (U.S. Toll Free), Meeting ID: 989 0268 7403, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/j/98902687403.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Education and Training Subcommittee (the ‘‘Subcommittee’’) will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—Subcommittee Chair

The Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—Subcommittee Chair

For Discussion and Possible Subcommittee Action

The Agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

➢ Subcommittee action only to be taken in designated areas on agenda.

IV. Review and Approval of Subcommittee Minutes From the August 26, 2021 Subcommittee Meeting—Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from the August 26, 2021 Subcommittee meeting via teleconference will be reviewed. The Subcommittee will consider action to approve.

V. Audit Module 2 Development Discussion—UCR Operations Manager

The UCR Operations Manager will discuss and provide updates on development of the Audit Module 2.

VI. New Module Development—Subcommittee Chair and UCR Operations Manager

The UCR Operations Manager will provide updates on the Roadside Enforcement and Roadside Officers and Focused Anomaly Reviews (FARs) modules.

VII. Other Business—Subcommittee Chair

The Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

VIII. Adjournment—Subcommittee Chair

The Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, October 1, 2021 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2021–21811 Filed 10–1–21; 11:15 am]

BILLING CODE 4910–YL–P

FEDERAL REGISTER

Vol. 86 Tuesday,
No. 190 October 5, 2021

Part II

Environmental Protection Agency

40 CFR Parts 9 and 84
Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program Under the American Innovation and Manufacturing Act; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 84

[EPA–HQ–OAR–2021–0044; FRL–8458–02–OAR]

RIN 2060–AV17

Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program Under the American Innovation and Manufacturing Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency is issuing regulations to implement certain provisions of the American Innovation and Manufacturing Act, as enacted on December 27, 2020. This Act mandates the phasedown of hydrofluorocarbons, which are highly potent greenhouse gases, by 85 percent over a period ending in 2036. The Act directs the Environmental Protection Agency to implement the phasedown by issuing a fixed quantity of transferrable production and consumption allowances, which producers and importers of hydrofluorocarbons must hold in quantities equal to the amount of hydrofluorocarbons they produce or import. To establish the allowance allocation program, this rulemaking determines the hydrofluorocarbon production and consumption baselines, from which allowed production and consumption will decrease consistent with the statutory phasedown schedule; provides an initial approach to allocating calendar-year allowances and allowing for the transfer of those allowances; establishes provisions for the international transfer of allowances; and establishes recordkeeping and reporting requirements. Additionally, it establishes provisions to support implementation, compliance with, and enforcement of, statutory and regulatory requirements under the Act's phasedown provisions. Over the time period from 2022–2050, this rulemaking will avoid cumulative emissions of 4,560 million metric tons of exchange value equivalent of HFCs in the United States with a present value of cumulative net benefits of $272.7 billion.

DATES:

Effective dates: This rule is effective on November 4, 2021, except for amendatory instruction 3 adding 40 CFR part 84, which is effective on October 5, 2021.

Operational dates: For operational purposes under the American Innovation and Manufacturing Act of 2020 (AIM Act or the Act), the regulatory text established in amendatory instruction 3, is operational as of September 23, 2021, and effective as of October 5, 2021. The remainder of this rule, and its associated regulatory text outlined in amendatory instructions 1, 2, and 4 through 10, is effective November 4, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2021–0044. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard-copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Andy Chang, U.S. Environmental Protection Agency, Stratospheric Protection Division, telephone number: 202–564–6658; email address: *chang.andy@epa.gov*. You may also visit EPA's website at *https://www.epa.gov/climate-hfcs-reduction* for further information.

SUPPLEMENTARY INFORMATION: *Effective dates:* Portions of this rule are effective less than 30 days from publication in the **Federal Register**. Section 553(d) of the Administrative Procedure Act (APA), 5 U.S.C. chapter 5, generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. As further discussed in Section II.B, this rule is covered by the rulemaking procedures in section 307(d) of the Clean Air Act (CAA). See CAA section 307(d)(1)(I); AIM Act subsection (k) (providing that section 307 of the CAA ''shall apply to . . . any rule, rulemaking, or regulation promulgated . . . pursuant to the [AIM Act] as though [the AIM Act] were expressly included in title VI'' of the CAA). Section 307(d)(1) of the CAA states that: ''The provisions of section 553 through 557 . . . of Title 5 shall not, except as expressly provided in this section, apply to actions to which this subsection applies.'' Thus, section 553(d) of the APA does not apply to this rule. EPA is nevertheless acting consistently with the policies underlying APA section 553(d) in making a portion of the revisions finalized in this rule effective immediately, while the remainder of the rule will be effective 30 days after publication. The purpose of the general rule in section 553(d) of the APA that 30 days must be provided between publication and the effective date is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996); *see also United States* v. *Gavrilovic,* 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). Accordingly, in determining if there is ''good cause'' to forgo the 30-day delayed effective date per the exception at section 553(d)(3), an agency should ''balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling.'' *Gavrilovic,* 551 F.2d at 1105. Here, EPA has determined that the portions of this rule that are effective less than 30 days from publication in the **Federal Register** are not binding on any third parties, and therefore the above-stated purpose of the 30-day effective date delay is not relevant to the consideration here. The provisions of the rule taking immediate effect are only binding on the Agency in how it will determine allowance allocations, and the AIM Act establishes a deadline for these determinations, namely that by October 1 of each calendar year EPA must calculate and determine the quantity of production and consumption allowances for the following year. In addition, having these provisions become operational immediately upon signature will allow EPA to make determinations regarding allowance allocations earlier than if the effective date were delayed, which in turn will facilitate earlier notification to regulated entities about what their allowance allocation will be and provide them more time to plan accordingly. Thus, EPA's action is consistent with the APA's provision for an effective date of less than 30 days where an agency demonstrates good cause to do so.

Accordingly, it is in keeping with the policy underlying the APA for regulatory text in 40 CFR 84.3, 84.7, 84.9, 84.11, 84.13, 84.15, and 84.31(h)(2) and (3), to take effect immediately. Finally, this rule undertaken in accordance with section 307(d) of the CAA is promulgated upon signature and widespread dissemination. For operational purposes under the AIM

Act, EPA is making the regulatory text established in 40 CFR 84.3, 84.7, 84.9, 84.11, 84.13, 84.15, and 84.31 (h)(2) and (3) operational as of September 23, 2021, which is the date of signature.

Acronyms and Abbreviations. Throughout this document, whenever ''we,'' ''us,'' ''the Agency,'' or ''our'' is used, we mean EPA. Acronyms that are used in this rulemaking that may be helpful include:

AD/CVD—Anti-Dumping/Countervailing Duties
AIM Act—American Innovation and Manufacturing Act of 2020
ANPRM—Advanced Notice of Proposed Rulemaking
APA—Administrative Procedure Act
CAA—Clean Air Act
CBI—Confidential Business Information
CBP—Customs and Border Protection
CFC—Chlorofluorocarbon
CO_2—Carbon Dioxide
CVD—Chemical Vapor Deposition
DRE—Destruction and Removal Efficiency
ECHO—Enforcement and Compliance History Online
e-GGRT—Electronic Greenhouse Gas Reporting Tool
EFCTC—European FluoroCarbons Technical Committee
EPA—Environmental Protection Agency
EVe—Exchange Value Equivalent
GHG—Greenhouse Gas
GHGRP—Greenhouse Gas Reporting Program
GWP—Global Warming Potential
HCFC—Hydrochlorofluorocarbon
HFC—Hydrofluorocarbon
HFO—Hydrofluoroolefin
IPCC—Intergovernmental Panel on Climate Change
IWG—Interagency Working Group
MDI—Metered Dose Inhaler
$MMTCO_2$ eq—Million Metric Tons of Carbon Dioxide Equivalent
MMTEVe—Million Metric Tons of Exchange Value Equivalent
MT—Metric tons
$MTCO_2$ eq—Metric Tons of Carbon Dioxide Equivalent
MVAC—Motor Vehicle Air Conditioning
NAICS—North American Industry Classification System
NATA—National Air Toxics Assessment
NODA—Notice of Data Availability
NPRM—Notice of Proposed Rulemaking
NRC—National Research Council
ODP—Ozone Depletion Potential
ODS—Ozone-Depleting Substances
RACA—Request for Additional Consumption Allowance
RIA—Regulatory Impact Analysis
RSEI–GM—Risk-Screening Environmental Indicators Geographic Microdata
SC–GHG—Social Cost of Greenhouse Gases
SC–HFCs—Social Costs of Hydrofluorocarbons
TRI—Toxics Release Inventory
TSCS—Toxic Substances Control Act
UNFCCC—United Nations Framework Convention on Climate Change
USGCRP—United States Global Change Research Program
WMO—World Meteorological Organization

This supplementary information section is arranged as follows:

I. Executive Summary

A. Purpose of the Regulatory Action

EPA is issuing regulations to implement certain provisions of the American Innovation and Manufacturing (AIM) Act, as enacted on December 27, 2020. The Act mandates the phasedown of hydrofluorocarbons (HFCs), which are highly potent greenhouse gases (GHGs), by 85 percent over a period ending in 2036. The Act directs EPA to implement the phasedown by issuing a fixed quantity of transferrable production and consumption allowances, which producers and importers of HFCs must hold in quantities equal to the amount of HFCs they produce or import. To establish the allowance allocation program, this rulemaking establishes HFC production and consumption baselines, codifies the statutory phasedown schedule of allowed production and consumption relative to the baseline level, provides an initial approach to allocating calendar-year allowances and allowing for the transfer of those allowances, establishes provisions for the international transfer of allowances, and establishes recordkeeping and reporting requirements. Additionally, it establishes provisions to support implementation, compliance with, and enforcement of, statutory and regulatory requirements under the AIM Act's phasedown provisions.

The AIM Act directs EPA to issue a final rule accomplishing these Congressionally directed tasks by September 23, 2021. Additionally, under the AIM Act, by October 1 of each calendar year EPA must calculate and determine the quantity of production and consumption allowances for the following year. EPA intends to issue allowances for the 2022 calendar year no later than October 1, 2021, using the procedure established through this rulemaking, and intends to issue individual allowances for the 2023 calendar year no later than October 1, 2022, using the procedure established through this rulemaking.

The AIM Act further directs EPA to issue a final rule by September 23, 2021, governing the transfer of production and consumption allowances. The AIM Act also directs EPA to issue regulations by December 27, 2021, related to the international transfer of production allowances. This final rule addresses these statutory directives as well.

B. Summary of the Major Provisions of the Regulatory Action

Baselines: This rule establishes the HFC production and consumption baselines from which the phasedown steps are measured. Using the equation provided in the AIM Act, and based on the data available to the Agency through the Greenhouse Gas Reporting Program (GHGRP) and outreach conducted for this rulemaking, EPA determines that the production baseline is 382.6 Million Metric Tons of Exchange Value Equivalent (MMTEVe) and the consumption baseline is 303.9 MMTEVe.

Allocation: The total annual allocations for 2022 and 2023 are 344.3 MMTEVe of production allowances and 273.5 MMTEVe of consumption allowances. EPA intends to issue allowances for 2022 by October 1, 2021, according to the framework and procedure established through this rulemaking. Company production and consumption allowance allocations are based on the three highest years (not necessarily consecutive) of production or consumption between 2011 and 2019. EPA is issuing allowances to active HFC producers and importers operating in 2020 and is giving individualized consideration to circumstances of historical importers that were not active in 2020. EPA is establishing the allowance allocation framework for two years and intends to undertake a subsequent rulemaking to govern allocations for calendar years 2024 and beyond.

Application-specific Allowances: EPA is issuing ''application-specific allowances'' to end users in six applications established by the AIM Act: Propellants in metered dose inhalers (MDIs), defense sprays, structural composite preformed polyurethane foam for marine use and trailer use, etching of semiconductor material or wafers and the cleaning of chemical vapor deposition (CVD) chambers within the semiconductor manufacturing sector, mission-critical military end uses, and onboard aerospace fire suppression. The rule details the framework for how many allowances are issued for each end use. End users within a specific application may transfer their allowances only with another end user in that same application. Allowances may also be conferred, as frequently as needed, to effectuate the production or import of HFCs for that specific use.

Set-Aside Allowances: EPA is establishing a set-aside pool of 7.5 MMTEVe (less than 3 percent of allowances to be allocated for 2022) that is available to three groups of companies: (1) End users in application-specific sectors that EPA has not yet identified or verified by the date of the final rule, (2) importers that otherwise would have qualified for consumption allowances but are not yet identified or verified by the date of the final rule, and (3) importers that are new market entrants. Companies seeking to receive allowances via the set-aside should submit applications by November 30, 2021.

HFC-23 Controls: By the established compliance date, entities that create HFC-23 must capture the HFC-23 and either (1) expend production and consumption allowances for the amounts sold for consumptive uses and/or (2) timely destroy the captured HFC-23 using a technology approved by the Administrator. As compared with the amount of chemical intentionally produced on a facility line, no more than 0.1 percent of HFC-23 created on the line may be emitted after the compliance date.

Enforcement and Compliance: EPA is finalizing a multifaceted approach to deter, identify, and penalize illegal activity. These tools include administrative consequences for allowance holders, requiring use of refillable cylinders, increased oversight of imports including transhipments and HFCs imported for transformation, comprehensive tracking of containers of HFCs as they are imported, sold and distributed, and third-party auditing. EPA has also determined that much of the quarterly production and consumption data provided to the Agency will not be provided confidential treatment and will be affirmatively released without further process. This data transparency will incentivize compliance and allow the public and competing companies to identify and report noncompliance to EPA.

C. Costs and Benefits

EPA has estimated the costs and benefits of this action to provide the public with information and to comply with executive orders. EPA estimates that in 2022 the annual net benefits of this rule are $1.7 billion, reflecting compliance costs associated with recordkeeping and reporting and refillable cylinders and cost savings due to lower refrigerant replacement costs and reduced energy consumption of $300 million and social benefits of $1.4 billion. In 2036, when the final phasedown step is reached at 15 percent of the statutorily defined HFC baseline, the estimated annual net benefits of this rule are $16.4 billion. The present value of cumulative net benefits evaluated from 2022 through 2050 is $272.7 billion at a three percent discount rate or $260.9 billion at a seven percent discount rate. Over the same time

period the equivalent annualized value (EAV) of benefits is $13.6 billion when using a 3 percent discount rate; the EAV of costs is negative $0.6 billion when using a 3 percent discount rate and negative $0.5 billion when using a 7 percent discount rate; and the EAV of cumulative net benefits over the period 2022–2050 is $14.2 billion when using a 3 percent discount rate and $14.1 billion when using a 7 percent discount rate.[1] The present value of net benefits is calculated over the 29-year period from 2022–2050 to account for additional years that emissions will be reduced following the consumption reductions from 2022–2036.

TABLE 1—SUMMARY OF ANNUAL VALUES, PRESENT VALUES, AND EQUIVALENT ANNUALIZED VALUES FOR THE 2022–2050 TIMEFRAME FOR ESTIMATED ABATEMENT COSTS, BENEFITS, AND NET BENEFITS FOR THE FINAL RULE

[Billions of 2020$, discounted to 2022] [a] [b]

Year	Climate benefits (3%) [c] [d]	Costs [c]		Net benefits	
		3%	7%	3%	7%
Present Value	$260.9	−$11.8	−$6.4	$272.7	$267.4
Equivalent Annualized Value	13.6	−0.6	−0.5	14.2	14.1

[a] Rows may not appear to add correctly due to rounding.
[b] The annualized present value of costs and benefits are calculated over a 29-year period from 2022 to 2050.
[c] The costs presented in this table are consistent with the costs presented in RIA Chapter 3, Table 3–6.
[d] Climate benefits are based on changes (reductions) in HFC emissions and are calculated using four different estimates of the SC–HFCs (model average at 2.5 percent, 3 percent, and 5 percent discount rates; and 95th percentile at 3 percent discount rate). The IWG emphasized, and EPA agrees, on the importance and value of considering the benefits calculated using all four estimates. As discussed in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990 (IWG 2021), a consideration of climate benefits calculated using discount rates below 3 percent, including 2 percent and lower, are also warranted when discounting intergenerational impacts.

Over the 15-year period of the phasedown of HFCs, at a three percent discount rate, the present value of cumulative compliance costs is negative $5.4 billion, or $5.4 billion in savings; the present value of cumulative social benefits is $94.8 billion; and the present value of cumulative net benefits is $100.2 billion. Evaluated at a seven percent discount rate, the present value of cumulative compliance costs is negative $3.7 billion, or $3.7 billion in savings, and the present value of cumulative net benefits is $98.5 billion. Over the time period of 2022–2036 the EAV of benefits is $7.9 billion when using a 3 percent discount rate; the EAV of costs is negative $0.5 billion when using a 3 percent discount rate and negative $0.4 billion when using a 7 percent discount rate; and the EAV of cumulative net benefits is $8.4 billion when using a 3 percent discount rate and $8.3 billion when using a 7 percent discount rate.

EPA estimates that for the years 2022–2036 this action will avoid cumulative consumption of 3,152 MMTEVe of HFCs in the United States. The annual consumption avoided is estimated at 42 MMTEVe in the year 2022 and 282 MMTEVe in 2036. In order to calculate the climate benefits associated with consumption abatement, the consumption changes were expressed in terms of emissions reductions. EPA estimates that for the years 2022–2050 this action will avoid emissions of 4,560 MMTEVe of HFCs in the United States. The annual avoided emissions are estimated at 22 MMTEVe in the year 2022 and 171 MMTEVe in 2036.

Climate benefits are based on changes (reductions) in HFC emissions and are calculated using four different estimates of the social costs of HFCs (SC–HFCs) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; and 95th percentile at 3 percent discount rate). The SC–HFCs estimates used in this analysis were developed using methodologies consistent with the methodology underlying the Interagency Working Group on the Social Cost of Greenhouse Gases' (IWG) interim estimates of the social cost of other greenhouse gases (social cost of carbon SC-CO_2, social cost of methane SC-CH_4, and social cost of nitrous oxide SC-N_2O) that were developed over many years, using a transparent process, peer-reviewed methodologies, the best science available at the time of that process, and with input from the public. The benefits presented in this paragraph are the benefits associated with the average SC–HFCs at a 3 percent discount rate, but the Agency does not have a single central SC–HFCs point estimate. The IWG emphasized the importance and value of considering the benefits calculated using all four estimates.

As summarized further in Section XI of the preamble and described more fully in the Regulatory Impact Analysis (RIA), EPA's analysis indicates the principal costs (or savings) result from industry transitioning to substitute chemicals and technology. The principal benefits result from a decrease in emissions of HFCs into the atmosphere and the corresponding effects on global warming. The benefits are monetized by using the SC–HFCs. SC–HFCs is estimated using a method consistent with the method used to estimate the Social Cost of Greenhouse Gases (SC–GHGs). An alternative method was also considered that estimates SC–HFCs by using the global warming potential (GWP) (or exchange value) of HFCs and scaling to the known social cost of another GHG, *e.g.,* CO_2, CH_4, or N_2O.

II. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you produce, import, export, destroy, use as a feedstock, reclaim, package, or otherwise distribute HFCs. You may also be potentially affected by this rule if you use HFCs to manufacture products, such as refrigeration and air conditioning systems, foams, aerosols, and fire suppression systems, or use HFCs in one of the six applications eligible for an allocation under section (e)(4)(B)(iv) of the AIM Act. Potentially affected categories, by North American Industry Classification System (NAICS) code, are included in Table 2.

[1] All values for costs and benefits in this section are given in 2020 dollars and are calculated by discounting future costs and benefits to 2022 using a three percent discount rate. Calculations using other discount rates and discussion of the impact of the discount rate are found in the Regulatory Impact Analysis.

TABLE 2—NAICS CLASSIFICATION OF POTENTIALLY AFFECTED ENTITIES

NAICS code	NAICS industry description
211120	Crude Petroleum Extraction.
221210	Natural Gas Distribution.
236118	Residential Remodelers.
236220	Commercial and Institutional Building Construction.
238220	Plumbing, Heating, and Air-Conditioning Contractors.
238990	All Other Specialty Trade Contractors.
311351	Chocolate and Confectionery Manufacturing from Cacao Beans.
322299	All Other Converted Paper Product Manufacturing.
325120	Industrial Gas Manufacturing.
325180	Other Basic Inorganic Chemical Manufacturing.
325199	All Other Basic Organic Chemical Manufacturing.
325211	Plastics Material and Resin Manufacturing.
325320	Pesticide and Other Agricultural Chemical Manufacturing.
325412*	Pharmaceutical Preparation Manufacturing.
325414*	Biological Product (except Diagnostic) Manufacturing.
325992	Photographic Film, Paper, Plate and Chemical Manufacturing.
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing.
326150*	Urethane and Other Foam Product.
331420	Copper Rolling, Drawing, Extruding, and Alloying.
332312	Fabricated Structural Metal Manufacturing.
332313	Plate Work Manufacturing.
333132	Oil and Gas Field Machinery and Equipment Manufacturing.
333314	Optical Instrument and Lens Manufacturing.
333316	Photographic and Photocopying Equipment Manufacturing.
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing.
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing.
333611	Turbine and Turbine Generator Set Unit Manufacturing.
333996	Fluid Power Pump and Motor Manufacturing.
334413*	Semiconductor and Related Device Manufacturing.
334419*	Other Electronic Component Manufacturing.
334515	Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals.
334516	Analytical Laboratory Instrument Manufacturing.
334613	Blank Magnetic and Optical Recording Media Manufacturing.
336212*	Truck Trailer Manufacturing.
336214*	Travel Trailer and Camper Manufacturing.
336411*	Aircraft Manufacturing.
336510	Railroad Rolling Stock Manufacturing.
336611*	Ship Building and Repairing.
336612*	Boat Building.
336992*	Military Armored Vehicle, Tank, and Tank Component Manufacturing.
339999*	All Other Miscellaneous Manufacturing.
SIC 373102*	Military Ships, Building, and Repairing.
423120	Motor Vehicle Supplies and New Parts Merchant Wholesalers.
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers.
423460	Ophthalmic Goods Merchant Wholesalers.
423730	Warm Air Heating and Air-Conditioning Equipment and Supplies Merchant Wholesalers.
423740	Refrigeration Equipment and Supplies Merchant Wholesalers.
423830	Industrial Machinery and Equipment Merchant Wholesalers.
423860*	Transportation Equipment and Supplies (except Motor Vehicle) Merchant Wholesalers.
423990*	Other Miscellaneous Durable Goods Merchant Wholesalers.
424210	Drugs and Druggists' Sundries Merchant Wholesalers.
424410	General Line Grocery Merchant Wholesalers.
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers.
424690	Other Chemical and Allied Products Merchant Wholesalers.
424910	Farm Supplies Merchant Wholesalers.
441310	Automotive Parts and Accessories Stores.
443141	Household Appliance Stores.
443142	Electronics Stores.
444130	Hardware Stores.
446191	Food (Health) Supplement Stores.
452311	Warehouse Clubs and Supercenters.
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores).
454110	Electronic Shopping and Mail-Order Houses.
481111	Scheduled Passenger Air Transportation.
482111	Line-Haul Railroads.
488510	Freight Transportation Arrangement.
493110	General Warehousing and Storage.
522293	International Trade Financing.
523130	Commodity Contracts Dealing.
531110	Lessors of Residential Buildings and Dwellings.
531120	Lessors of Nonresidential Buildings (except Miniwarehouses).

TABLE 2—NAICS CLASSIFICATION OF POTENTIALLY AFFECTED ENTITIES—Continued

NAICS code	NAICS industry description
532420	Office Machinery and Equipment Rental and Leasing.
541330	Engineering Services.
541519	Other Computer Related Services.
541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).
561210	Facilities Support Services.
561910	Packaging and Labeling Services.
561990	All Other Support Services.
562920	Recovery and Reclamation.
722511	Full-Service Restaurants.
811219	Other Electronic and Precision Equipment Repair and Maintenance.
811412	Appliance Repair and Maintenance.
922160*	Fire Protection.

*Codes marked with an asterisk may apply to sectors that receive application-specific allowances under the AIM Act.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the regulatory text at the end of this notice. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What is the agency's authority for taking this action?

On December 27, 2020, the AIM Act was enacted as section 103 in Division S, Innovation for the Environment, of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260).[2] The AIM Act directs EPA to address HFCs by providing new authorities in three main areas: Phasing down the production and consumption of listed HFCs; managing these HFCs and their substitutes; and facilitating the transition to next-generation technologies by restricting use of these HFCs in the sector or subsectors in which they are used. This rulemaking focuses on the first area: The phasedown of the production and consumption of HFCs.

Subsection (e) of the AIM Act gives EPA authority to phase down the production and consumption of listed HFCs through an allowance allocation and trading program. The Act uses the term ''produce'' to mean ''the manufacture[3] of a regulated substance from a raw material or feedstock chemical,'' but excludes from that definition the destruction of HFCs using approved technologies; reclamation, reuse, or recycling of HFCs; and HFCs for transformation.[4] The Act uses the term ''consumption'' to refer to the amount of HFCs produced in and imported to the United States, subtracting the amount exported.

The Act lists 18 saturated HFCs, and by reference any of their isomers not so listed, that are covered by the statute's provisions, referred to as ''regulated substances'' under the Act. Congress also assigned an ''exchange value''[5][6] to each regulated substance (along with other chemicals that are used to calculate the baseline). The table in subsection (c)(1), reproduced here in Table 3, lists the 18 regulated substances and their exchange values.

TABLE 3—LIST OF REGULATED SUBSTANCES AND THEIR EXCHANGE VALUES

Chemical name	Common name	Exchange value
CHF_2CHF_2	HFC-134	1,100
CH_2FCF_3	HFC-134a	1,430
CH_2FCHF_2	HFC-143	353
$CHF_2CH_2CF_3$	HFC-245fa	1,030
$CF_3CH_2CF_2CH_3$	HFC-365mfc	794
CF_3CHFCF_3	HFC-227ea	3,220
$CH_2FCF_2CF_3$	HFC-236cb	1,340

[2] EPA interprets the phrase ''under this section'' in the AIM Act to refer to section 103 of the Consolidated Appropriations Act, 2021, and thus to mean ''under the AIM Act.'' This approach would be consistent with the language included in the Act, such as subsection (a) which states that ''[t]his section may be cited as American Innovation and Manufacturing Act of 2020.''

[3] While the AIM Act and the definition in this rule use the term ''manufacture'' in defining the term ''produce,'' in implementing EPA's CAA title VI programs, the Agency has historically used the term ''production'' when referring to the manufacture of chemicals and ''manufacture'' when referring to the manufacture of equipment. EPA intends to continue using this framing when describing production of chemicals and manufacture of equipment under the AIM Act to help distinguish between the two activities.

[4] The AIM Act uses the phrase ''a regulated substance that is used and entirely consumed (except for trace quantities) in the manufacture of another chemical'' instead of ''transformation'' in this definition. The quoted phrase mirrors the definition used in 40 CFR part 82, subpart A for the term ''transform.'' The AIM Act subsequently uses the terms ''transformation'' and ''use as a feedstock'' interchangeably. EPA interprets the use of these two terms in the statute as being intended to have the same meaning and accordingly EPA will use them interchangeably.

[5] EPA has determined that the exchange values included in subsection (c) of the AIM Act are identical to the GWPs included in IPCC (2007). EPA uses the terms ''global warming potential'' and ''exchange value'' interchangeably. One MMTEVe is therefore equivalent to one $MMTCO_2e$.

[6] IPCC (2007): Solomon, S., D. Qin, M. Manning, R.B. Alley, T. Berntsen, N.L. Bindoff, Z. Chen, A. Chidthaisong, J.M. Gregory, G.C. Hegerl, M. Heimann, B. Hewitson, B.J. Hoskins, F. Joos, J. Jouzel, V. Kattsov, U. Lohmann, T. Matsuno, M. Molina, N. Nicholls, J. Overpeck, G. Raga, V. Ramaswamy, J. Ren, M. Rusticucci, R. Somerville, T.F. Stocker, P. Whetton, R.A. Wood and D. Wratt, 2007: Technical Summary. In: *Climate Change 2007: The Physical Science Basis. Contribution of Working Group I to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change* [Solomon, S., D. Qin, M. Manning, Z. Chen, M. Marquis, K.B. Averyt, M. Tignor and H.L. Miller (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA. Available at *https://www.ipcc.ch/report/ar4/wg1.*

TABLE 3—LIST OF REGULATED SUBSTANCES AND THEIR EXCHANGE VALUES—Continued

Chemical name	Common name	Exchange value
CHF_2CHFCF_3	HFC-236ea	1,370
$CF_3CH_2CF_3$	HFC-236fa	9,810
$CH_2FCF_2CHF_2$	HFC-245ca	693
$CF_3CHFCHFCF_2CF_3$	HFC-43-10mee	1,640
CH_2F_2	HFC-32	675
CHF_2CF_3	HFC-125	3,500
CH_3CF_3	HFC-143a	4,470
CH_3F	HFC-41	92
CH_2FCH_2F	HFC-152	53
CH_3CHF_2	HFC-152a	124
CHF_3	HFC-23	14,800

The AIM Act requires EPA to phase down the consumption and production of the statutorily listed HFCs on an exchange value-weighted basis according to the schedule stated in (e)(2)(C) as shown in Table 4. The phasedown schedule begins on January 1 of each year.

TABLE 4—PHASEDOWN SCHEDULE

Date	Percentage of production baseline	Percentage of consumption baseline (percent)
2020–2023	90	90
2024–2028	60	60
2029–2033	30	30
2034–2035	20	20
2036 and thereafter	15	15

The AIM Act requires that the EPA Administrator ensure the annual quantity of all regulated substances produced or consumed [7] in the United States does not exceed the applicable percentage listed for the production or consumption baseline.

In order to execute this statutory directive, EPA must determine both a production and consumption baseline from which the yearly targets are calculated. The AIM Act provides formulas for how to set a baseline. The equations are composed of an HFC component, a hydrochlorofluorocarbon (HCFC) component, and a chlorofluorocarbon (CFC) component. Specifically, EPA is directed to calculate the production baseline by adding: (i) The average annual quantity of all regulated substances produced in the United States from January 1, 2011, through December 31, 2013, and (ii) 15 percent of the production level of HCFCs in calendar year 1989, and (iii) 0.42 percent of the production level of CFCs in calendar year 1989.

EPA is directed to calculate the consumption baseline by adding: (i) The average annual quantity of all regulated substances consumed in the United States from January 1, 2011, through December 31, 2013, and (ii) 15 percent of the consumption level of HCFCs in calendar year 1989, and (iii) 0.42 percent of the consumption level of CFCs in calendar year 1989. To implement the directive that the production and consumption of regulated substances in the United States does not exceed the statutory targets, the AIM Act in subsection (e)(3) requires EPA to issue regulations within 270 days of the Act's enactment establishing an allowance allocation and trading program to phase down the production and consumption of the listed HFCs. These allowances are limited authorizations for the production or consumption of regulated substances. Subsection (e)(2)(D) directs EPA to ''determine the quantity of allowances for the production and consumption of regulated substances that may be used for the following calendar year'' by October 1 each year. Subsection (e)(2) of the Act has a general prohibition that no person [8] shall produce or consume a quantity of regulated substances in the United States without a corresponding quantity of allowances. Also, within 270 days, EPA is directed in subsection (g) to establish regulations governing the transfer of production and consumption allowances. Subsection (e)(2)(A) provides that no person shall hold, use, or transfer an allocated production or consumption allowance except in accordance with the transfer regulations. Under subsection (g), the transfer regulations are to use the applicable exchange values and ''ensure that the transfers . . . will result in greater total reductions'' in production and consumption ''than would occur during the year in the absence of the transfers.''

Subsection (e)(4)(B)(iv) of the Act requires EPA to allocate allowances sufficient to meet the full quantity needed for production and consumption for six specific applications for five

[7] In the context of allocating and expending allowances, EPA interprets the word ''consume'' as the verb form of the defined term ''consumption.'' For example, subsection (e)(2)(A) states the phasedown consumption prohibition as ''no person shall . . . *consume* a quantity of a regulated substance without a corresponding quantity of consumption allowances.'' While a common usage of the word ''consume'' means ''use,'' EPA does not believe that Congress intended for every possible use of an HFC to require the expenditure of allowances. For example, we do not believe that Congress intended everyone who charges an appliance or fills an aerosol can with an HFC to expend allowances for that use.

[8] Under the Act's term, this general prohibition applies to any ''person.'' Because EPA anticipates that the parties that produce or consume HFCs—and that would thus be subject to the Act's production and consumption controls—are companies or other entities, we frequently use those terms to refer to regulated parties. Using this shorthand, however, does not alter the applicability of the Act's requirements and prohibitions.

years following enactment. EPA is to determine the necessary allowance amount for these applications ''based on projected, current, and historical trends.'' The six statutorily listed applications are: Propellants in metered dose inhalers; defense sprays (*e.g.,* bear spray); structural composite preformed polyurethane foam for marine use and trailer use; etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector; mission-critical military end uses; and onboard aerospace fire suppression. The allowances EPA allocates for these applications are for the ''exclusive use'' in one of the six applications.

Subsection (j) of the AIM Act speaks to international cooperation. Of particular relevance to this rulemaking, subsection (j)(4) requires EPA to promulgate a rule by December 27, 2021, to carry out the subsection. The AIM Act contains several restrictions and requirements governing international transfers of production allowances in subsections (j)(1) and (j)(2) and also provides some discretionary authority to EPA in (j)(3) regarding the effect of such transfers on production limits.

In subsection (k)(1)(A), the AIM Act provides EPA with the authority to promulgate necessary regulations to carry out EPA's functions under the Act, including its obligations to ensure that the Act's requirements are satisfied. Subsection (k) of the AIM Act explicitly makes certain sections of the CAA applicable to the AIM Act and regulations promulgated under its authority, stating ''Sections 113, 114, 304, and 307 of the Clean Air Act (42 U.S.C. 7413, 7414, 7604, 7607) shall apply to this section and any rule, rulemaking, or regulation promulgated by the Administrator pursuant to this section as though this section were expressly included in title VI of that Act (42 U.S.C. 7671 *et seq.*).'' Accordingly, this rulemaking is subject to CAA section 307(d) (42 U.S.C. 7607(d)(1)(I)), which provides that CAA section 307(d) applies to ''promulgation or revision of regulations under subchapter VI of this chapter (relating to stratosphere and ozone protection)'' (*i.e.,* title VI of the CAA)). Violation of the requirements established in this rulemaking is subject to federal enforcement and the penalties laid out in CAA section 113 including, but not limited to, the penalties in section 113(b) for civil judicial enforcement and section 113(c) criminal penalties. In addition, although there is limited legislative history available on the AIM Act, Congress is generally presumed to legislate with an awareness of the existing law that is pertinent to enacted legislation. Given the similarities in the text, structure, and function of the production and consumption phasedown provisions of the AIM Act and EPA's program phasing out ozone-depleting substances (ODS) under title VI of the CAA,[9] EPA finds it reasonable to build on its experience phasing out ODS when developing the AIM Act's HFC allowance allocation and trading program, while also recognizing that there are areas where the AIM Act's requirements diverge from the text and framework of title VI of the CAA. There are many instances where the definitions and structure are either identical or have only slight differences. For example, the definitions of ''import'' in the AIM Act and CAA section 601 are materially similar though they have slightly different phrasing. In at least some instances, Congress adopted language in the AIM Act that matches EPA's implementation approach for ODS production and consumption controls under CAA title VI as reflected in 40 CFR part 82, subpart A. For example, the definition for ''produce'' in the AIM Act mirrors the parallel definition in CAA section 601 in many respects, but in contrast to the CAA definition, the AIM Act explicitly excludes the destruction of regulated substances using technologies approved by the Administrator from being counted in production. While the CAA definition does not explicitly exclude destruction from production, EPA's regulatory definition for ''production'' in 40 CFR 82.3 does exclude destruction from being counted as production. Throughout this rulemaking, EPA explains how the Agency is relying on and building from its experience implementing the ODS phaseout provisions in the CAA and its implementing regulations where such considerations are relevant to creating the framework structure for the AIM Act's required HFC allowance allocation and trading program. Given EPA's extensive experience phasing out ODS under similar CAA authority for a regulated community that bears marked resemblance to entities that could be impacted by this rulemaking, reliance on EPA's expertise will help achieve the goals required by Congress in implementing the AIM Act.

[9] EPA's well-established regulatory program at 40 CFR part 82, subpart A, provides for the allocation of ODS production and consumption allowances, implementing the ODS production and consumption controls of title VI of the CAA and facilitating an orderly phaseout.

III. Background

A. What are HFCs?

HFCs are anthropogenic [10] fluorinated chemicals that have no known natural sources. HFCs are used in the same applications that ODS have historically been used in, such as refrigeration and air conditioning, foam blowing agents, solvents, aerosols, and fire suppression. HFCs are potent GHGs with 100-year GWPs (a measure of the relative climatic impact of a GHG) that can be hundreds to thousands of times more potent than carbon dioxide (CO_2).

Although HFCs represent a small fraction (~1.5 percent) of the current total GWP-weighted amount of GHG emissions,[11] their use is growing worldwide due to the global phaseout of ODS under the *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol), and the increasing use of refrigeration and air conditioning equipment globally. HFC emissions had previously been projected to increase substantially over the next several decades, but global adherence to the Kigali Amendment to the Montreal Protocol (Kigali Amendment) would substantially reduce future emissions, leading to a peaking of HFC emissions before 2040.[12]

Atmospheric observations of most currently measured HFCs confirm their amounts are increasing in the global atmosphere at accelerating rates. Total emissions of HFCs increased by 23 percent from 2012 to 2016 and the four most abundant HFCs in the atmosphere, in GWP-weighted terms, are HFC-134a, HFC-125, HFC-23, and HFC-143a.[13]

In 2016, HFCs accounted for a radiative forcing of 0.025 W/m^2, not including additional forcing from HFC-23 of 0.005 W/m^2: This is a 36 percent increase in total HFC forcing relative to 2012. This radiative forcing was projected to increase by an order of magnitude to 0.25 W/m^2 by 2050, not including additional forcing from HFC-23. In 2016, in Kigali, Rwanda, countries agreed to adopt an amendment to the Montreal Protocol, known as the Kigali Amendment, which provides for a global phasedown of the

[10] While the overwhelming majority of HFC production is intentional, HFC-23 can be a byproduct associated with the production of other chemicals, including but not limited to HCFC-22.

[11] World Meteorological Organization (WMO), *Scientific Assessment of Ozone Depletion: 2018,* World Meteorological Organization, Global Ozone Research and Monitoring Project—Report No. 58, 588 pp., Geneva, Switzerland, 2018. Available at *https://ozone.unep.org/sites/default/files/2019-05/SAP-2018-Assessment-report.pdf.*

[12] Ibid.

[13] Ibid.

production and consumption of HFCs. If the Kigali Amendment were to be fully implemented, it would be expected to reduce the future radiative forcing due to HFCs (excluding HFC-23) to 0.13 W/m^2 in 2050: A reduction of about 50 percent compared to the radiative forcing projected in the business-as-usual scenario of uncontrolled HFCs.[14] A global HFC phasedown consistent with the Kigali Amendment to the Montreal Protocol is expected to avoid up to 0.5 °C of warming by 2100.[15]

There are hundreds of possible HFC compounds. The 18 HFCs listed as regulated substances by the AIM Act are some of the most commonly used HFCs and have high impacts as measured by the quantity emitted multiplied by their respective GWPs. These 18 HFCs are all saturated, meaning they have only single bonds between their atoms and therefore have longer atmospheric lifetimes.

In the United States, HFCs are used primarily in refrigeration and air conditioning equipment in homes, commercial buildings, and industrial operations (~75 percent of total HFC use in 2019) and in air conditioning in vehicles and refrigerated transport (~8 percent). Smaller amounts are used in foam products (~11 percent), aerosols (~4 percent), fire protection systems (~1 percent), and solvents (~1 percent).[16]

EPA considered the emissions reductions from an HFC consumption phasedown in the United States and presented the results in the 2016 Biennial Report to the United Nations Framework Convention on Climate Change (UNFCCC).[17] At that time, EPA provided a reductions estimate of 113 million metric tons of carbon dioxide equivalent ($MMTCO_2e$) of reduced HFC emissions in the United States associated with the implementation of an amendment proposal submitted in 2015 by the United States, Canada, and Mexico that was under consideration by the parties to the Montreal Protocol and was very similar to the Kigali Amendment. While the Kigali Amendment ultimately adopted under the Montreal Protocol has certain marked differences from the AIM Act, given that the two documents have a nearly identical list of HFCs to be phased down following the same schedule, the 2016 Biennial Report provides useful information. The Biennial Report included estimates for HFC actions under CAA section 612 modeled in the *2016 Current Measures* scenario. HFC emissions reductions through additional measures in 2020 and 2025 relative to the *2016 Current Measures* scenario were presented under the *Additional Measures* scenario and included both options for continued action under the CAA and the implementation of an HFC phasedown in the United States, which is similar to the requirements of the AIM Act with an earlier start date.[18] The emissions reductions for the *Additional Measures* scenario were estimated to be 63 $MMTCO_2e$ in 2020 and 113 $MMTCO_2e$ in 2025.

B. How do HFCs affect public health and welfare?

As EPA has previously recognized, elevated concentrations of GHGs including HFCs have been warming the planet, leading to changes in the Earth's climate including changes in the frequency and intensity of heat waves, precipitation, and extreme weather events; rising seas; and, retreating snow and ice. Similarly, EPA has previously recognized that the changes taking place in the atmosphere are a result of the well-documented buildup of GHGs due to human activities and are changing the climate at a pace and in a way that threatens human health, society, and the natural environment. While EPA is not statutorily required to make any particular scientific or factual findings in order to regulate HFCs under the AIM Act's phasedown provisions, in this section EPA is providing some scientific background on climate change to offer additional context for this rulemaking and to help the public understand the environmental impacts of GHGs such as HFCs.

Extensive additional information on climate change is available in the scientific assessments and the EPA documents that are briefly described in this section, as well as in the technical and scientific information supporting them. One of those documents is EPA's 2009 Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the CAA (74 FR 66496, December 15, 2009).[19] In the 2009 Endangerment Finding, the Administrator found under section 202(a) of the CAA that elevated atmospheric concentrations of six key well-mixed GHGs—CO_2, CH_4, N_2O, HFCs, perfluorocarbons (PFCs), and sulfur hexafluoride (SF_6)—''—''may reasonably be anticipated to endanger the public health and welfare of current and future generations'' (74 FR 66523, December 15, 2009). The 2009 Endangerment Finding, together with the extensive scientific and technical evidence in the supporting record, documented that climate change caused by human emissions of GHGs (including HFCs) threatens the public health of the population of the United States. It explained that by raising average temperatures, climate change increases the likelihood of heat waves, which are associated with increased deaths and illnesses (74 FR 66497, December 15, 2009). It noted that while climate change also increases the likelihood of reductions in cold-related mortality, evidence indicates that the increases in heat mortality will be larger than the decreases in cold mortality in the United States (74 FR 66525, December 15, 2009). The 2009 Endangerment Finding further explained that compared with a future without climate change, climate change is expected to increase tropospheric ozone pollution over broad areas of the United States,

[14] Ibid.

[15] Ibid.

[16] Calculations are based on EPA's Vintaging Model, which estimates the annual chemical emissions from industry sectors that historically used ODS, including refrigeration and air-conditioning, foam blowing, solvents, aerosols, and fire suppression. The model uses information on the market size and growth for each end use, as well as a history and projections of the market transition from ODS to alternatives. The model tracks emissions of annual ''vintages'' of new equipment that enter into operation by incorporating information on estimates of the quantity of equipment or products sold, serviced, retired, or converted each year, and the quantity of the compound required to manufacture, charge, and/or maintain the equipment. Information on these estimates is available in U.S. EPA, April 2016, EPA Report EPA–430–R–16–002. *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990–2014.* Available at *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2014.*

[17] U.S. Department of State. Second Biennial Report of the United States of America Under the United Nations Framework Convention on Climate Change. Washington, DC, 2016. Available at *http://unfccc.int/national_reports/biennial_reports_and_iar/submitted_biennial_reports/items/7550.php.*

[18] The *Current Measures* scenario in the Biennial Report included HFC reductions estimated under a rule EPA issued on July 20, 2015, under section 612 of the CAA, which, among other things, changed listings under the Significant New Alternatives Policy program for certain HFCs and blends from acceptable to unacceptable in various end uses in the aerosols, refrigeration and air conditioning, and foam blowing sectors. The *Additional Measures* scenario in the Biennial Report included additional actions that EPA anticipated under a proposed amendment to the Montreal Protocol to phase down HFC production and consumption, some of which were included in a rule EPA issued on December 1, 2016, under section 612 of the CAA. Since the 2016 Biennial Report, after a challenge to the 2015 rule, the U.S. Court of Appeals for the D.C. Circuit (''the court'') issued a partial vacatur of the 2015 rule ''to the extent [it] requires manufacturers to replace HFCs with a substitute substance,'' and remanded the rule to EPA for further proceedings. Later, the court issued a similar decision on portions of the rule issued December 1, 2016. *See Mexichem Fluor, Inc.* v. *EPA,* 760 F. App'x 6 (D.C. Cir. 2019) (per curiam).

[19] As noted in the NRPM for this action, in describing the 2009 Findings in this rulemaking, EPA is neither reopening nor revisiting them (see 86 FR 27516, May 19, 2021).

including in the largest metropolitan areas with the worst tropospheric ozone problems, and thereby increase the risk of adverse effects on public health (74 FR 66525, December 15, 2009). Climate change is also expected to cause more intense hurricanes and more frequent and intense storms of other types and heavy precipitation, with impacts on other areas of public health, such as the potential for increased deaths, injuries, infectious and waterborne diseases, and stress-related disorders (74 FR 66525 December 15, 2009). Children, the elderly, and the poor are among the most vulnerable to these climate-related health effects (74 FR 66498 December 15, 2009).

The 2009 Endangerment Finding also documented, together with the extensive scientific and technical evidence in the supporting record, that climate change touches nearly every aspect of public welfare [20] in the United States with resulting economic costs, including: changes in water supply and quality due to changes in drought and extreme rainfall events; increased risk of storm surge and flooding in coastal areas and land loss due to inundation; increases in peak electricity demand and risks to electricity infrastructure; and the potential for significant agricultural disruptions and crop failures (though offset to some extent by carbon fertilization). These impacts are also global and may exacerbate problems outside the United States that raise humanitarian, trade, and national security issues for the United States (74 FR 66530, December 15, 2009).

In 2016, the Administrator similarly issued Endangerment and Cause or Contribute Findings for greenhouse gas emissions from aircraft under section 231(a)(2)(A) of the CAA (81 FR 54422, August 15, 2016).[21] In the 2016 Endangerment Finding, the Administrator found that the body of scientific evidence amassed in the record for the 2009 Endangerment Finding compellingly supported a similar endangerment finding under CAA section 231(a)(2)(A), and also found that the science assessments released between the 2009 and the 2016 Findings ''strengthen and further support the judgment that GHGs in the atmosphere may reasonably be anticipated to endanger the public health and welfare of current and future generations'' (81 FR 54424, August 15, 2016).

Since the 2016 Endangerment Finding, the climate has continued to change, with new records being set for several climate indicators such as global average surface temperatures, greenhouse gas concentrations, and sea level rise. Additionally, major scientific assessments continue to be released that further improve our understanding of the climate system and the impacts that GHGs have on public health and welfare both for current and future generations. According to the IPCC's Sixth Assessment Report, ''it is unequivocal that human influence has warmed the atmosphere, ocean and land. Widespread and rapid changes in the atmosphere, ocean, cryosphere and biosphere have occurred.'' These updated observations and projections document the rapid rate of current and future climate change both globally and in the United States.[22] [23] [24] [25]

IV. How is EPA considering environmental justice?

Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14008 (86 FR 7619, January 27, 2021) establish federal executive policy on environmental justice. Executive Order 12898's main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA defines environmental justice as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.[26] Meaningful involvement means that: (1) Potentially affected populations have an appropriate opportunity to participate in decisions about a proposed activity that will affect their environment and/or health; (2) the public's contribution can influence the regulatory agency's decision; (3) the concerns of all participants involved will be considered in the decision-making process; and (4) the rule-writers and decision-makers seek out and facilitate the involvement of those potentially affected.[27] The term ''disproportionate impacts'' refers to differences in impacts or risks that are extensive enough that they may merit Agency action. In general, the determination of whether there is a disproportionate impact that may merit Agency action is ultimately a policy judgment which, while informed by analysis, is the responsibility of the decision-maker. The terms ''difference'' or ''differential'' indicate an analytically discernible distinction in impacts or risks across population groups. It is the role of the analyst to assess and present differences in anticipated impacts across population groups of concern for both the baseline and proposed regulatory options, using the best available information (both quantitative and qualitative) to inform the decision-maker and the public.[28]

A regulatory action may involve potential environmental justice concerns if it could: (1) Create new disproportionate impacts on minority populations, low-income populations, and/or indigenous peoples; (2) exacerbate existing disproportionate

[20] The CAA states in section 302(h) that ''[a]ll language referring to effects on welfare includes, but is not limited to, effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants.'' 42 U.S.C. 7602(h).

[21] As noted in the NRPM for this action, in describing the 2016 Findings in this rulemaking, EPA is neither reopening nor revisiting them (see 86 FR 27516, May 19, 2021).

[22] USGCRP, 2018: *Impacts, Risks, and Adaptation in the United States: Fourth National Climate Assessment, Volume II* [Reidmiller, D.R., C.W. Avery, D.R. Easterling, K.E. Kunkel, K.L.M. Lewis, T.K. Maycock, and B.C. Stewart (eds.)]. U.S. Global Change Research Program, Washington, DC, USA, 1515 pp. doi: 10.7930/NCA4.2018. Available at *https://nca2018.globalchange.gov.*

[23] IPCC, 2021: Summary for Policymakers. In: *Climate Change 2021: The Physical Science Basis. Contribution of Working Group I to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change* [Masson-Delmotte, V., P. Zhai, A. Pirani, S.L. Connors, C. Péan, S. Berger, N. Caud, Y. Chen, L. Goldfarb, M.I. Gomis, M. Huang, K. Leitzell, E. Lonnoy, J.B.R. Matthews, T.K. Maycock, T. Waterfield, O. Yelekçi, R. Yu and B. Zhou (eds.)]. Cambridge University Press. In Press.

[24] National Academies of Sciences, Engineering, and Medicine, 2019. *Climate Change and Ecosystems.* Washington, DC: The National Academies Press. Available at *https://doi.org/10.17226/25504.*

[25] NOAA National Centers for Environmental Information, State of the Climate: Global Climate Report for Annual 2020, published online January 2021. Available at *https://www.ncdc.noaa.gov/sotc/global/202013.*

[26] See, *e.g.,* Environmental Protection Agency. ''Environmental Justice.'' Available at *https://www.epa.gov/environmentaljustice.*

[27] The criteria for meaningful involvement are contained in EPA's May 2015 document ''Guidance on Considering Environmental Justice During the Development of an Action.'' Environmental Protection Agency, 17 Feb. 2017. Available at *https://www.epa.gov/environmentaljustice/guidance-considering-environmental-justice-during-development-action.*

[28] The definitions and criteria for ''disproportionate impacts,'' ''difference,'' and ''differential'' are contained in EPA's June 2016 document ''Technical Guidance for Assessing Environmental Justice in Regulatory Analysis.'' Available at *https://www.epa.gov/sites/production/files/2016-06/documents/ejtg_5_6_16_v5.1.pdf.*

impacts on minority populations, low-income populations, and/or indigenous peoples; or (3) present opportunities to address existing disproportionate impacts on minority populations, low-income populations, and/or indigenous peoples through the action under development.

Executive Order 14008 calls on agencies to make achieving environmental justice part of their missions ''by developing programs, policies, and activities to address the disproportionately high and adverse human health, environmental, climate-related, and other cumulative impacts on disadvantaged communities, as well as the accompanying economic challenges of such impacts.'' Executive Order 14008 further declares a policy ''to secure environmental justice and spur economic opportunity for disadvantaged communities that have been historically marginalized and overburdened by pollution and under-investment in housing, transportation, water and wastewater infrastructure, and health care.''

Further, under Executive Order 13563 (76 FR 3821, January 18, 2011), federal agencies may consider equity, human dignity, fairness, and distributional considerations, where appropriate and permitted by law. Likewise, the Presidential Memorandum on Modernizing Regulatory Review calls for procedures to ''take into account the distributional consequences of regulations, including as part of any quantitative or qualitative analysis of the costs and benefits of regulations, to ensure that regulatory initiatives appropriately benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities.'' [29] EPA also released its June 2016 ''Technical Guidance for Assessing Environmental Justice in Regulatory Analysis'' (2016 Technical Guidance) to provide recommendations that encourage analysts to conduct the highest quality analysis feasible, recognizing that data limitations, time and resource constraints, and analytic challenges will vary by media and circumstance.[30]

As described elsewhere in this preamble, this rule establishes the framework for the United States' phasedown of HFCs, which will achieve significant benefits by reducing production and consumption of certain chemicals with high GWPs. Section III.B of this rule briefly summarizes the public health and welfare effects of GHG emissions (including HFCs) as documented in EPA's 2009 and 2016 Endangerment Findings. As part of these Endangerment Findings, the Administrator considered climate change risks to minority populations and low-income populations, finding that certain parts of the population may be especially vulnerable based on their characteristics or circumstances, including the poor, the elderly, the very young, those already in poor health, the disabled, those living alone, and/or indigenous populations dependent on one or limited resources due to factors including but not limited to geography, access, and mobility.

More recent assessment reports by the United States Global Change Research Program (USGCRP), the Intergovernmental Panel on Climate Change (IPCC), and the National Research Council (NRC) of the National Academies demonstrate that the potential impacts of climate change raise environmental justice issues.[31] These reports concluded that low-income communities can be especially vulnerable to climate change impacts because they tend to have more limited capacity to bear the costs of adaptation and are more dependent on climate-sensitive resources such as local water and food supplies. In corollary, some communities of color, specifically populations defined jointly by both ethnic/racial characteristics and geographic location, may be uniquely vulnerable to climate change health impacts in the United States. Native American tribal communities also possess unique vulnerabilities to climate change, particularly those impacted by degradation of natural and cultural resources within established reservation boundaries and threats to traditional subsistence lifestyles. The Technical Support Document for the 2009 Endangerment Finding also specifically noted that Southwest native cultures are especially vulnerable to water quality and availability impacts, and Native Alaskan communities are already experiencing disruptive impacts, including coastal erosion and shifts in the range or abundance of wild species crucial to their livelihoods and well-being.

This rulemaking, as part of the phasedown of HFCs in the United States, achieves significant benefits associated with reducing emissions of potent GHGs. However, as described in the RIA and summarized below, there is significant uncertainty about how the phasedown of HFC production and the issuance of allowances by themselves, as well as the interactions with market trends independent of this rulemaking, could affect production of HFCs and HFC substitutes—and associated emissions—at individual facilities, particularly in communities that are disproportionately burdened by air pollution. In its proposed rulemaking, EPA solicited comment, data, and other information that could be helpful to EPA in future rulemaking actions in analyzing and, as appropriate, reducing the potential for inadvertent or unexpected distributional effects from this program, including the potential for environmental justice concerns due to the release of toxic chemicals that are feedstocks, catalysts, or byproducts in the production of HFCs or HFC substitutes. Information provided in response to this solicitation is available in the docket for this rulemaking, and EPA intends to take it into account, as appropriate, as the Agency moves forward in implementing the AIM Act.

A reasonable starting point for assessing the need for a more detailed environmental justice analysis is to review the available evidence from the published literature and from community input on what factors may make population groups of concern more vulnerable to adverse effects (*e.g.,* cumulative exposure from multiple stressors), including but not limited to the 2009 and 2016 Endangerment Findings and the reports from USGCRP, IPCC, and NRC. It is also important to evaluate the data and methods available for conducting an environmental justice analysis.

EPA's 2016 Technical Guidance does not prescribe or recommend a specific approach or methodology for conducting an environmental justice analysis, though a key consideration is consistency with the assumptions underlying other parts of the regulatory analysis when evaluating the baseline and regulatory options.

The environmental justice analysis performed to support this rulemaking is described in the associated RIA and is based on public data from the Toxics Release Inventory (TRI), GHGRP, EJSCREEN (an environmental justice mapping and screening tool developed by EPA), Enforcement and Compliance History Online (ECHO), and Census data. In addition, this analysis integrates suggestions received during the public comment period to the extent possible. Where applicable and practicable, the Agency examined certain metrics for an

[29] See *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/modernizing-regulatory-review.*

[30] See *https://www.epa.gov/sites/default/files/2016-06/documents/ejtg_5_6_16_v5.1.pdf.*

[31] *Supra* footnotes 22, 23, and 24. See also EPA. 2021. Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency, EPA 430–R–21–003.

environmental justice analysis comprising more than just climate change effects, including: The proximity of companies receiving allowances to populations disaggregated by race and ethnicity, low-income populations, and/or indigenous peoples; the number of companies receiving allowances that may be adversely affecting population groups of concern; the nature, amounts, and location of regulated HFC production that may adversely affect population groups of concern; and potential exposure pathways associated with the production of the regulated HFCs or with chemicals used as feedstocks, catalysts, or byproducts of HFC production unique to particular populations (*e.g.,* workers). The environmental justice analysis also contains information on non-production releases (as defined by TRI), water releases, and offsite disposal for chemicals used in HFC production. The analysis of potential environmental justice concerns focused mainly on characterizing baseline emissions of air toxics that are also associated with chemical feedstock use for HFC production. As noted in the RIA, there is uncertainty around the role that HFC production plays in emissions of these air toxics. In addition, EPA conducted a proximity analysis to examine community characteristics within one and three miles of these facilities. The Agency also explored larger radii (five and 10 miles) in response to public comments that releases from these facilities may travel longer distances. The relatively small number of facilities directly affected by this rule enabled EPA to assemble a uniquely granular assessment of the characteristics of these facilities and the communities where they are located.

Overall, this rule reduces GHG emissions, which will benefit populations that may be especially vulnerable to damages associated with climate change. However, the manner in which producers transition from high-GWP HFCs could drive changes in future risk for communities living near facilities that produce HFCs and HFC substitutes, to the extent the use of toxic feedstocks, byproducts, or catalysts changes and those chemicals are released into the environment with adverse local effects. The environmental justice analysis, which examined racial and economic demographic and health risk information, found heterogeneity in community characteristics around individual facilities. The analysis showed that the total baseline cancer risk and total respiratory risk from air toxics (not all of which stem from HFC production) varies, but is generally higher, and in some cases much higher, within one to ten miles of an HFC production facility. The analysis also found that higher percentages of low-income and Black or African-American individuals live near several HFC production facilities compared with the appropriate national and state level average. EPA noted in the proposed rulemaking, and reiterates here, that it is not clear the extent to which these baseline risks are directly related to HFC production, but some feedstocks, catalysts, and byproducts are toxic, particularly with respect to potential carcinogenicity (*e.g.,* carbon tetrachloride, tetrachloroethylene, and trichloroethylene). All HFC production facilities are near other industrial facilities that could contribute to the cumulative National Air Toxics Assessment (NATA) cancer and respiratory risk; the number of neighboring TRI facilities within one mile of an HFC production facility ranges from two to 14, within three miles there are two to 19 neighboring TRI facilities, within five miles there are two to 34 neighboring TRI facilities, and within 10 miles there are six to 66 neighboring TRI facilities. At this time, it is not clear how emissions related to HFC production compare to other chemical production at the same or nearby facilities. Additionally, some HFC alternatives, such as hydrofluoroolefins (HFOs), use the same chemicals as feedstocks in their production or release the same chemicals as byproducts, potentially raising concerns about local exposure. Emissions from production facilities manufacturing non-fluorinated substitutes (*e.g.,* hydrocarbons, ammonia) could also be affected by the phasedown of HFCs. However, given limited information regarding where substitutes will be produced and what other factors might affect production and emissions at those locations, it is unclear to what extent this rule may affect baseline risks from hazardous air toxics for communities living near HFC production facilities. Further, the HFC phasedown schedule prescribed by Congress—with a 10 percent reduction by 2022, a 40 percent reduction by 2024, a 70 percent reduction by 2029, an 80 percent reduction by 2034 and an 85 percent reduction by 2036—may also reduce the potential for a facility to increase emissions above current levels for a prolonged period.

EPA requested commenters provide data or other information to help better characterize these changes and their implications for nearby communities. Several commenters asserted that the RIA for the proposed rulemaking overestimated the environmental justice benefits, in part because emissions at HFC production facilities have likely declined since the 2014 NATA that EPA relied upon in its analysis. EPA responds that the Agency relied on the 2014 NATA data as a proxy for cumulative exposure to air toxics near HFC production facilities, which is the most recent year of data available. EPA plans to use more recent NATA data in future analyses of potential environmental justice concerns as it becomes available. EPA has not quantitatively assessed the potential benefits in terms of reductions in risk or exposure to environmental justice communities from changes in HFC production resulting from the rule. The absence of this assessment is due to data constraints and uncertainty about where HFCs and HFC alternatives will be produced in the future and where some HFC alternatives are produced now (*e.g.,* for non-HFC technologies). EPA also lacks information on which alternative(s) or type(s) of alternative (fluorinated, non-fluorinated, etc.) will take the dominant market share for the current uses of HFCs.

One commenter provided extensive suggestions for how EPA could augment and strengthen its environmental justice analysis for the final rulemaking. Suggested factors and metrics included increasing the area of analysis and integrating the Risk-Screening Environmental Indicators Geographic Microdata (RSEI–GM), which incorporates data from the TRI together with factors such as each chemical's fate and transport through the environment, each chemical's relative toxicity, and potential human exposure. One other commenter suggested that EPA use existing data available in EJSCREEN to identify whether certain communities should be prioritized by EPA in mitigating any adverse impacts, and also to serve as a benchmark for measuring the effects of this rule over time. EPA will explore opportunities to prioritize areas with environmental justice concerns, particularly those related to multiple or cumulative exposures to environmental hazards, and to improve environmental justice analysis in future rulemakings. Updates to the environmental justice analysis can be found in the RIA for this final rulemaking, and notably, EPA explored larger radii (five and 10 miles) from identified facilities. Results at these larger radii are similar to the average aggregate community characteristics near HFC production facilities at one-

and three-mile distances contained in the proposed rulemaking RIA. To examine the potential exposure of nearby communities to all reported TRI air emissions from each HFC production facility, EPA extracted concentrations weighted by toxicity for chemicals emitted by each facility over a 50-kilometer radius from the RSEI–GM model. The one-, three-, five- and 10 mile-buffers are shown on these maps and indicate that the highest concentrations are immediately adjacent to the facilities (*i.e.,* within a mile). Toxicity-weighted concentrations decline further from the facility as these releases disperse. The area with moderate concentrations is mostly within the 10-mile buffer. However, because of prevailing wind directions, toxicity-weighted concentrations are not uniformly distributed around the facilities and, in some cases, communities outside of the 10-mile buffer are still exposed to elevated concentrations. Linking these toxicity-weighted concentrations with specific communities of concern is an area of investigation to improve environmental justice analyses. EPA will further consider use of RSEI–GM for future regulatory analyses. EPA also added information from EJSCREEN on wastewater discharges, proximity to hazardous waste, ground-level ozone concentrations, and particulate matter concentrations near HFC production facilities. The Agency reiterates, consistent with our view in the proposed rulemaking, that there is uncertainty around the role that HFC production plays in emissions of these air toxics, as well as the impact that this program will have on the location and amount of production of HFCs and their substitutes and any associated air pollution emissions. The environmental justice analysis is intended as a tool to inform potential concerns. While EPA finds evidence of environmental justice concerns near HFC production facilities from cumulative exposure to existing environmental hazards in these communities, at this early stage in the development of the HFC allowance allocation program, EPA cannot, on the basis of this analysis, determine the extent to which this rule will contribute to or reduce existing environmental justice concerns for communities of color, low-income people, and/or indigenous peoples. This is primarily due to uncertainty with regard to where and in what quantities substitutes for high-exchange-value HFCs will be produced.

In the proposed rulemaking, EPA specifically sought comment on whether changes in emissions, particularly in communities that are already disproportionately affected by air pollution, could occur as the result of the HFC allowance allocation program, the associated ability to transfer allowances, or other unrelated changes in the market. EPA also sought comment on whether there are remedies that could be applied as part of the design of the program in the event the Agency determines such unintended distributional impacts exist. In addition, EPA solicited comment on whether other regulatory authorities would be more appropriate to address any inadvertent or unexpected distributional effects that are identified, for example, if a producer obtained allowances in sufficient quantities to increase HFC production, which could potentially increase air emissions at that location.

EPA received comments in response to the question of what the Agency should consider for future rulemakings with respect to environmental justice. Several commenters noted that the AIM Act does not require EPA to consider environmental justice. Some commenters also noted that enforcing existing controls or limits promulgated under various other CAA authorities (*e.g.,* criteria pollutants and air toxics) or state and local regulations (*e.g.,* permitted air toxics limits) that would be applicable to HFCs and alternatives are sufficient to address any potential environmental justice concerns, and are also the most direct strategy for addressing such concerns.

In response, EPA reiterates that Executive Order 12898 (59 FR 7629; February 16, 1994) and Executive Order 14008 (86 FR 7619, January 27, 2021) establish federal executive policy on environmental justice. As outlined at the beginning of this section, the main provision of Executive Order 12898 directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. Additionally, Executive Order 14008 calls on agencies to make achieving environmental justice part of their missions ''by developing programs, policies, and activities to address the disproportionately high and adverse human health, environmental, climate-related and other cumulative impacts on disadvantaged communities, as well as the accompanying economic challenges of such impacts.'' Executive Order 14008 further declares a policy ''to secure environmental justice and spur economic opportunity for disadvantaged communities that have been historically marginalized and overburdened by pollution and under-investment in housing, transportation, water and wastewater infrastructure, and health care.'' Further, under Executive Order 13563 (76 FR 3821, January 18, 2011), federal agencies may consider equity, human dignity, fairness, and distributional considerations, where appropriate and permitted by law. In addition, the Presidential Memorandum on Modernizing Regulatory Review calls for procedures to ''take into account the distributional consequences of regulations, including as part of a quantitative or qualitative analysis of the costs and benefits of regulations, to ensure that regulatory initiatives appropriately benefit, and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities.'' EPA has promulgated other regulations or limits under different authorities that may affect the facilities identified in the RIA and the surrounding communities, but EPA is also committed to taking a holistic view of facilities affected by these rulemakings pursuant to the two above-cited executive orders that direct EPA to make environmental justice part of its mission for any and all rulemaking processes. In such instances where other authorities may be a more appropriate avenue, EPA expects that effects on surrounding communities and associated mitigating solutions would be addressed through those regulatory processes and under commensurate timelines.

Additionally, one commenter disagreed with assumptions underlying EPA's environmental justice analysis. First, the commenter asserted that Congress has previously recognized that feedstock emissions are too insignificant to be a concern and has already provided other authority to protect communities near industrial facilities (*i.e.,* standards for hazardous air pollutants contained in sections 112(d) and (f) of the CAA and codified in 40 CFR 63, specifically subparts F, G, H, and I). Second, the commenter asserted that the Toxic Substances Control Act (TSCA) risk evaluations are deficient and should not be used as a basis for environmental justice regulations. Lastly, the commenter asserted that more information is needed on background concentrations and sources. EPA continues to rely on the latest information available from the TSCA risk evaluation process to inform the

potential for worker exposure from HFC feedstocks. These risk evaluations did not assess air, water, or disposal exposures to the general population when these exposure pathways are or can be regulated under other EPA-administered statutes. However, EPA recently announced plans to conduct additional analysis for the risk evaluations for seven of the first 10 chemicals evaluated under the amended TSCA to ensure that the risk evaluations did not overlook risk to fenceline communities (*i.e.,* communities near industrial facilities). EPA is also revisiting the assumptions from the risk evaluations regarding the assumed use of personal protective equipment for purposes of risk determination. Following these additional analyses, EPA will issue revised risk determinations on the whole chemical substance, rather than on each condition of use. This has the potential to change the unreasonable risk determinations under TSCA for some of the first 10 chemicals, including the four chemicals with risk evaluations completed in 2020 (*i.e.,* carbon tetrachloride, tetrachloroethylene, trichloroethylene, and methylene chloride).

EPA is finalizing requirements for other provisions in this rule that are relevant for environmental justice. For example, as further explained in Section X.C.1, some commenters stated that providing facility-level chemical-specific production data would be beneficial to communities located adjacent to chemical manufacturing facilities. EPA is determining in this final rulemaking that facility-level production data is not entitled to confidential treatment, and EPA intends to release this information to the public. This additional transparency will allow neighboring communities to see how emissions from a particular facility compare to changes in HFC production levels.

Finally, EPA received suggestions for additional ways that EPA could consider environmental justice in future rulemakings, including but not limited to: Considering indirect pollution effects, *e.g.,* increased motor vehicle emissions; considering a comprehensive emissions and release evaluation approach for all facilities including all media and all applicable limits; integrating existing and newly deployed fenceline monitoring data; evaluating the effects of producing certain HFC substitutes on air and water quality; and evaluating how exports of products and equipment containing HFCs could affect other countries' environmental justice concerns. EPA acknowledges receipt of these various comments, and will consider them, as appropriate, as we develop future rulemakings.

As noted in the proposed rule and reiterated here, EPA intends to develop another rule before allowances are allocated for calendar year 2024 that may alter the framework and procedure for issuing allowance allocations established in this rule. EPA will continue to monitor the impacts of this program on HFC and substitute production, and emissions in neighboring communities, as we move forward to implement this rule. EPA may consider taking appropriate action in the future—including action—under CAA authorities, in future HFC allocation rules, or under other relevant authorities, if we develop further information indicating there is a risk of disproportionate impacts.

EPA notes that this rule affects a small number of entities through a unique phasedown and allocation program, and that these entities manufacture a wide variety of products and are subject to a number of distinct market and regulatory forces independent of this HFC program. As such, the issues and possible remedies identified here may not be broadly applicable or practicable in other rulemakings.

V. What definitions is EPA establishing to implement the AIM Act?

EPA is establishing definitions to implement the framework for the AIM Act generally and the allowance allocation and trading program specifically. EPA proposed to define new terms that arise from the text of the AIM Act. EPA also proposed to adopt existing definitions as written in 40 CFR part 82, subpart A, with modifications as needed to conform to differences in the AIM Act. EPA proposed this approach because these definitions are commonly understood by those familiar with the ODS phaseout experience.

Many proposed definitions did not garner specific comment. EPA is finalizing them as proposed and further discussion of those terms can be found in the proposed rule. These terms are: Central Data Exchange, Consumption allowances, Destruction, Exporter, Facility, Foreign country, Importer, Individual shipment, Non-objection notice, Person, Production allowances, Production line, Transform, and Used regulated substances.

The remainder of this section discusses comments received on the remaining proposed definitions.

Allowance. The AIM Act defines allowance as a limited authorization for the production or consumption of a regulated substance established under subsection (e). EPA is adopting that definition and adding that an allowance allocated under this subsection does not constitute a property right as stated in subsection (e)(2)(D)(ii)(aa). The framework for issuing allowances is subject to change through notice and comment rulemaking.

One commenter stated that the discretion to retire, revoke, or withhold allowances should not be within the definitions of allowance or application-specific allowance. EPA is removing this text from the regulatory definitions of allowance and application-specific allowance in this final rulemaking. While the Agency has the authority to adjust allowances and is finalizing regulatory text outlining the circumstances in which such adjustments may occur and a process for levying administrative consequences, reiterating a statement of that authority in the definitions is unnecessary.

Bulk. EPA is defining this term as ''a regulated substance of any amount that is in a container for the transportation or storage of that substance such as cylinders, drums, ISO tanks, and small cans. A regulated substance that must first be transferred from a container to another container, vessel, or piece of equipment in order to realize its intended use is a bulk substance. A regulated substance contained in a manufactured product such as an appliance, an aerosol can, or a foam is not a bulk substance.'' The examples provided in the definition are not exclusive. This definition serves to distinguish between a regulated substance that is in a container from a regulated substance that is in a product or other type of use system. Imported equipment and products that contain HFCs are outside the scope of the allowance-based phasedown component of the AIM Act.

One commenter requested that EPA clarify that the reference to small cans in the proposed definition does not include consumer products such as air conditioning recharge kits, drain cleaners, and other products that contain HFCs. The commenter expressed concern that requiring tracking of such products would impose significant regulatory burdens and costs. EPA responds that small cans of HFCs qualify as containers of bulk HFCs under this rule and the HFC allowance allocation program it establishes if the HFC must first be transferred from the small can to a piece of equipment in order to realize its intended use. Air conditioning recharge kits are small cans of refrigerant used to recharge motor vehicle air conditioners and would therefore qualify as a container of bulk HFC. Their size and intended

customer do not change the fact that they are containers and not products for purposes of this program, notwithstanding the commenter's concern, which EPA acknowledges, that tracking such products could be burdensome. The fact that some HFCs are housed in small containers does not remove them from the total inventory of HFCs for which EPA must account in implementing the phasedown mandate prescribed in the AIM Act. Thus, under the structure being finalized in this rule, allowances will be needed to import these air conditioning recharge kits. Similarly, those that have provided data on historical imports of small cans of refrigerant are eligible to receive an allowance allocation from the Agency under the framework finalized here. Entities that have not reported previously have options to receive allowances under the set-aside discussed in section VII.E. Without more information on drain cleaners, EPA cannot confirm whether this would be a container of bulk HFCs. If it can realize its intended use (*e.g.,* cleaning drains) without the need to transfer HFCs from a container to a piece of equipment, it would likely not be a bulk container.

One commenter argued that cylinders containing HFCs that are used in total flooding fire suppression systems are not bulk containers and so import of these cylinders would be considered as a ''product containing'' HFCs under the proposed rule. EPA disagrees. System cylinders are pressurized cylinders that contain a chemical (in this case an HFC), and therefore resemble other bulk chemicals. Regardless of its intended use, it is an HFC in a container that needs to be transferred to a piece of equipment to realize its intended purpose (*i.e.,* the extinguishant is incorporated into the total flooding system from these containers). Consistent with regulations under CAA title VI, EPA has treated pressurized system cylinders used in total flooding fire suppression systems differently than handheld, wheeled, and other fire suppression systems. The latter are self-contained, ready-to-use systems that can realize their intended use without transfer of the HFCs to another product or container. Fire suppression system cylinders must be connected to the rest of the fire suppression system to realize their intended use. EPA has previously considered whether system cylinders in total flooding applications were covered by the Nonessential Products Ban under section 610 of the CAA. The Agency stated: ''EPA recognizes that total flooding agents contained in total fire suppression systems used to extinguish fires are different from a portable device used to extinguish fires.'' The Agency went on to explain: ''These total flooding systems differ from an aerosol product or pressurized dispenser in that total flooding systems are 'systems' that are completely installed and can be triggered to be automatically activated during an emergency situation. The extinguishant is incorporated into the system from bulk containers. Accordingly, ''such systems thus do not constitute a pressurized dispenser or aerosol product within the meaning of section 610. Portable fire extinguishers, on the other hand, do constitute a pressurized dispenser, as they provide the product and dispensing apparatus in a self-contained portable unit.'' (58 FR 69647, December 30, 1993)

Additionally, under the class I ODS phaseout regulations in 40 CFR part 82, subpart A, fire suppression system cylinders are treated as a bulk substance. Companies that import used halons must petition the Agency prior to import under 40 CFR 82.13, with the exception of halon aircraft bottles, and report these imports to EPA. Given fire suppression system cylinders using HFCs have the same function as those for ODS, EPA concludes that it is reasonable to treat system cylinders of HFCs as bulk substances under this rule and the HFC allowance allocation program it establishes. The fact that some HFCs are housed in fire suppression system cylinders does not remove them from the total inventory of HFCs for which EPA must account in implementing the phasedown mandate prescribed in the AIM Act.

Chemical vapor deposition chamber cleaning. EPA proposed to define this term as ''in the context of semiconductor manufacturing, a process type in which chambers used for depositing thin films are cleaned periodically using plasma-generated fluorine atoms and other reactive fluorine-containing fragments.'' This definition is based closely on the source category definition for electronics manufacturing in the GHGRP (40 CFR 98.90(a)(2)).

Some commenters suggested that EPA use the GHGRP term and definition for ''chamber cleaning'' from 40 CFR 98.98 for consistency with reporting under that program. EPA is defining ''chemical vapor deposition chamber cleaning'' in this rule because Congress provided that EPA allocate allowances necessary for ''the etching of semiconductor material or wafers and the *cleaning of chemical vapor deposition chambers* within the semiconductor manufacturing sector'' (emphasis added) in subsection (e)(4)(B)(iv). This is narrower than the term defined under GHGRP, which is ''chamber cleaning.'' The term ''chamber cleaning'' under the GHGRP is broader and contains more process types than chemical vapor deposition. EPA is not aligning the term with the term defined under GHGRP given the specific language of the AIM Act. EPA is, however, broadening the description of the process type to explicitly include chamber cleaning by thermally dissociated fluorine fragments.

Confer. EPA is defining this term as ''to shift unexpended application-specific allowances obtained in accordance with subsection (e)(4)(B)(iv) of the AIM Act from the end user allocated such allowances to one or more entities in the supply chain for the production or import of a regulated substance for use by the end user.'' This term is intended to distinguish conferring an allowance from an allowance transfer. A company receiving conferred allowances may produce or import HFCs with those application-specific allowances on behalf of the conferrer rather than expending calendar year production or consumption allowances. There is no offset for the conferring of allowances.

A few commenters stated that there may be more than one entity in the supply chain between the producer/importer and the application-specific end user, such as a purifier. In that instance, a commenter wanted EPA to allow for the re-conferral of application-specific allowances without the transaction being considered a transfer. EPA understands that the supply chains may be unique to each particular end use and is clarifying that application-specific allowances may be re-conferred as needed. EPA has amended the definition of ''confer'' finalized in this rulemaking to state that application-specific allowances may be conferred one or multiple times to entities in the supply chain. EPA is also amending the recordkeeping and reporting provisions to ensure that all entities in the conferral chain are identified.

Consumption. With respect to the definition of ''consumption,'' commenters stated that the statutory definition of consumption in the AIM Act includes ''all imports'' and does not distinguish between imports of chemicals in large quantities for later use in a product manufactured in the United States and imports of the same chemical already contained in such a product manufactured abroad. The commenters disagreed with EPA excluding HFCs contained in imported products from the calculation of consumption, thereby excluding

imported products containing HFCs from the calculation of the baseline and from the requirement to obtain and expend allowances.

EPA responds that the Agency is finalizing its proposed reading of the definition of consumption, and in this context, the adopted reference of the term ''import,'' as being limited to bulk substances. In doing so, EPA is drawing a distinction between the import of bulk regulated substances and the import of regulated substances contained in products, and concludes, as explained below, that the definition of ''consumption'' is appropriately read to be limited to import of bulk substances.[32] The effect of this decision is that consumption allowances are required for the import of bulk HFCs and not for the import of products containing HFCs. As explained here and in section VI.A, the definition of ''consumption'' in the AIM Act is ambiguous and does not speak directly to whether imported products containing HFCs be included in the consumption baseline or subject to the allowance obligation. EPA further concludes that the AIM Act's definition of ''consumption'' is reasonably interpreted *not* to encompass imports of products containing HFCs, because doing so: (1) Is consistent with EPA's longstanding practice under the closely related provisions of title VI of the CAA; and (2) would create severe implementation difficulties, requiring EPA to obtain decades-old baseline data that almost certainly no longer exist, vastly expanding the number of regulated entities, and sweeping in a range of businesses (such as retailers) that likely did not anticipate being subject to these regulations.

EPA's resolution of this interpretive issue begins with the text of the statute. The AIM Act does not directly address whether products containing HFCs that are imported to the country should be included in the Agency's consideration of ''consumption.'' In subsection (b)(3), Congress defined ''consumption'' to include ''the quantity of regulated substance imported into the United States,'' but did not direct EPA as to how to determine such ''quantity.'' Congress particularly did not direct EPA as to whether this includes the import of products that contain regulated substances versus the import of regulated substances themselves. Because the statute does not address this, the Agency is left to interpret the statute in a reasonable manner. Because this instance ''involves an administrative agency's construction of a statute that it administers, [the] analysis is governed by *Chevron.*'' *Food & Drug Admin.* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132 (2000). Under the *Chevron* framework, the initial inquiry is ''whether Congress has directly spoken to the precise question at issue.'' *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U.S. 837, 842 (1984). ''In determining whether Congress has specifically addressed the question at issue, [the analysis] should not [be confined] to examining a particular statutory provision in isolation. The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context.'' *FDA,* 529 U.S. at 133. Here, there is no statutory text in the AIM Act—and the commenter was not able to provide any citation to such text—that unambiguously requires EPA to consider imports of products containing regulated substances in the calculation of ''consumption,'' in addition to considering the imports of bulk regulated substances.

While EPA understands that the phrase ''quantity of the regulated substances into the United States'' could be read to include regulated substances contained in products imported into the United States, that is not the only permissible reading. Rather, this language can also reasonably be read to include only imported bulk substances. To inform the Agency's analysis of whether Congress has directly spoken to the precise question at issue, the Agency has looked to the definition of ''consumption'' under title VI of the CAA. The title VI statutory definition of ''consumption'' is analogous to the parallel definition in the AIM Act, and thus EPA looked to the title VI definition on the question of whether the AIM Act statutory language is unambiguous. The AIM Act language is substantially similar to the definition of ''consumption'' provided by Congress for the phaseout of ODS in section 601(1) of the CAA, which defines the term ''consumption'' to include ''the amount'' of ODS ''imported,'' but additionally states that ''[s]uch term shall be construed in a manner consistent with the Montreal Protocol.'' This demonstrates that Congress understood, in the context of the CAA, that the term ''consumption,'' including the embedded phrase ''the amount imported,'' could reasonably be read in different ways. Under the Montreal Protocol, calculation of a country's consumption is limited to bulk substances and does not include imports of products containing ODS. Consistent with that practice, EPA has applied the ODS production and consumption controls under title VI of the CAA to bulk ODS, but not to products containing ODS. The term ''the amount'' in the CAA is substantially similar to ''the quantity'' in the parallel definition of the AIM Act, which demonstrates that the AIM Act provision can be interpreted in multiple ways, so Congress did not speak directly to the question of whether ''consumption'' under the AIM Act should include imports of products containing regulated substances. As further explained elsewhere in this preamble, EPA is reasonably interpreting the AIM Act to have a similar scope and meaning as title VI. *Lawson* v. *FMR LLC,* 571 U.S. 429, 459 (2014) (''[P]arallel text and purposes counsel in favor of interpreting . . . two provisions consistently.'').

In addition, looking to the larger statutory context, in defining ''consumption'' in subsection (a)(3) of the AIM Act, Congress used the phrase ''the quantity of'' the regulated substance not only to refer to the quantity of the regulated substance imported into the United States, but also to refer to the quantity of the regulated substance produced in the United States, as well as the quantity exported from the United States. The ''quantity of'' the regulated substance produced in the United States is readily understood to include bulk substances, particularly in light of the statutory definition of ''produce,'' but it would be difficult to interpret this phrase to extend to products containing HFCs. Such products could include either domestic or imported HFCs. Interpreting the phrase ''the quantity of'' a regulated substance to include only bulk substances reasonably applies the same understanding of this term across all the instances where it is used in the definition of consumption. These points further support EPA's views that ''the quantity'' as used in the AIM Act is open to more than one possible construction and that it can reasonably be read to be limited to bulk substances. Since the definition of ''consumption'' in the AIM Act can be read in different ways, this issue is not decided under the first step of the *Chevron* analysis.

[32] As discussed earlier in this definitions section, EPA is defining a bulk substance as ''a regulated substance of any amount that is in a container for the transportation or storage of that substance such as cylinders, drums, ISO tanks, and small cans. A regulated substance that must first be transferred from a container to another container, vessel, or piece of equipment in order to realize its intended use is a bulk substance. A regulated substance contained in a manufactured product such as an appliance, an aerosol can, or a foam is not a bulk substance.''

Since the AIM Act does not provide unambiguous direction as to whether imported products containing HFCs should be considered part of ''consumption,'' EPA is given discretion to interpret the statute, as long as such construction is reasonable, under the second step of the *Chevron* analysis. Where Congress has not directly spoken to an issue or has left ambiguity in the statute, that silence or ambiguity creates an assumption that ''Congress implicitly delegated to the agency the power to make policy choices that represent a reasonable accommodation of conflicting policies that are committed to the agency's care by the statute.'' *National Ass'n of Mfrs.* v. *United States DOI,* 134 F.3d 1095, 1106 (D.C. Cir. 1998). The ''power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.'' *Chevron,* 467 U.S. at 843–44. The Supreme Court has explained ''[w]e accord deference to agencies under *Chevron* . . . because of a presumption that Congress, when it left ambiguity in a statute meant for implementation by an agency, understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows.'' *Smiley* v. *Citibank (S.D.), N.A.,* 517 U.S. 735, 740–41 (1996). Accordingly, Congress's silence with regard to whether imports of products containing HFCs should be considered in the determination of ''consumption'' leaves a gap for the Agency to fill, which EPA is doing in this rulemaking.

Excluding imports of products containing HFCs from the definition of ''consumption'' is consistent with EPA's longstanding practice in implementing nearly identical statutory language governing a nearly identical industry under title VI of the CAA. As further explained in Section II.B, there are significant similarities in the text, structure, function, and purpose of the provisions for production and consumption in the AIM Act and those in title VI of the CAA. Accordingly, EPA is utilizing its experience interpreting similar statutory terms under the CAA to phase out ODS when developing the AIM Act's HFC allowance allocation and trading program.[33] Moreover, the close similarities in text, structure, function, and purpose between title VI and the AIM Act make it reasonable to infer that Congress was aware of EPA's approach of applying the ODS production and consumption controls under title VI to bulk substances but not products, including imported products, and did not intend to require EPA to depart from that approach under the AIM Act. *See FPC* v. *Sierra Pacific Power,* 350 U.S. 348 (1956) (determining that an interpretation of the Natural Gas Act was ''equally applicable'' to the Federal Power Act given that ''the provisions of the Federal Power Act relevant to [the] question are in all material respects substantially identical to the equivalent provisions in the Natural Gas Act.''). *See also Arkansas Louisiana Gas Co.* v. *Hall,* 435 U.S. 571 (1981) (citing to *FPC* v. *Sierra Pacific Power* for a similar premise); *NTEU* v. *Chertoff,* 452 F.3d 839, 857 (D.C. Cir. 2006) (''There is a presumption that Congress uses the same term consistently in different statutes.''); *Smith* v. *City of Jackson, Miss.,* 544 U.S. 228, 233 (2005) (emphasizing the ''premise that when Congress uses the same language in two statutes having similar purposes, . . . it is appropriate to presume that Congress intended that text to have the same meaning in both statutes'').

In addition to these considerations, including imports of products containing HFCs in the calculation of consumption, and thereby including them in the regulatory allocation and phasedown program, would significantly increase the universe of regulated entities and reporters subject to this program. New categories of affected industries would include large-scale retailers that directly import products such as air conditioning units, refrigerators, fire extinguishers, and consumer aerosol products. These entities have never been subject to allowance obligations under title VI, and EPA finds it reasonable to infer that Congress did not expect or intend to place allowance obligations on this vast array of entities under the closely related provisions of the AIM Act. Courts have previously supported statutory interpretations that enable sensible regulations as opposed to readings that ''would radically transform those programs and render them unworkable as written.'' *Utility Air Regulatory Group* v. *EPA,* 134 S. Ct. 2427, 2442 (2014) (holding that EPA was not compelled to interpret the Clean Air Act's reference to ''any air pollutant'' as requiring the Agency to consider greenhouse gases in determining whether a source was major for purposes of new source review and CAA Title V permitting).

Further, it would be administratively impossible for EPA to gather data necessary to incorporate imports of products containing HFCs into the statutorily defined calculation of the baseline to a degree that matches the surety and caliber of data otherwise included in that calculation. Congress directed EPA to add figures for consumption of HCFCs and CFCs in 1989 in calculating baselines. If EPA were to read such a reference to ''consumption'' as encompassing imports of products containing chemicals, the Agency would need data on imports of products containing HCFCs and CFCs back in 1989. We are not aware of any source of this information, and it seems impossible that a comprehensive set of businesses would have actual data from that time period that EPA could obtain. One commenter noted that EPA could rely on estimates or modeled data from that time period and provided trade data for certain types of products that were imported in 1989, but such imprecise calculations would not match the certainty of data on which EPA is currently relying to calculate the baseline. In light of these challenges, the ambiguity of the statutory text, and the close similarities in the term ''consumption'' as used in title VI and the AIM Act, EPA concludes that it is reasonable to interpret the statutory term ''consumption,'' and the adopted reference of the term ''import,'' as including only bulk substances.

Defense spray. EPA is defining this term as ''an aerosol-based spray used for self-defense, including pepper spray and animal sprays, and containing the irritant capsaicin and related capsaicinoids (derived from oleoresin capsicum), an emulsifier, and an aerosol propellant.'' Two commenters stated their support of the proposed definition for defense spray. EPA is finalizing the definition as proposed.

Etching. EPA proposed to define etching as, ''in the context of semiconductor manufacturing, a process type that uses plasma-generated fluorine atoms and other reactive fluorine-containing fragments that chemically react with exposed thin-films (*e.g.,* dielectric, metals) or substrate (*e.g.,*

[33] For purposes of implementing the ODS phaseout regulations (40 CFR part 82, subpart A), EPA defined a controlled substance, in part, as any listed ODS, whether existing alone or in a mixture, but excluding any such substance or mixture that is in a manufactured product other than a container used for the transportation or storage of the substance or mixture. Any amount of a listed substance that is not part of a use system containing the substance is a controlled substance. If a listed substance or mixture must first be transferred from a bulk container to another container, vessel, or piece of equipment in order to realize its intended use, the listed substance or mixture is a ''controlled substance.''

silicon) to selectively remove portions of material. This includes production processes using fluorinated GHG reagents to clean wafers.'' This definition is closely based on the definition of the electronics manufacturing source category in the GHGRP (40 CFR 98.90(a)(1)) and on the GHGRP definition of ''wafer cleaning'' (40 CFR 98.98).

Some commenters suggested that EPA expand the definition of ''etching'' to include ''wafer cleaning.'' EPA agrees that it is appropriate to include ''wafer cleaning'' in the definition of ''etching'' and is doing so in the final rule. Wafer cleaning involves using fluorinated GHG reagents to remove residual material from wafers, and other etching processes involve using fluorinated GHG reagents to remove materials from a substrate, which includes wafers. Under the GHGRP, the same emission factors are used for wafer cleaning as for other etching processes. Commenters also recommended that EPA use the GHGRP definition of ''etching'' at 40 CFR 98.98 for consistency with the GHGRP. In the final rule, we are retaining the language from the description of etching in the GHGRP source category definition for electronics at 40 CFR 98.90. This language is briefer and more comprehensive than the definition of ''etching'' at 98.98, which includes potentially limiting language. Another commenter said that EPA should clarify that ''etching'' includes the use of HFCs as heat transfer fluids in chillers used ''to control the temperature during the etching process.'' EPA responds that the Agency interprets the AIM Act's language on the ''exclusive use of the regulated substance solely for . . . the etching of semiconductor material or wafers . . .'' to not include processes adjacent to or in support of the application itself. Therefore, EPA is not accepting this proposed addition to the term.

Exchange value. The AIM Act defines ''exchange value'' as the value assigned to a regulated substance in accordance with subsections (c) and (e), as applicable. Subsection (c) includes a list of regulated substances with listed exchange values. Subsection (e) includes a list of ODS with listed exchange values. EPA is adopting the definition contained in the AIM Act, including the tables, which EPA is replicating in Appendix A of 40 CFR part 84.

Exchange value equivalent. EPA uses the term ''exchange value equivalent'' or ''EVe'' to provide a common unit of measure between HFCs. EVe is determined by multiplying the mass of a regulated substance by the exchange value of that substance. For example, 50 kilograms of HFC-134a would be 71,500 kgEVe (50 × 1,430). This can also be written as 71.5 metric tons exchange value equivalent (MTEVe). As explained further in Section VII.A on allowances, EPA is issuing allowances in units of 0.1 MTEVe. EPA is also using the term ''EV-weighted'' to describe a number presented in exchange value equivalents. For example, the size of an allowance is one EV-weighted ton.

EVe allows for the comparison between different regulated substances. For example, a blend containing multiple regulated substances would have an EVe that could be used to determine the quantity of allowances needed to produce or consume the regulated HFCs that are components of the blend. However, the EVe would only reflect the components of the blend that are regulated substances under the AIM Act. In situations where the blend contains components that are not regulated substances (*e.g.,* HFOs), the EVe would not match the GWP of the blend and would be slightly lower. This would be the case for blends R-448A,[34] R-449A, and R-450A, which contain a mix of HFCs and HFOs.

One commenter agreed with EPA's proposed definition of ''exchange value equivalent'' and the calculation of EVe for blends. The commenter stated that the term correctly incentivizes the use of low-GWP components.

Export. EPA is finalizing its proposed definition for export and is clarifying that under this definition, HFCs admitted into a foreign-trade zone or other duty deferral program under CBP regulations are not exported for purposes of Part 84 regulations.

Final customer. EPA proposed to define this term as ''the last person to purchase a bulk regulated substance before its intended use.'' For each use of HFCs, the final customer can be different. For example, an air conditioning contractor would generally be the final customer in the residential air conditioning market. For foams, the foam systems house would be the final customer, as they are making a product (*i.e.,* a foam system). Likewise, aerosol fillers, semiconductor manufacturers, air conditioning and refrigeration equipment manufacturers that ship equipment pre-charged, and fire extinguisher manufacturers would be final customers. EPA requested comment on whether a list of examples like this should be incorporated into the definition and the Agency received comments in support of doing so. EPA is finalizing the definition with a list of example final customers to provide clarity. The examples provided in the definition are not exhaustive.

Commenters also requested additional detail on who the final customer would be in particular circumstances. Commenters were primarily concerned with the burden associated with the certification ID tracking system and sought to reduce uncertainty about who would be subject to those requirements. EPA responds to this comment in Section IX.G of this preamble.

Import. EPA is adopting the definition of the term ''import'' contained in subsection (b) of the AIM Act, which is nearly identical to the definition of ''import'' in 40 CFR part 82, and adding one of the three exemptions from the part 82 definition as proposed. EPA is also clarifying that under this definition, whether HFCs are admitted into or exiting a foreign-trade zone or other duty deferral program under CBP regulations does not affect whether the HFCs are being imported for purposes of Part 84. The AIM Act defines import as to land on, bring into, or introduce into, or attempt to land on, bring into, or introduce into, any place subject to the jurisdiction of the United States, regardless of whether that landing, bringing, or introduction constitutes an importation within the meaning of the customs laws of the United States.

EPA is including an exemption for the offloading of used regulated substances from a ship during servicing in a U.S. port. The Agency does not consider material recovered from equipment onboard a vessel to be an import as it is analogous to material that has been recovered from air conditioning and refrigeration equipment during servicing, maintenance, repair, and disposal on that vessel. The exemption is limited to HFCs that are in an appliance or other piece of equipment (*e.g.,* for fire suppression) as it moves across international borders. This exemption recognizes that sometimes onboard equipment needs to be serviced and used refrigerant offloaded. As noted in the proposal, treating this as an import would create a perverse incentive to improperly manage

[34] Many blends contain HFCs and non-regulated substances such as HFOs. For example, R-448A is made of five components, three of which are HFCs regulated under the AIM Act and two of which are HFOs. The percentage of the blend and the exchange value of the constituents are: 26 percent HFC-32 (675), 26 percent HFC-125 (3,500), 21 percent HFC-134a (1,430), 20 percent HFO-1234yf (0), and 7 percent HFO-1234ze (0). The contribution of each HFC to the total EVe of the blend is calculated by multiplying the percentage of the blend made up of that HFC times its EVe, and the sum of the contributions of all the blend constituents is the blend EVe. Thus, the EVe of R-448A is (0.26 × 675) + (0.26 × 3,500) + (0.21 × 1,430) + (0.20 × 0) + (0.07 × 0) = 1,385.8.

regulated substances. EPA has taken a similar approach under CAA title VI. Given such material is used, further sales or offer for sale of this offloaded material for any purpose other than reclamation, recycling for reuse onboard the vessel, recycling of fire suppression agents, or destruction is prohibited. This limited exemption only applies to used HFCs that were recovered during servicing from equipment in use on the vessel. It does not apply to containers of virgin HFCs. This situation is different from an import of used regulated substances that is transported over the border, because it would not otherwise be traveling across the border without the intent to import into the United States. To ensure the integrity of the allowance allocation and trading program, the marine vessel, aircraft, or other aerospace vehicle must maintain records documenting the company name, location of the appliance, date of recovery, person doing the recovery, and the amount of HFC recovered and type of refrigerant recovered for each servicing event.

One commenter recommended that EPA broaden the exemption for the offloading of used material to aircraft and space vehicles since the global nature of maritime vessels is similar to aerospace vehicles. EPA agrees that servicing of aircraft and other aerospace vehicles that arrive in the United States from another country is similar to the servicing of marine vessels. Therefore, EPA is clarifying in the definition that offloading used regulated substances recovered from equipment onboard a marine vessel, aircraft, or other aerospace vehicle during servicing in the United States is not considered an import.

EPA notes that overseas U.S. government locations, including on vessels, in military units, and at fixed facilities (*e.g.,* military bases, embassies, or consulates) often require a supply of HFCs in support of equipment, for example in air-conditioning, refrigeration, and fire suppression. Some of these HFCs are routinely returned to the United States and these returns by federal entities are not classified as ''imports'' under current customs laws and regulations. EPA had not considered the return of federally owned ODS to the United States to be an import under CAA title VI and is maintaining that interpretation for purposes of the HFC allowance allocation and trading program. Examples of situations that would not qualify as imports include:

- U.S. naval vessels routinely carry spare HFC refrigerant and fire suppressant cylinders for potential servicing and replenishment requirements while deployed. If the HFCs in these cylinders are not used while the vessel is underway, the vessel may return to the United States and off-load the cylinders.
- U.S. Armed Forces units deploying to overseas locations often transport HFCs in cylinders to service their military equipment and upon return from deployment will bring any remaining HFCs back to the United States with them.
- U.S. Government fixed facilities overseas have refrigerants removed and recovered during equipment servicing or when the equipment is replaced or retired from service. Since this refrigerant may be excess or may need to be reclaimed prior to reuse in other equipment, the recovered refrigerants may be shipped back to the United States for reclamation or disposal if the host nation does not have refrigerant reclamation or disposal capabilities.

Metered dose inhaler. EPA is defining an MDI as ''a handheld pressurized inhalation system that delivers small, precisely measured therapeutic doses of medication directly to the airways of a patient. MDIs treat health conditions such as asthma and chronic obstructive pulmonary disease and are approved for such use by the United States Food and Drug Administration (FDA).'' This definition is substantially similar to the definition of ''essential metered dose inhaler'' in 40 CFR part 82.

Commenters generally agreed with this definition. One commenter recommended that the definition should be expanded beyond the treatment of asthma and chronic obstructive pulmonary disease (COPD) to include other conditions. EPA responds that the definition as proposed encompasses other uses of MDIs so long as they are approved by the FDA. While asthma and COPD may be the two most common conditions treated by MDIs, the list is not exclusive, as indicated by the words ''such as.'' EPA is therefore finalizing the definition as proposed. We have updated the market characterization to include other conditions treated by MDIs.

Mission-critical military end uses. EPA proposed to define this term as ''those uses of regulated substances by an agency of the Federal Government responsible for national defense which have a direct impact on mission capability, as determined by the U.S. Department of Defense (DOD), including, but not limited to uses necessary for development, testing, production, training, operation, and maintenance of Armed Forces vessels, aircraft, space systems, ground vehicles, amphibious vehicles, deployable/expeditionary support equipment, munitions, and command and control systems.''

Commenters suggested that the definition is too narrow or ambiguous and excludes uses of regulated substances by non-DOD federal entities that are involved in national defense or security, and local, state, and foreign governments. Commenters also requested that EPA ensure the definition covers use of HFCs in equipment approved by the United States Government for either Foreign Military Sales or Direct Commercial Sales. Commenters asked for clarification that uses by federal defense contractors, including those used within the manufacture of mission-critical products, are covered.

EPA is not expanding the definition of ''mission-critical *military* end uses'' (emphasis added) to cover non-military applications. Expanding the definition to cover non-military applications, even if related to national defense or security, would not be consistent with the statute. The definition directs the DOD to determine what end uses are mission-critical; it is not appropriate to provide that authority to state, local, or foreign governments. EPA is also not amending its proposed definition to include Foreign Military Sales and Direct Commercial Sales. Under Foreign Military Sales, the United States Government manages new sales of defense equipment to foreign allies and partners. Under Direct Commercial Sales, the U.S. Department of State provides regulatory approvals for sales negotiated privately between foreign end users and American companies. DOD is involved in reviewing both types of sales. Such sales could already be covered under the proposed definition as they are included in the ''production . . . of Armed Forces vessels . . .'' DOD must determine such sales to be mission-critical.

Onboard aerospace fire suppression. EPA is finalizing a definition of this term as ''use of a regulated substance in fire suppression equipment used onboard commercial and general aviation aircraft, including commercial-derivative aircraft for military use; rotorcraft; and space vehicles,'' which differs in some respects from the proposed definition based on EPA's consideration of public comments. EPA is also finalizing a separate definition for space vehicles consistent with the definition in 40 CFR 82.3. EPA requested comment on whether the definition of onboard aerospace fire suppression should include general aviation, which consists of private and/

or business aircraft, which may not have the same requirements as commercial aircraft for onboard aerospace fire suppression systems. The proposed definition excluded military aircraft because they are covered under the definition of mission-critical military end uses.

Commenters from the onboard aerospace fire suppression sector requested that EPA provide flexibility in the use of application-specific allowances within the aerospace and defense sectors or revise the definition for onboard aerospace fire suppression to allow the use of HFCs for military onboard aerospace fire suppression so that fire suppression systems are not limited to commercial aircraft applications, as opposed to aircraft used for military, recreational, or test purposes. Specifically, one commenter stated that there is not a clear distinction between commercial use and military use of HFCs for onboard aerospace fire suppression equipment. The commenter explained that in some cases, aircraft intended for sale to military customers are built using commercial aircraft designs that are modified for military use, and in other cases, the aircraft is built to commercial specifications and then modified for military use (''commercial derivatives''). Another commenter recommended that EPA allow for the use of HFCs for military onboard aerospace fire suppression under this application due to uncertainties involved in the mission-critical military end use application. EPA is modifying the definition to include commercial derivatives for military use and rotorcraft.

As noted in the proposal, EPA has previously defined ''space vehicle'' under title VI regulations at 40 CFR 82.3 as a man-made device, either manned or unmanned, designed for operation beyond Earth's atmosphere. This definition includes integral equipment such as models, mock-ups, prototypes, molds, jigs, tooling, hardware jackets, and test coupons. Also included is auxiliary equipment associated with test, transport, and storage, which through contamination can compromise the space vehicle performance. EPA requested comment on whether ''space vehicle,'' as defined in 82.3, is inclusive of applications that would be considered as onboard aerospace fire suppression.

A comment regarding the definition of ''space vehicle'' asked that it explicitly cross-reference the part 82 definition and extended to include aircraft in addition to space vehicles. EPA has included a definition of ''space vehicle'' that is consistent with the definition in 40 CFR 82.3 for clarity. It appears that in asking the definition to be extended to include aircraft, the commenter is requesting that HFCs used for fire suppression systems in models, mock-ups, prototypes, etc. for any onboard aerospace application, including aircraft, also be included within the definition of onboard aerospace fire suppression. EPA is not finalizing this suggestion. The Agency understands that there are a limited number of space vehicles and that the conditions they operate in are unique and include exposure to extreme heat and cold cycling, ultra-vacuum, atomic oxygen, and high-energy radiation. Given this set of factors does not apply to aircraft, it is appropriate to use a narrower definition for space vehicles that is consistent with the approach taken under the CAA.

Some commenters asked for the definition for onboard aerospace fire suppression to include aerospace applications of HFCs necessary to suppress the development of in-flight fires, and not solely fire extinguishing ''equipment'' and ''systems.'' A commenter provided an example of HFC solvents to clean or flush oxygen systems. The Agency does not view this as fire suppression but as a solvent use. The Agency will only consider HFC use in systems or equipment that are discharged to extinguish live fires, or in specialized applications for explosion suppression and inerting against explosions and fires. These are the technical definitions of what these systems and equipment are made to do.[35] An overly broad interpretation of ''onboard aerospace fire suppression'' would undercut the intent of the AIM Act.

Process agent. The AIM Act uses the term ''process agent'' without defining it. EPA is defining the term as ''the use of a regulated substance to form the environment for facilitating a chemical reaction or inhibiting an unintended chemical reaction (*e.g.,* use as a solvent, catalyst, or stabilizer) where the regulated substance is not consumed in the reaction, but is removed or recycled back into the process and where no more than trace quantities remain in the final product. A feedstock, in contrast, is consumed during the reaction.'' [36] This definition matches the definition used by the Montreal Protocol's Technology and Economic Assessment Panel (TEAP) and is well-established and understood in the ODS context.[37]

EPA received comments that the proposed definition of process agent is too narrow in that it is limited to processes involving chemical reactions. Commenters suggested that the definition be expanded to include physical processes. Commenters did not provide additional information to explain what the differences are between a chemical reaction and a physical process, nor did they explain what specific actions may be excluded by using the proposed definition. EPA has been unable to find physical processes discussed in TEAP documents related to process agents; however, the Agency has found discussion of process agents inhibiting an unintended chemical reaction. This fits within the proposed definition that process agents are used to ''form the environment'' where the process occurs. EPA is finalizing the definition with the additional description of inhibiting unintended chemical reactions but is not including reference to physical processes, as the Agency does not have sufficient information supporting a change.

Production/Produce. EPA is adopting the definition of the term ''produce'' that is found in subsection (b) of the AIM Act. While substantially similar to the definition of the term ''production'' at 40 CFR 82.3, there are a few differences. First, the AIM Act definition does not use the word ''transformed'' but rather textually incorporates most of the definition of the defined term ''transform'' from § 82.3. Second, the definition specifically excludes the reclamation of a regulated substance from the term production. This exclusion was not found in § 82.3 but matches EPA's long-held interpretation in CAA title VI programs that reclamation does not constitute production and that reclaimed material is inherently reused/recycled.

EPA proposed that the definition of production specifically exclude ''the inadvertent or coincidental creation of insignificant quantities of a regulated

[35] Robert T. Wickham. ''Status of Industry Efforts to Replace Halon Fire Extinguishing Agents,'' March 2002. Available at *https://www.epa.gov/sites/default/files/2015-07/documents/status.pdf.*

[36] The term ''consume'' in the AIM Act has two separate meanings. In the context of describing transformation/feedstock uses of HFCs, the word ''consume'' is used to mean the decomposition of the substance. For example, subsection (b)(7)(B) excludes from the definition of ''produce'' ''the manufacture of a regulated substance that is used and entirely *consumed* (except for trace quantities) in the manufacture of another chemical.'' (emphasis added).

[37] Montreal Protocol on Substances that Deplete the Ozone Layer, *Medical and Chemical Technical Options Committee 2018 Assessment Report.* United Nations Environment Programme, 2018. Available at *https://ozone.unep.org/sites/default/files/2019-04/MCTOC-Assessment-Report-2018.pdf.*

substance during a chemical manufacturing process, resulting from unreacted feedstock, from the listed substance's use as a process agent present as a trace quantity in the chemical substance being manufactured, or as an unintended byproduct of research and development applications.'' This phrase appears in the 40 CFR 82.3 definition of ''controlled substance.'' The exclusion of these four types of insignificant quantities is more properly considered in defining what qualifies as production, given they describe acts of ''creation'' or ''resulting from'' or ''byproduct of.'' Such insignificant quantities created in the above-listed circumstances are considered regulated substances, but are not considered production. Combining all of the exclusions under one term increases clarity when interpreting the terms ''produce'' and ''regulated substance'' together.

Based on public comments received, EPA is finalizing an addition to the listed circumstances addressed by the exclusion, specifically clarifying that it covers the inadvertent or coincidental creation of insignificant quantities of a regulated substance ''during semiconductor manufacturing processes.'' EPA estimates that 6 to 9 metric tons of HFC-23 were generated as a byproduct per year from 2017 to 2019 across all semiconductor manufacturing facilities that reported to the GHGRP. Semiconductor manufacturers reporting to the GHGRP are estimated to have accounted for 98 percent of HFC-23 generating activity (*i.e.,* layer-weighted area of semiconductors produced) by semiconductor manufacturers in the United States in 2017.[38] Total byproduct generation of HFC-23 from 2017 to 2019 was calculated by first estimating consumption of HFC-23 based on reported emissions of HFC-23 to the GHGRP, reported emissions of other fluorinated greenhouse gases, the emission factors used, and the reported fab-wide destruction or removal efficiencies. Byproduct generation was then estimated by using the ratio of byproduct emissions to total calculated uncontrolled emissions of HFC-23. The resulting estimates showed a decline between 2017 and 2019. Byproduct generation of HFC-23 from individual fabrication plants was estimated to average approximately 140 kg per plant, with no fabrication plant generating more than 1.1 metric tons. Such a small amount falls under EPA's intended definition of ''insignificant quantities,'' and therefore EPA finds it reasonable to finalize a definition that includes text clarifying that such insignificant quantities are excluded from the definition of production.

In addition, EPA is finalizing a change to this regulatory text to clarify that each of the listed circumstances is an independent circumstance and if insignificant quantities are inadvertently or coincidentally created in any of these five circumstances, they are exempt from the definition of production. Specifically, EPA is finalizing the following text in the regulations: ''Insignificant quantities of a regulated substance inadvertently or coincidentally generated from any of the following, independent circumstances:'' before listing the five circumstances.

Reclaim. EPA is defining reclaim as ''the reprocessing of regulated substances to all of the specifications in Appendix A of 40 CFR part 82, subpart F [based on AHRI Standard 700–2016] that are applicable to that regulated substance and to verify that the regulated substance meets these specifications using the analytical methodology prescribed in section 5 of Appendix A of 40 CFR part 82, subpart F.'' The final definition is unchanged from the proposal.

Some commenters recommended that EPA establish in the definition of ''reclaim'' a limit on the amount of virgin refrigerant that could be included. Put another way, if a recovered refrigerant is blended with more than a certain threshold of virgin refrigerant to bring it to AHRI 700 standards, the resulting refrigerant would not meet the regulatory definition of reclaimed material. Commenters noted California's proposed requirement that reclaimed HFCs contain no greater than 15 percent new refrigerant by weight, and recommended that EPA adopt a similar benchmark in its definition of reclaim. EPA may consider establishing standards regarding the amount of virgin product permitted to be used in ''reclaimed'' material in the future, but this regulatory definition is not the appropriate place to address this issue. Given the early stage of AIM Act implementation and stakeholder engagement, EPA also does not have sufficient information at this time to make a reasoned decision on what benchmark to set, if any.

Regulated substance. The AIM Act uses the term ''regulated substance'' to refer to HFCs statutorily listed in the AIM Act and any such substance added to the list in the future consistent with subsection (c)(3)(A). EPA is defining the term as ''a hydrofluorocarbon listed in the table contained in subsection (c)(1) of the AIM Act and a substance included as a regulated substance by the Administrator under the authority granted in subsection (c)(3). A current list of regulated substances can be found in Appendix A of this part.'' The final definition is unchanged from the proposal.

One commenter suggested EPA clarify that only saturated HFCs can be added to the list of regulated substances through the procedure in subsection (c)(3). EPA declines to make this addition to the definition. Subsection (c)(3) contains multiple limitations on what can be designated as a regulated substance, including that the chemical is a saturated HFC and has a minimum exchange value. For purposes of clarity, EPA is keeping the definition of regulated substances distinct from the process and limitations for designating additional regulated substances.

Structural composite preformed polyurethane foam. EPA is defining this term as ''a foam blown from polyurethane that is reinforced with fibers and with polymer resin during the blowing process, and is preformed into the required shape (*e.g.,* specific boat or trailer design) to increase structural strength, while reducing the weight of such structures.'' The final definition is unchanged from the proposal.

One commenter suggested a modified definition, which would describe ''structural composite preformed polyurethane foam'' as ''a foam blown from polyurethane that is extruded or injected into reinforcing fiber fabric material to impart the fabric with dimensional shape to create preformed elements that are later assembled together, impregnated with resin and/or otherwise cured to form a composite structure (*e.g.,* specific boat or trailer design).'' The commenter explained that the modified definition more accurately and succinctly describes the structural composite preform technology for marine and trailer use. EPA is finalizing the definition as proposed to avoid creating an inadvertently restrictive definition and to keep the ideas of increased structural strength and weight reduction in the definition.

Transhipment. EPA proposed to define transhipment consistent with the definition in 40 CFR 82.3 for ODS. However, based on interagency consultation, EPA is revising its definition slightly by replacing the phrase ''interstate commerce'' with ''U.S. commerce.'' This minor alteration in terminology will align this

[38] World Fab Forecast (2017). Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990–2019. U.S. EPA 2021. Available at *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2017.*

requirement more closely with trade regulations administered by CBP and is a more accurate expression of EPA's intended meaning. The term ''transhipment'' is defined as the continuous shipment of a regulated substance, from a foreign country of origin through the United States or its territories, to a second foreign country of final destination, as long as the shipment does not enter U.S. commerce. A transhipment, as it moves through the United States or its territories, cannot be repackaged, sorted, or otherwise changed in condition.

EPA's use of this term is similar but not identical to an ''entry for transportation and exportation'' under 19 U.S.C. 1553 and 19 CFR 18.20 through 18.24, and a ''transportation entry'' under 19 CFR 18.1. CBP regulations expressly allow in-bond merchandise to be transferred from one conveyance to another—what the shipping industry typically calls ''transloading'' or a ''transshipment'' (see 19 CFR 18.3). CBP regulations also allow in-bond merchandise to be shipped in a conveyance that contains other merchandise that is not being shipped in-bond, so long as the in-bond merchandise is clearly identified (see 19 CFR 18.4(b)). However, EPA is not fully aligning with those practices for transhipments of HFCs. Under the definition finalized in this rule, a transhipment, as it moves through the United States or its territories, cannot be repackaged, sorted, or otherwise changed in condition. The full text of all definitions finalized in this rule can be found in 40 CFR 84.3.

VI. How is EPA establishing the HFC production and consumption baselines?

The first step in phasing down HFCs through an allowance allocation and trading program is to establish the U.S. production and consumption baselines. It is from these baselines that EPA determines the total amount of allowances. By applying the AIM Act's percentage-based phasedown, which EPA implements via the total annual production and consumption allocations, the Agency derives in a stepwise manner the amount of allowances available compared to the baseline over the period of time encompassed in the statutory phasedown schedule.

A. What are the components of the production and consumption baselines?

Subsection (e)(1) of the AIM Act directs EPA to establish a production baseline and a consumption baseline and provides the equations for doing so. The equations comprise an HFC component, an HCFC component, and a CFC component. Specifically, the production baseline is equal to the sum of: (i) The average annual quantity of all regulated substances produced in the United States from January 1, 2011, through December 31, 2013, and (ii) 15 percent of the production level of HCFCs in calendar year 1989, and (iii) 0.42 percent of the production level of CFCs in calendar year 1989. For the purposes of establishing the baselines, EPA must use the exchange values assigned by Congress to develop an exchange value-weighted amount for both production and consumption. The equation representing the production baseline calculation is:

Equation 1: Production Baseline

$$\text{Production Baseline} = 100\% \left[\frac{2011 + 2012 + 2013 \text{ HFC EV-weighted production level}}{3}\right] / \frac{2011 + 2012 + 2013 \text{ HFC EV-weighted production level}}{3} + 15\% \text{ [1989 HCFC EV-weighted production level]} + 0.42\% \text{ [1989 CFC EV-weighted production level]}$$

Similarly, the AIM Act defines the consumption baseline as equal to the sum of (i) the average annual quantity of the consumption [39] of regulated substances in the United States from January 1, 2011, through December 31, 2013, and (ii) 15 percent of the consumption of HCFCs in calendar year 1989, and (iii) 0.42 percent of the consumption of CFCs in calendar year 1989. The equation representing the consumption baseline calculation is below.

Equation 2: Consumption Baseline

$$\text{Consumption Baseline} = 100\% \left[\frac{2011+2012+2013 \text{ HFC EV-weighted consumption level}}{3}\right] + 15\% \text{ [1989 HCFC EV-weighted consumption level]} + 0.42\% \text{ [1989 CFC EV-weighted consumption level]}$$

EPA's proposal that the HFC consumption baseline consist of bulk HFCs and not include imports of HFCs contained in products garnered multiple comments, both opposed and in favor. Similarly, some commenters raised the

[39] Consumption is equal to production plus imports minus exports.

related issue of whether consumption allowances should be required to import HFCs contained in products. Some commenters pointed to the AIM Act's description of the consumption baseline in subsection (e)(1)(C), which states that it includes ''*all* regulated substances consumed in the United States'' (emphasis added) to include imports of HFCs contained in products in the baseline period. Commenters stated that the AIM Act does not distinguish between ''bulk'' HFCs and those contained in products but, rather, plainly states that all regulated substances are to be included.

As explained further in the definitions portion of this final notice, the AIM Act definition of ''consumption'' does not directly or unambiguously address whether that term should include imports of products containing HFCs or be limited to imports of bulk HFCs. Because the statute is ambiguous, EPA has discretion to develop a reasonable definition of the term in order to implement the statutorily required HFC phasedown. For the reasons provided in Section V on definitions, EPA is defining ''consumption'' to be limited to bulk substances. Therefore, the statutory language commenters cite in AIM Act subsection (e)(1)(C), which addresses the calculation of the consumption baseline and which refers to ''all regulated substances consumed in the United States,'' is better understood to refer to all *consumption,* which necessarily limits this directive to bulk substances in light of EPA's previously described interpretation of that term. Accordingly, EPA is finalizing the consumption baseline calculation with only bulk HFCs as proposed.

While EPA recognizes that the AIM Act is a distinct authority from title VI of the CAA, it is also true that many of the AIM Act's statutory provisions addressing the HFC phasedown are written and structured similarly to statutory or regulatory provisions under title VI addressing the ODS phaseout. Under the phaseout requirements for ODS (40 CFR part 82, subpart A), only imports and exports of bulk controlled substances are counted as part of the consumption cap.[40] As explained in more detail in Section V of this final notice, it is reasonable to interpret and implement those terms in a similar manner when there is no indication to suggest disparate treatment. Further, during Congressional testimony on the AIM Leadership Act (a prior version of the AIM Act, but similar to the allowance allocation and trading text in the final AIM Act) before the House Energy and Commerce Committee, EPA was asked how the legislation compared to CAA title VI, and EPA responded that ''most of the main components, particularly the phasedown, [are] very similar.'' [41] If members of the Committee had intended the terms ''consume'' and ''consumption''—which are identical to the terms used under CAA title VI—to include products containing HFCs, it is reasonable to anticipate that they would have made their intention clear in the statutory text given that such an interpretation would be a significant divergence from EPA's implementation of the ODS phaseout under title VI of the CAA.

There would be severe implementation difficulties resulting from including imports of products containing HFCs in the consumption baseline and requiring allowances for imports of such products. If the HFC allocation framework under the AIM Act were expanded beyond bulk substances to include imports of products containing HFCs, the regulated importer community would be at least double in number. Many if not all of these entities have never been subject to regulation of this kind and would therefore likely be caught unawares and be unfamiliar with EPA's general approach to the allocation program. Some commenters were not persuaded by this concern, which EPA also described in the proposed rule. A few commenters stated that this is also true of establishing the program of application-specific allowances while others stated that these concerns do not override the clear language of the statute. EPA disagrees that the statutory language is clear on this point. As noted in the definitions portion of this final rule, the language in the AIM Act is ambiguous as to whether ''consumption'' should include imports of products containing HFCs, and thus is also ambiguous as to whether the baseline calculation and allowance system should include imported products containing HFCs. Given the statutory ambiguity, EPA is taking many considerations into account to determine that the definition of ''consumption'' is most appropriately read to be limited to import of bulk substances. Including imported products in the consumption baseline calculation would by necessity require the Agency to issue consumption allowances to all importers of products containing HFCs. Put another way, all such products would be prohibited from being imported effective January 1, 2022, absent participation in an allowance allocation system.

Commenters did not dispute EPA's estimate that the regulated universe would at least double—or more—if HFCs contained in imported products were included in the allowance system. EPA's experience with the ODS phaseout taught the Agency that regulated substances can be in products ranging from silly string to niche medical devices. These products were often manufactured or imported by small businesses that only learned of the phaseout when informed by their suppliers. While it is true that the application-specific allowance system will require allocations to end users, which is different than under title VI, Congress limited the universe to a discrete number of applications, which are expressly listed in (e)(4)(B)(iv).

Commenters in favor of including imports of HFCs contained in products expressed concern that domestic manufacturers of such products would be at a competitive disadvantage to imported products. They argue that because product manufacturers abroad can acquire HFCs that are not subject to the AIM Act's phasedown restrictions, domestic manufacturers would be disadvantaged by needing to acquire HFCs within the United States which they believe would be more expensive. Other commenters argued that undercounting the baseline results in a more stringent phasedown schedule than Congress intended. Some commenters expressed concern that the volume of HFCs in products is currently equal to 10 percent of bulk HFC consumption and is growing. Without controls, commenters said failure to include imports of HFCs in products will continue to allow HFCs into the country, further damaging the Earth's climate system.

EPA plans to achieve the objectives in the AIM Act to phase down HFCs and at the same time avoid the relocation of HFC production. Among the authorities provided in the AIM Act, EPA's assessment is that other subsections of the Act present opportunities for addressing use of HFCs in products separate from the production and consumption controls being finalized in this rule. In particular, subsection (i) of the AIM Act is a powerful tool in and of itself, providing both interested parties and EPA with significant

[40] This approach is also consistent with the approach taken under the Montreal Protocol. Decision I/12A, taken at the first Meeting of the Parties to the Montreal Protocol, defines ''controlled substances'' as bulk chemical. As such, the production and consumption schedules under the Montreal Protocol only apply to bulk chemical.

[41] See *https://www.congress.gov/116/meeting/house/110388/documents/HHRG-116-IF18-Transcript-20200114.pdf* on pages 22 and 23.

potential to address the use of HFCs in products. This view appears to be consistent with other stakeholders as well, given the Agency has received more than a dozen petitions from companies, industry associations, environmental groups, and states under AIM Act subsection (i). The submitted petitions request restrictions on HFCs in a wide range of applications, including use of HFCs in the types of products mentioned in comment.[42]

EPA disagrees with commenters that not including imports of products containing HFCs in the definition of consumption puts domestic manufacturers at a competitive disadvantage or will not achieve necessary environmental benefits. More than 120 countries have joined the Kigali Amendment to the Montreal Protocol, including most if not all of the countries with significant trade in products containing HFCs with the United States, such as Mexico, Japan, Germany, and China. Joining the Kigali Amendment entails a phasedown of HFC production and consumption, so the supply of HFCs in those countries will be limited in ways that are similar to the AIM Act restrictions implemented in the United States. Major United States trading parties, including Japan and Germany, have baseline figures based on the same historical data points as directed by the AIM Act and used to establish the baseline in this rule, and the Kigali Amendment phasedown schedule for those countries matches the phasedown schedule established in the AIM Act.

For some countries, including Mexico and China, baselines for the phasedown of HFCs consistent with the Kigali Amendment will be set based on 2020–2022 production and consumption. In those countries, a cap on production and consumption becomes effective as of January 1, 2024. Any HFC production or consumption that is used to manufacture and export products containing HFCs would count as production and consumption in the country exporting the products, not the country receiving the products via import. Commenters are concerned that companies in countries with a later phasedown schedule could increase their production and consumption in the years used to determine the baseline for those countries, resulting in increased access to HFCs for the duration of the phasedown. In the near term, it is very unlikely companies operating in those countries would find it worthwhile or even be able to expand their production or consumption to service a hypothetical expanded products market for the United States. The time remaining to execute tactics aimed at expanding the baseline is exceedingly brief given that it is already late in 2021 and it is difficult to dramatically ramp up production and manufacturing in a short timeframe. It is also unlikely there would be significant incentive to do so prior to the cap on production that begins in 2024 since the reduction in allowed U.S. consumption in 2022 and 2023 is limited to 10 percent and would not create much ''room'' or demand for an increase in imports of products containing HFCs in the near term. Further, companies would also need to make investments to offshore or ramp up production in other countries while the U.S. regulatory landscape is actively unfolding and could run the risk of stranding assets depending on decisions EPA makes in near term rules. Combined, these are additional reasons to expect that importation of products containing HFCs will not affect the environmental benefits of the program established in this rule or the competitiveness of U.S. domestic manufacturers.

EPA's experience in implementing title VI of the CAA supports these expectations. Under the Agency's experience in phasing out ODS under title VI of the CAA, where other countries committed to similar phaseouts under the Montreal Protocol, the Agency did not see unaddressed documented harm to domestic product manufacturers or lack of environmental benefits. Where EPA did see the potential for harm, the Agency established requirements to address products containing ODS through other authorities under title VI, which ameliorated competitive impacts on domestic manufacturers in sectors that might have otherwise experienced such impacts. In addition, there is reason to believe that manufacturers of products that currently contain HFCs will respond to the HFC phasedown by transitioning away from HFCs themselves. EPA is aware that some categories of products containing HFCs, including appliances where the refrigerant is factory-charged, such as household refrigerators, are already transitioning from HFC-134a to hydrocarbons and a full transition is anticipated no later than 2025. Therefore, EPA does not agree with comments that suggest significant growth for all products containing HFCs. However, if there are unanticipated documented challenges for domestic product manufacturers or lagging environmental benefits counter to EPA's expectations, EPA retains the discretion to revisit its approach to products containing HFCs in the future.

Lastly, we note that this rulemaking only addresses the framework for allocating production and consumption allowances under subsection (e) of the AIM Act. EPA intends to consider opportunities for addressing products containing HFCs under other subsections of the AIM Act in future actions. One authority currently under consideration by EPA is subsection (i) of the AIM Act, which authorizes EPA to ''restrict, fully, partially, or on a graduated schedule, the use of a regulated substance in the sector or subsector in which the regulated substance is used.'' Subsection (i) also provides opportunity for outside parties to file a petition with EPA for a rule establishing such a restriction and establishes a time frame for EPA to act on those petitions. As noted previously, EPA has received more than a dozen petitions under subsection (i) requesting restrictions on the use of HFCs in products including aerosols, foams, refrigeration units, air conditioners (*e.g.,* residential, commercial, and motor vehicle), and dehumidifiers. The statutory deadline under subsection (i) for granting or denying the first five of the pending petitions received by the agency is October 10, 2021, and EPA intends to meet that deadline. If EPA were to finalize rulemaking consistent with the requests in these petitions, it would result in restrictions on the use of HFCs in domestically manufactured and imported products under subsection (i). As with any rulemaking, EPA anticipates that a rulemaking under subsection (i) would include an opportunity for public participation on these issues.

In response to comments that EPA is undercounting the baseline by not including products, and thereby accelerating the HFC phasedown, EPA disagrees. The commenter's suggestion seems premised on a misconception that imports of products containing HFCs could be included in the baseline, but not in the allowance system. The key question is whether imports of products containing HFCs are included in the terms ''consume'' and ''consumption.'' If imports of products containing HFCs are part of consumption, they would be calculated into the consumption baseline, but also consumption allowances would be required for future import of products containing HFCs. As explained previously, the statute does not speak directly to this question, so

[42] The petitions received to date are publicly available at *https://www.epa.gov/climate-hfcs-reduction/petitions-under-aim-act* and at *https://www.regulations.gov*, under Docket ID No. EPA–HQ–OAR–2021–0289.

EPA is using its discretion to interpret the terms ''consume'' and ''consumption'' to not include imports of products containing HFCs. Under this interpretation, HFCs contained in imported products are not covered by the allocation system, and they cannot be included in the baseline. Consumption allowances will not be required to import products containing HFCs, and as described in the prior paragraph, EPA intends to consider ways to address HFC use in products under other subsections of the AIM Act. For this rule, we are using a consistent accounting system for both the baseline and the allowance system that does not incorporate products containing HFCs.

Further, without adequate data to establish a baseline that accurately reflects products, EPA would run a significant risk of creating a baseline that is too small to account for the full scope of imported products used today. While Subpart QQ of the GHGRP contains data about imports of foams and appliances containing HFCs, it does not capture all regulated substances contained in items including fire suppression equipment or consumer aerosol products. If the Agency were to include HFCs contained in products in the baseline figures, it also would need to include data reflecting HCFCs and CFCs contained in products in 1989 to complete the baseline formula. The Agency does not have these data and it would be administratively impossible to comprehensively collect such decades-old data now (as opposed to bulk CFC and bulk HCFC data which the Agency already collected many years ago and has used under title VI of the CAA as a basis for establishing and implementing the phaseout schedule and allowances for both CFCs and HCFCs for 30 years).

Some commenters disagreed that it would be administratively impossible to collect data on HCFCs and CFCs contained in products in 1989 to complete the baseline formula. Commenters noted that volumes would be small given most appliances were domestically produced at that time. One commenter provided data on imports of window units to that effect. When multiplied by the percentages in the baseline formula, commenters stated, the effect would be minimal compared to the HFC element of the calculation. EPA does not dispute commenters' points, but the commenters also do not dispute EPA's fundamental point that it is administratively impossible to collect a comprehensive set of data on HCFCs and CFCs imported into the United States inside of products in 1989 of a similar quality to the data EPA holds on bulk HCFCs and CFCs. Commenters, at most, allege that EPA could make an informed guess at a number to add to the baseline calculation. But such a guess would not match the surety and caliber of data otherwise included in the baseline calculation—which is based on actual data—and is not sufficient to determine the baseline calculation with a level of certainty that is necessary to meet the directive Congress provided to EPA in the AIM Act. Further, it is reasonable to presume that Congress knew that we would lack such 1989 data given EPA's implementation of the ODS phaseout was limited to bulk substances, and this provides further support that EPA's interpretation of ''consumption'' as limited to bulk is reasonable. Furthermore, even if commenters' statement that we could develop a figure to estimate 1989 imports for products imported that contained CFCs and HCFCs were correct, this does not undermine all the other reasons EPA has provided for its reasonable interpretation that ''consumption'' is limited to bulk substances.

EPA is also finalizing its approach of not including transhipment amounts within the baseline. In addition to the prior discussion on why imports of HFCs contained in products are not included in the baseline calculation, transhipment imports are not included in the definition of ''consumption.'' A transhipment is the continuous shipment of a regulated substance, from a foreign country of origin through the United States, to a second foreign country of final destination. Transhipments do not enter U.S. commerce. The sum effect of this activity is zero since the regulated substance is both imported (which would be added to the consumption baseline) and exported (which would be subtracted from the consumption baseline) in identical quantities.

1. How is EPA determining the HFC component of the production and consumption baselines?

In order to calculate the production and consumption baselines, EPA has determined the annual production and consumption of the statutorily listed HFCs in the years 2011, 2012, and 2013. EPA has used multiple sources of data to calculate HFC consumption and production figures for 2011 through 2013: (1) Data reported to EPA's GHGRP; (2) data received in response to the notice of data availability (NODA) published February 11, 2021; (3) data from Customs in the Automated Customs Environment (ACE) and confirmed through letters sent out under CAA section 114 (EPA ICR 2685.01); and (4) data received in response to the notice of proposed rulemaking by the comment due date. EPA received new or revised production, import, export, and destruction data, all of which affect the final baseline values.

The GHGRP requires various facilities and suppliers to annually report data related to GHGs to EPA (see 40 CFR part 98). Subpart OO, ''Suppliers of Industrial Greenhouse Gases,'' is the section relevant to reporting on HFC production and consumption. Because the HFCs listed as regulated substances under the AIM Act are industrial GHGs, EPA has collected a significant amount of data relevant to HFC production and consumption as defined under the AIM Act. EPA used these data as a starting point for estimating the historical HFC production and consumption figures necessary to calculate baselines under the AIM Act. Further discussion of the GHGRP can be found in the notice for the proposed rule.

The data available through GHGRP significantly contribute to EPA's ability to calculate the amount of HFCs produced and consumed in the United States in 2011–2013 for purposes of determining the AIM Act baselines. However, there are known gaps in the GHGRP data, and EPA has made best efforts to fill these gaps. EPA published a NODA on February 11, 2021, outlining available information and perceived data gaps (86 FR 9059). Further discussion of the NODA and data collection efforts taken prior to proposal can be found in the proposed rule.

EPA invited additional public input through the proposed rulemaking and has separately sent letters under the authority of subsection (k)(1)(C) of the AIM Act and section 114 of the CAA to companies that may have relevant data.[43] Specifically, EPA attempted to contact companies that may not have been reporting to GHGRP, either because they had failed to report and were out of compliance or because they were below the GHGRP reporting threshold. These companies were asked to submit any data on HFC production, import, export, transformation, and destruction between 2011 and 2019 that they had not already submitted to GHGRP Subpart OO. To find these companies, EPA obtained a list from U.S. Customs and Border Protection (CBP) of all companies that appeared to import HFCs between 2011 and 2019. This list contained roughly 400 companies. EPA first sent letters to

[43] View Information Collection Request (ICR) Package at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202103-2060-005*.

these companies, requesting they submit any relevant data. EPA then attempted to find email addresses for these companies and sent a copy of the request letter by email as well.

Roughly 130 companies responded to the letter or the follow-up email. A small fraction of these companies actually had relevant data to submit. EPA reviewed any new or updated data for accuracy. EPA used this more complete dataset to calculate the AIM baseline and each company's historical annual HFC production and consumption.

2. What is the HFC component of the production and consumption baselines?

The equations in the AIM Act for the production and consumption baselines include the average annual production and consumption of HFCs between January 1, 2011, and December 31, 2013. Based on the information reported to the GHGRP and gathered through recent data collection efforts, average HFC consumption in 2011 through 2013 was 260.7MMTEVe and average HFC production in 2011 through 2013 was 338.3 MMTEVe for those three years. A memo to the docket (''HFC Production and Consumption Data—Final Rule'') provides the aggregated data for each of the three years similar to that provided in the NODA and the proposed rule. As envisioned in the proposed rule, these values have changed by about 2 percent based on the data collected since the rule was proposed.

3. What are the HCFC and CFC components of the production and consumption baselines?

The equations in the AIM Act for the production and consumption baselines include HCFC and CFC components from 1989. That year was designated under the Montreal Protocol as the baseline year used for several class I substances (Groups III, IV, and V in the Montreal Protocol) as well as for class II substances (HCFCs). See, *e.g.,* 74 FR 66412 (December 15, 2009). As a result, EPA has previously developed a complete accounting of ODS production, import, and export during that year.[44] These values are unchanged from the proposed rule.

Specifically, the 1989 production and consumption levels for HCFCs are 216.9 MMTEVe and 210.3 MMTEVe respectively, and the 1989 production and consumption baselines for CFCs are 2,799.8 MMTEVe and 2,784.5 MMTEVe respectively. Fifteen percent of the 1989 HCFC production and consumption baselines is 32.5 MMTEVe and 31.5 MMTEVe respectively, while 0.42 percent of the 1989 CFC production and consumption baselines is 11.8 MMTEVe and 11.7 MMTEVe respectively.

B. What are the final HFC production and consumption baselines?

Using the equation provided in the AIM Act, and based on the data available to the Agency, EPA is establishing in this final rule the production baseline of 382.6 MMTEVe and the consumption baseline of 303.9 MMTEVe. 40 CFR 84.7(b) includes the baseline values in MTEVe.

TABLE 5—INPUTS FOR CALCULATION OF PRODUCTION AND CONSUMPTION BASELINES

Input	Value (MMTEVe)	Percentage in baseline (%)	Modified value (MMTEVe)
2011–2013 average HFC production	338.3	100	338.3
1989 HCFC production	216.9	15	32.5
1989 CFC production	2,799.8	0.42	11.8
Production baseline	.....	.....	382.6
2011–2013 average HFC consumption	260.7	100	260.7
1989 HCFC consumption	210.3	15	31.5
1989 CFC consumption	2,784.5	0.42	11.7
Consumption baseline	.....	.....	303.9

EPA received a comment that providing draft baselines that are subject to change in the final rule deprives commenters of the ability to comment on the actual baseline. EPA disagrees. EPA provided the best data available to the Agency at the time of proposal. After further analysis EPA finds that these values have increased by approximately 8 MMTEVe and 5 MMTEVe, respectively. This is a 2.3 percent and 2.0 percent increase and is substantively similar to the proposed value for commenters to consider. While EPA acknowledges that the exact baseline figures were not identified at the proposal stage, EPA did provide sufficient information regarding the methodology to be used to reach a final baseline figure, and commenters were able to provide comment on this methodology. EPA provided notice of the steps the Agency would take to collect data to further inform the baseline calculation, including highlighting known data gaps in the numbers provided at proposal. Commenters were also given notice of the calculation methodology EPA would use to determine the production and consumption baselines given that the formulas are provided for in the statute.

Another commenter stated that the GHGRP data are heavily flawed and result in a ''possibly significant'' undercount of imports because they exempt from reporting companies that import below a 25,000 $MTCO_2e$ threshold. EPA acknowledges this difference between data available through GHGRP and data needed to inform the baseline calculations under AIM. The Agency noted this difference in the NODA and in the proposed rule. EPA has made best efforts to identify non-reporters to the GHGRP. EPA analyzed import data from Customs reported through the Automated Commercial Environment/International Trade Data System (ACE/ITDS), which has no minimum threshold for reporting, to identify potential HFC importers and then contacted them by email and certified letter. As a result, additional companies reported production and consumption data for the first time and EPA has included all verified data from these efforts into the baseline calculation. The commenter did not identify an alternate dataset or

[44] For more information on historical U.S. ODS production and consumption data, please visit the United Nations Environment Programme's website at *https://ozone.unep.org/countries/profile/usa.*

suggest another means of establishing the baselines.

VII. How is EPA establishing allowances?

This section provides an overview of the system for providing HFC production and consumption allowances and EPA's methodology for issuing allowances. The AIM Act in subsection (e)(3) requires EPA to phase down production and consumption of regulated substances in the United States through an allowance allocation and trading program. In contrast to the significant detail provided in the AIM Act on how to establish production and consumption baselines and the required set percentage reductions in specific years from that baseline, the AIM Act provides EPA considerable discretion in determining how to establish the allowance program and how to allocate allowances in that program.

A. What is an allowance?

Subsection (e)(2)(D)(ii) of the AIM Act specifies that an allowance allocated by EPA under the AIM Act is a limited authorization for the production or consumption of a regulated substance and does not constitute a property right. As proposed, the Agency will issue allowances that are valid between January 1 and December 31 of a given year, also known as a ''calendar-year allowance.'' A calendar-year allowance represents the privilege granted to a company to produce or import regulated substances in that year. Unused calendar-year allowances cannot be used in a subsequent year.

EPA is establishing three types of allowances: Production allowances, consumption allowances, and ''application-specific allowances'' for six uses specified in the Act. Producing HFCs will require expending both production allowances and consumption allowances, since production is a component of the AIM Act definition of what comprises consumption. This design helps EPA ensure that both the production and consumption caps from the AIM Act will be met through the allowances allocated. Importing HFCs will require expending only consumption allowances. This framework matches EPA's practice from the ODS phaseout and accordingly is familiar to many producers and importers of HFCs. As discussed later, ''application-specific allowances'' are a third category of allowances that can be expended to either produce or import HFCs.

EPA is finalizing the proposal that allowances issued under the AIM Act be exchange value-weighted. This will help EPA align the baseline (which Congress directed be calculated in exchange value terms) with the allowances available for allocation under the statutory phasedown schedule. It also maintains flexibility for a producer or importer to select the appropriate regulated substance for their business since allowances will be allocated in and transferred on an exchange value-weighted basis, as opposed to being specific to a chemical. This allows entities to efficiently distribute allowances as the market needs and may encourage transitions into regulated substances with lower exchange values earlier than would happen under the statutory schedule, which could lead to greater environmental and health benefits. Multiple commenters expressed support for allowances being EVe-weighted and agreed with EPA's basis for noting that this provides flexibility and aligns with the EVe-weighted baseline. One commenter asked that EPA consider using the 20-year GWP value for HFCs in addition to the 100-year value to better address the near-term harm caused by HFCs. The AIM Act directs the Agency to use the exchange values provided in the Act to calculate the baseline from which the statutory phasedown is calculated. In order to ensure that allowances are allocated in an amount permissible under the statutory phasedown schedule, EPA has determined it is reasonable and necessary to rely on the exchange values provided in the AIM Act.

EPA is finalizing its proposal that one allowance is equal to one MTEVe. To determine the total number of allowances needed, producers and importers must multiply the quantity of the HFC they seek to produce or import by its exchange value. For example, an importer would need to expend 143 consumption allowances to import 100 kilograms of HFC-134a. Given the variation in exchange values, one would need to expend between 5.3 allowances to produce 100 kg of HFC-152 and 1,480 allowances to produce 100 kg of HFC-23. As demonstrated in this example, allowances are to be expended down to the tenth, with any necessary rounding after calculating the total. If any production or consumption occurs, that does not fall under a permitted exception, a person must expend at least 0.1 allowances. As proposed, EPA is adopting the table of regulated substances and their corresponding exchange values provided in section (c) of the AIM Act into appendix A to 40 CFR part 84.

EPA notes that the exchange values listed in the AIM Act for each regulated HFC, and for the CFCs and HCFCs used in the baseline calculations, are numerically identical to the 100-year GWPs of each substance, as given in the Errata to Table 2.14 of the IPCC's Fourth Assessment Report (AR4) [45] and Annexes A, C, and F of the Montreal Protocol. In practical terms, producers, importers, and exporters would be able to use the AR4 GWP of a blend that contains only regulated HFCs in determining the amount of allowances necessary to produce or import that blend, or more precisely, the regulated HFC components contained in the blend. If a blend contains components that are not listed as a regulated substance, only the components of the blend that are regulated HFCs are included in determining the amount of allowances necessary to import that blend in EVe weight. As a result, allowances required to be expended would be lower than the CO_2e value for blends that are not limited to regulated substances.

Another commenter suggested that an allowance be based on multiple factors including its GWP, global temperature potential, market prevalence, and whether or not a viable alternative exists for the type of HFC in question. The allowance system established in this rulemaking is for purposes of executing the Congressionally mandated phasedown schedule, which is based in exchange-value weighted terms. It is therefore reasonable to base allowances on exchange value. If other factors were taken into account in determining allowances, that would not ensure EPA is meeting the Congressionally mandated phasedown schedule. In practice, the commenter's approach would also be unworkable since it would require a chemical-specific and use-specific allocation. The Agency could not determine how all allowances would be used prior to issuing them. EPA notes, however, that there are other provisions under the AIM Act where prevalence of viable alternatives may be relevant, and so factors such as those cited by the commenter may be relevant in future Agency rulemakings.

Unlike the approach taken under the CAA to phase out ODS, EPA's proposed approach to determine allowance allocations does not rely on the creation of company-specific baseline

[45] IPCC, 2007: Summary for Policymakers. In: Climate Change 2007: The Physical Science Basis. Contribution of Working Group I to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change [Solomon, S., D. Qin, M. Manning, Z. Chen, M. Marquis, K.B. Averyt, M. Tignor and H.L. Miller (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA. Available at *https://www.ipcc.ch/report/ar4/wg1*.

allowances. Under the ODS phaseout, baseline allowances were revisited periodically and updated based on transfers between companies. Baseline allowances effectively became ''permanent'' and had value across control periods. Companies that stopped producing ODS had the ability to continue receiving allowances annually until the phaseout date, or could sell their market share to another company by transferring their baseline and/or calendar-year allowances. Under the AIM Act, EPA proposed to only issue calendar-year allowances, which are only usable in the year they are issued, without the system of baseline allowances. This approach provides flexibility in the future to adjust approaches, such as the allocation for 2024. Rather than being tied to a fixed amount in the past, this approach allows EPA to react to a dynamic marketplace associated with a phasedown as opposed to a phaseout.

As discussed, an allowance is a limited authorization for the production or consumption of a regulated substance. Typically, an allowance is expended upon the creation or import of a regulated substance. However, the AIM Act provides certain exceptions to that general rule. Producing or importing HFCs that will be used and entirely consumed (except for trace quantities) in the manufacture of another chemical (*i.e.,* for use as a feedstock, which is also known as transformation) does not require expending production or consumption allowances. In general, such HFCs are exempted from the term ''produce'' under subsection (b) of the AIM Act. However, HFCs intended to be used for transformation are regulated substances and thus certain provisions, such as recordkeeping and reporting, apply to them to verify that they are in fact transformed. The few commenters who spoke to this issue were supportive of this proposal.

The definition of ''produce'' in the AIM Act and as finalized in this rulemaking explicitly excludes the reclamation, reuse, or recycling of a regulated substance. Because the definition of ''consumption'' includes production, EPA is not including the amounts of domestically reclaimed HFCs for calculating the yearly production or consumption limits. The AIM Act does not exempt HFCs that have been reclaimed or otherwise reprocessed from consideration when determining the volume of HFCs imported into the United States. EPA is therefore requiring consumption allowances for the import of reclaimed HFCs, unless the reclaimed HFCs are being imported solely for the purpose of destruction. In that situation, if the imported reclaimed HFCs were counted toward consumption, it would be subtracted back out when destroyed. In this circumstance, it seems appropriate to simply permit reclaimed HFCs to be imported solely for purposes of destruction without expenditure of an allowance, assuming it can be reasonably demonstrated that the HFC will in fact be destroyed. Related recordkeeping and reporting requirements are found in § 84.31. There is further discussion of the process to import used HFCs for destruction in Section IX.E of this preamble.

Producers of HFCs do not need to expend production or consumption allowances if the HFCs are destroyed in a timely manner using an approved technology. This approach is consistent with the definition of ''produce'' in the AIM Act, which excludes ''the destruction of a regulated substance by a technology approved by the Administrator.'' HFCs that are domestically produced but are intended for destruction are regulated substances and thus certain provisions, such as recordkeeping and reporting, apply to them to verify that they are in fact destroyed. If a company intends to utilize onsite destruction capability, the company does not need to expend allowances for the HFC production if the HFCs are destroyed within 30 days of being generated. If a company intends to utilize offsite destruction capability, EPA is finalizing that the company need not expend allowances for the HFC production if the HFCs are destroyed within 120 days of being generated, which is 30 days longer than the proposed 90 days. These timelines seem achievable as a practical matter while being short enough to avoid potential malfeasance that could occur over an elongated time horizon.

One commenter argued that the timeline for destruction should begin when the company has a sufficient ''batch'' of chemicals to run through a destruction process. According to the commenter, the clock should run after such a ''batch'' was collected and then a company would have 90 days to destroy that batch offsite before triggering the requirement to expend allowances for such chemicals. EPA is not adopting this suggestion in the final rule because the triggering event is the production of the regulated substance which would otherwise require the expenditure of an allowance. Also, finalizing a timeline that runs off development of a ''batch'' as the commenter suggests seems functionally unenforceable given the lack of clarity around when chemicals would be sufficiently ''batched.'' However, EPA acknowledges that the proposed required timeline for offsite destruction may have been short, so as noted previously, is extending that time period from 90 to 120 days running from the time the regulated substance is created in this final rule.

As discussed in Section V, EPA is excluding from production ''Insignificant quantities of a regulated substance inadvertently or coincidentally generated from any of the following, independent circumstances: During a chemical manufacturing process, resulting from unreacted feedstock, from the listed substance's use as a process agent present as a trace quantity in the chemical substance being manufactured, as an unintended byproduct of research and development applications, or during semiconductor manufacturing processes.'' Any other regulated substances created during the manufacturing process, either in quantities that are not insignificant or outside of the listed circumstances, *would* be considered ''production'' and would require expenditure of production and consumption allowances unless destroyed in a timely manner (there are additional restrictions related to HFC-23, as discussed further in Section VIII.C). This provision is intended to ensure that the regulated substances identified under the AIM Act are appropriately controlled and their production and consumption are reduced under the schedule required by Congress. Whether the regulated substance is inadvertently created through the chemical manufacturing process does not seem to be relevant to Congress's directive to phase down regulated substances on the statutorily defined schedule. EPA did not receive adverse comments on this proposed approach, except for the question regarding semiconductor manufacturing facilities, which the Agency addresses in Section V.

B. How is EPA determining allowance allocations?

1. Which years is EPA issuing allowances for?

As proposed, EPA intends to issue allowances for 2022 according to the framework and procedure established through this rulemaking by October 1, 2021. Likewise, EPA intends to issue 2023 allowances by October 1, 2022.[46]

[46] The exception to this general statement is that EPA intends to issue both 2022 and 2023 allowances from the set-aside pool to new entrants

Continued

EPA is establishing the allocation allowance framework for these two years and intends to undertake a subsequent rulemaking to govern allocations for calendar years 2024 and beyond.

Multiple commenters supported the Agency's plan to quickly establish an allowance allocation and trading program for the near term while further developing a longer-term program. Phasing down regulated substances as required under the AIM Act may have different implications for stakeholders than the Agency's past experience with phasing out ODS. EPA intends to better understand and respond to those differences by seeking input from stakeholders and developing another rule that may alter the approach and procedure for allowance allocations finalized in this rule, if necessary. However, to do so requires more time than the 270 days provided by the AIM Act. Furthermore, additional analysis of the market—as well as the effects of implementing other provisions of the AIM Act—may be necessary before issuing allowances for the 2024 stepdown, when the number of allowances will decrease from 90 percent of baseline to 60 percent of baseline.

Some commenters requested that the Agency issue allowances for 2022 and 2023 at the same time, rather than allocating on an annual basis. Commenters stated that this would increase certainty and improve business planning, something that commenters claim is challenging if only given a three month lead time. Some commenters recognized that EPA will need to adjust the allocations given updates to the application-specific allowance amounts for 2023. Those commenters encouraged EPA to issue the general pool of 2023 allowances now and adjust later in 2022 to account for any changes.

EPA responds that it does not intend to issue 2023 allowances (other than to new market entrants as discussed in Section VII.E on set-asides) in 2021. As discussed further in this section, the applications identified in AIM Act subsection (e)(4)(B)(iv) must be provided the level of allowances ''necessary'' to meet their market demands, so application-specific allowance holders are given priority access to the pool of available allowances. Until EPA can determine the number of application-specific allowances needed by the statutorily identified end users for 2023, it cannot know how many allowances remain from within the cap for general allowances. As a result, EPA intends to only allocate 2022 allowances on October 1, 2021, and subsequently provide individual company allocations in 2022 after determining the general pool of available allowances for 2023. EPA understands commenters' desire for more certainty and business planning lead time, but EPA is finalizing the structure that is best to meet the Congressional directive of providing application-specific allowance holders their necessary level of allowances from within the same cap on allowances overall. With respect to one commenter's suggestion to allocate allowances for 2023 on October 1, 2021, and make adjustments in 2022 if needed, EPA responds that the interests of certainty and planning are not well served by issuing allowances now and then modifying them next year. However, as discussed in the next section, EPA is establishing a methodology to govern calculation of allocation levels that will remain the same for 2022 and 2023 for general pool allowances. Therefore, allowance holders in this general pool can expect that their percentage share of the general pool of allowances will be approximately the same for 2022 and 2023.[47] With general pool allowance holders' percentage share staying close to the same for 2022 and 2023, the only differing factor will be how much of the total available allocation is available after accounting for application-specific allowances. The amount of allowances allocated for application-specific end uses in 2023 is unknown at this time. However, application-specific allowances represent less than 3 percent of total allowances, thus changes to application-specific allowances are not expected to have a significant impact on the amount of general pool allowances available.

2. Which companies is EPA issuing allowances to?

EPA proposed to issue allowances to companies that produced or imported HFCs in 2017, 2018, and/or 2019. EPA proposed to require that a company remain active in 2020 to be eligible to receive an allowance allocation from the Agency, but also noted that the Agency would be willing to consider individual circumstances. Considerations for determining who should receive allowances in this initial rulemaking include providing as seamless a transition as possible to a regime where allowances are needed to produce and import HFCs, promoting equity, timeliness of implementation, and availability of robust data. EPA is finalizing the proposal to issue allowances to active HFC producers and importers operating in 2020, but will also give individualized consideration to circumstances of historical importers that were not active in 2020. EPA is also creating a mechanism under which new market entrants can apply to the Agency for consumption allowances. EPA has determined that such a system balances the Agency's objectives of a smooth market transition while also not creating undue barriers to market entry for potential new participants.

Production allowances. EPA is issuing allowances to companies that produced HFCs in the United States in 2020. Since issuing the proposed rule, one additional company provided information documenting that it was a historical producer of HFCs.

Consumption allowances. EPA is generally allocating consumption allowances only to companies that produced or imported in 2020, even if they were active in prior years, to ensure that allowance holders are active in the HFC market. Except for the unique individual circumstances explained below, allocating consumption allowances to companies no longer producing or importing would be at the expense of companies that are still actively invested in HFC production and import. EPA stated in the proposal that the Agency would generally presume the business exited the production and/or import market if it did not actively produce or import in 2020. The proposal did note that EPA would undertake individual consideration of a company's inactivity, for example if it was due to the COVID–19 pandemic. Such companies would need to provide documentation to justify such inactivity and any other relevant information no later than the end of the comment period. EPA did receive requests for special consideration from certain companies.

EPA recognizes that some importers may not be aware of Congress's legislative activity in this area. EPA has undertaken best efforts to develop a comprehensive universe of importers for purposes of allowance allocation. The proposal was based on data available through the GHGRP; the February 11, 2021 NODA; stakeholder outreach

by October 1, 2021, in accordance with the process described in Section VII.E of the preamble.

[47] There may be a small adjustment between 2022 and 2023 to account for companies that were historical importers that are not required to report to GHGRP and that did not provide data in time for an allocation from the general pool for 2022. These companies are eligible for allowances under the set-aside, and would be added to the general pool in 2023 based on the same criteria as other historical importers. However, any such companies are anticipated to be small given the reporting thresholds provided in the GHGRP.

meetings; outreach to trade associations that can inform their members; and direct communication with companies that EPA suspects may have imported in relevant years that are not captured in the Agency's data sources. EPA continued to follow up with companies that may be eligible for allowances after proposal. EPA is issuing allowances to importers listed in the proposed rule, as well as importers that provided data that were sufficiently verifiable, for example through import records to EPA such as Customs forms or bills of lading. Additionally, as described further in Section VII.E, EPA will allow historical importers not yet identified or verified by the Agency to come in to request allowances based on their historical market activity if they were not previously required to report to the GHGRP.

EPA proposed to issue allowances at the parent company level if multiple companies that imported HFCs are controlled or owned by the same corporate entity. The proposed rationale for doing so is that it is administratively easier to implement and it improves transparency in the market. Commenters were generally in support of this proposal, with the exception of some application-specific allowance holders, which EPA will discuss in Section VII.C of this notice. One comment in support noted that it provides flexibility for retailers to address shifting needs and consumer demands across several brands, facilities, and locations. Another company recommended that ''parent'' company should be defined to be broader than simply ownership to determine if companies are related (*e.g.,* include management, employees, relatives). A few commenters suggested that companies that are under common control, but are not subsidiaries of a corporate parent, should be issued allowances together. EPA responds that for purposes of determining the quantity of past imports, EPA is treating all companies majority owned and/or controlled by the same individual(s) as a single company, even if there is no corporate parent. EPA does not agree with the comment that EPA should collect or analyze personally identifiable information to the scale that the commenter suggests. Data on the complete ownership of the company, including co-owners, is sufficient and is the type of information that corporate owners have a reasonable expectation may be requested.

Most commenters agreed with EPA's proposal to issue allowances to companies that have historical production and consumption data and were active in 2020. Some commenters noted that this will fairly include small to medium sized businesses that have recently entered or innovated within the market. Commenters agreed with EPA's focus on more recent years of data, such as basing qualification on being active at some point in 2017–2019 as well as being active in 2020, and stated that issuing allowances only to companies operating in 2011–2013 would exclude current market participants and not be reflective of current market conditions. Commenters provided examples of this concern. One commenter stated that users of HFCs for niche, non-refrigerant uses would be harmed if the current distribution system were interrupted. Another commenter noted that it would harm the current air conditioning aftermarket and distributors supported by that business.

A few commenters disagreed that importing in 2020 should be the sole metric in determining whether a company is currently participating in the market. Three companies provided information about their operations in 2020 and requested EPA to consider them as existing market participants that qualify for the general pool of consumption allowances.

EPA agrees with commenters that issuing allowances to active companies best maintains the current distribution architecture. Recognizing the unique nature of 2020, with economic disruptions caused by a global pandemic, EPA is issuing allowances to companies that did not import in 2020, but provided documentation showing that they were still active, either by selling or purchasing HFCs domestically in 2020.

3. What is EPA's framework for determining how many allowances each company receives?

This section discusses how EPA will determine how many allowances each company will receive from the general allocation pool. EPA proposed that the amount of allowances issued to each producer and importer be based on a company's highest year of production or consumption, on an EVe basis, in 2017–2019. EPA also took comment on using data from 2011–2013 or some other combination of years, including all years, between 2011 and 2019. Under the proposal, EPA would sum together every company's highest year amount(s), determine a percentage share for each company, and multiply each company's percentage by the total amount of available calendar-year allowances. EPA also requested comment on whether the Agency should consider individualized circumstances to take into account a company's 2020 data for determining allowances for companies that have newly entered the HFC import market, for example a company that entered the market or acquired another company late in 2019.

Most commenters supported using production and consumption data either from 2017–2019 or the full range of years from 2011–2019. Commenters favoring 2017–2019 assert that these years provide the most accurate reflection of current production, consumption, and use of HFCs. These commenters argue the HFC market has shifted significantly since 2011. A few commenters recommended that EPA also include 2020 data as it best represents the present refrigerant market. One commenter stated that 2016 is an appropriate end-point for determining the representative picture of the market as this is before anti-dumping and countervailing duty (AD/CVD) decisions by the Department of Commerce (DOC) and International Trade Commission (ITC) (see the memo to the docket discussing these duties) and before the Kigali Amendment was agreed. Many commenters suggested that EPA consider favoring 2011–2019 because they assert that 2017–2019 period does not fairly consider longstanding market participants. Some commenters stated that considering a larger range of years is more equitable by ensuring participants are not harmed by market manipulation.

EPA has considered all the comments received, which had a broad range of recommended approaches. EPA has determined to base allowance allocations on data from the entire period from 2011–2019. However, since we are pulling data from such a wide range of years, EPA has determined it is appropriate to average a company's three highest years of data (not necessarily consecutive), as opposed to going with a single high year. Commenters that supported this approach of using the full 2011–2019 time period argued that it is more accurate, equitable, and inclusive, and the Agency agrees. Using an average of the three highest years during the 2011–2019 period incorporates consideration of both industry history and ongoing growth and market change. EPA has determined that using the full range of years allows a balancing of using the most current data, which generally provide the most accurate information on the current market to provide for less market disruption, while also incorporating data from earlier years to account for changes in market behavior (*e.g.,* actively commercializing alternatives to high-GWP HFCs) that took place earlier in the transition as a

result of the global agreement to the Kigali Amendment or other countries enacting HFC phasedown regulations. More recent years also include orders issued by the DOC concerning anti-dumping and countervailing duties (see the memo to the docket discussing these duties). Such orders could be evidence that the overall market reflects some degree of unfair trade by foreign exporters. Bringing in consideration from earlier years will bring to bear a wider array of data to inform allocations.

EPA is not including 2020 data in its analysis because the Agency had not completed its regular quality assurance review of 2020 data reported to the GHGRP early enough in the process for consideration in this final rule. As explained in other sections, EPA is relying largely on data reported to GHGRP in this initial rule and in the initial allocation given that companies have not yet been reporting to EPA under the AIM Act. Typically, EPA releases GHGRP data in October for the prior year, which is after the analysis for this rule must be finalized.

EPA recognizes that there is no single year that is ''better'' for all market participants. There is no year in which a forward-looking company may not have been stockpiling in preparation for a restriction on HFCs or new duties that were imposed by the DOC. Though countries agreed to the Kigali Amendment in 2016, efforts to amend the Montreal Protocol took the better part of a decade. As such, taking an average of a wider range of years is more equitable to all companies in the market. Each company receives its ''best'' years regardless of actions taken by other companies.

One commenter noted that the production and consumption baselines years specified under the AIM Act, 2011–2013, were at a time when a greater proportion of what American producers made was exported compared with today. Larger exports mean their total consumption is lower, as those exports are subtracted from production. The commenter states that distributing allowances based on the high year between 2017 and 2019, when consumption is higher because producers' exports are lower, would accentuate the discrepancy between total amounts of production and consumption allowances and result in stranded production allowances or the need for producers to purchase additional consumption allowances. As EPA stated in the proposed rule, the discrepancy between the production and consumption baselines is due to producers exporting HFCs. Whenever this happens, there will be a discrepancy between production and consumption. However, EPA agrees with the commenter that basing the allowance allocation on years when the import market was larger will further reduce consumption allowances for producers. Using a longer period of years and averaging the highest three years (not necessarily consecutive) during that time addresses the commenter's concern, in part. For this and other reasons discussed in this section, EPA is not basing the allocation on the high year between 2017 and 2019.

One commenter stated that even if EPA expanded its allocation methodology to consider data from multiple years, it would still fail to account for market fluctuations if the Agency ultimately based the allocation on only a single high year of data because doing so would maximize the impact of market aberrations such as a large single-year client or other one-off business opportunities. The commenter recommended using the average of multiple years to more fairly account for fluctuations.

One commenter did not support averaging a small number of years and preferred using the high-water mark year. The commenter stated that this approach better accounts for companies with inconsistent import activities from year to year, which are typically smaller businesses. Additionally, the commenter stated that averaging across all of 2011–2019 would be problematic for companies that were not in the market in the early years.

As noted previously, when EPA was proposing to base allowance allocations from data from 2017–2019, the Agency proposed to choose the single high year. However, in light of the Agency finalizing an approach that will consider data over a wider range of years that reach further back in time, EPA has determined it is appropriate to base allowance allocations on the average of a company's three highest years. This allows for more evening out of fluctuations in the market and avoids the possibility of a company receiving a large share of allocations based on a single very high year that occurred several years in the past. One commenter noted concern that small importing businesses can have inconsistent business year to year; the approach EPA is finalizing to average three years of data, as opposed to averaging every year over the 2011–2019 timeframe, absolves this concern. Averaging a firm's highest three years over a longer time period is an equitable approach, avoiding crediting a single extraneous high year but also not requiring averaging of every year for small importers that may have inconsistent business. It also incorporates consideration of the market before Congress was considering legislation to regulate this industry and prior to the Kigali Amendment. Averaging softens the effects of outlier years where a company may have imported extra to avoid duties, to build stockpile, or to address a one-off large order or series of orders from customers. If a company does not have three years of data, EPA will take the average of the years between 2011 and 2019 for which the company produced or imported HFCs, assuming the company was active in 2020 or has applied for and received special consideration.

EPA requested comment on whether the Agency should be calculating historical production and import data on a total EVe-weighted basis or as a percentage of market share. EPA received comments in support of both approaches. Companies favoring market share noted it was an effective way to scale quantities produced and consumed in a year, while those opposed argued that using market share would provide undue extra weight to production and consumption that happened in a year where there was less overall production and consumption. Those in favor of using an EVe quantity noted this represented the actual EVe quantity of HFCs imported and would align better with that company's actual production and consumption. EPA compared the effect of selecting either approach and found that the differences between the two were minimal. EPA is finalizing an approach that allocates based on the reported EVe-weighted amount as it more closely reflects an individual company's participation in the market. EPA's overall approach to allocating allowances from the general pool is to reflect activity in the market and to minimize market disruption beyond what is inherently required to meet the Congressionally mandated phasedown. Using EVe-weighted amount best accomplishes this since it reflects actual volumes of regulated substances in the market, as opposed to market share which is not as directly connected.

Some commenters insisted that EPA correct historical market disruption through the allowance allocation program by using certain years of data or excluding specific companies. In brief, commenters urged EPA not to reward alleged anti-competitive behavior by issuing allowances based on that behavior. EPA responds that the Agency is not weighing in on unproven

allegations nor is the Agency adjusting production or consumption allowances for the benefit or detriment of any particular company. EPA reiterates that considerations for determining who should receive allowances includes providing as seamless a transition as possible to a regime where allowances are needed to produce and import HFCs, promoting equity, timeliness of implementation, and availability of robust data. EPA declines to issue allowances only to market participants in 2011–2013. As stated in the proposed rule, excluding all newcomers based on the actions of a few would penalize all recent market entrants. An attempt to reset the market to 2013 would also disrupt all existing market relationships for HFCs from the importer down the supply chain.

Given the longer timeframe of years, information reported to EPA indicate some companies that historically produced or imported HFCs have changed name or ownership. EPA is clarifying that for purposes of allocating allowances, if a company (Company A) purchased another company (Company B) or a portion of a company (*e.g.,* the refrigerants business unit of a larger company), the current owner of the business (Company A) would receive allowances based on its own past production and consumption, and the production and consumption of the acquired company (Company B). EPA has experience with similar situations under the ODS phaseout. EPA also notes here the opposite situation where a company spins off a business unit and that unit retains the allowances. EPA has treated such circumstances as a change in company ownership, name, and/or structure. The company would need to provide a formal request to EPA on company letterhead explaining the change, certifying that the new business entity is no longer under the same parent company or common ownership, and providing the name of the business unit that would retain the allowances, along with contact information for the new representative at the company.

Consistent with the definition of ''Produce,'' EPA is issuing production allowances based on the total EVe quantity produced minus amounts for transformation minus amounts destroyed. Consumption allowances are determined for each company based on the EVe quantity of HFCs they produced (subtracting out transformation and destruction) plus the amount they imported (excluding the amount imported for transformation or destruction) minus the amount exported. As such, companies producing and then exporting HFCs have more production allowances than consumption allowances, assuming the company did not import more HFCs than it exported. Overall, this approach results in more production allowances than consumption allowances, given the quantity of exports during the baseline years.

4. What is EPA's framework for issuing allowances?

This section contains EPA's formula for determining the amount of production and consumption allowances to be issued to each producer and importer. EPA is finalizing as proposed the calculation as a whole but is modifying step three for the reasons discussed in the prior section of this preamble.

First, EPA will multiply the United States production and consumption baselines by the current phasedown step in subsection (e)(2)(C) of the AIM Act. EPA is codifying the phasedown steps shown in the table in (e)(2)(C) into the regulations at § 84.7, as proposed. For 2022 and 2023, total production and consumption cannot exceed 90 percent of baseline. Thus, EPA is multiplying each baseline by 0.9 to determine the production and consumption caps for those years.

Second, before determining the quantity of allowances available to be issued from the general pool to each producer and importer, EPA must provide allowances for statutorily defined applications according to the AIM Act requirements in subsection (e)(4)(B)(iv). Subsection (e)(2)(D) of the AIM Act ensures that the total amount of allowances issued does not exceed the production and consumption caps, even including application-specific allowances.[48] Therefore, the pool of available calendar-year allowances must be determined after the amounts for uses in subsection (e)(4)(B)(iv) are determined. These calculations are conducted by EPA to protect company claims of CBI on previously reported data. EPA intends to issue allowances to individual companies for 2022 and release information on the amount of allowances allocated to each company publicly by October 1, 2021. For 2022 and 2023, EPA also proposed and is finalizing a set-aside of allowances. EPA is setting aside 7.5 MMTEVe (see Section VII.E for a fuller discussion). The remainder is the general allowance pool for that year.

Third, EPA will determine the average of each eligible company's three highest EV-weighted annual production and consumption amounts between 2011 and 2019. EPA will then divide each company's average by the sum of all companies' averages to determine each company's share of the allowances in the general pool.

Fourth, EPA will multiply each producer's or importer's share by the general allowance pool to determine each company's calendar year production and/or consumption allocation amounts. EPA is issuing allowances in to the tenth of an MTEVe.

Lastly, EPA will then issue by October 1st the list of companies receiving production and/or consumption allowances and application-specific allowances as well as the quantities of allowances each company received in the initial distribution. For 2022 calendar-year allowances, EPA intends to also issue allowances from the set-aside pool (see Section VII.E of the preamble) by March 31, 2022, and distribute pro rata any unused allowances from the set-aside to the companies in the general pool at the same time.

5. What process is EPA using to respond to requests for additional consumption allowances?

EPA proposed a process in § 84.17 to allow a person to obtain consumption allowances equivalent to the quantity of newly produced (''virgin'') regulated substances exported by that person, provided that the substances were originally produced or imported with consumption allowances in the same calendar year. Given that the AIM Act subtracts exports in the definition of ''consumption'' under subsection (b)(3), it is consistent with the Act to refund consumption allowances that were expended to import or produce regulated substances if those regulated substances were later exported from the country.

One commenter requested that EPA provide a timeframe by which the Agency must respond to a ''request for additional consumption allowances'' (RACA). The commenter noted that EPA proposed timeframes for many other petition requirements. EPA agrees that establishing a schedule on the length of time needed to either grant or deny a RACA request is reasonable and provides some element of certainty to the requestor. Based on timeframes needed to respond to RACAs for ODS, EPA is establishing a 15 working day

[48] Under CAA title VI, essential use production and consumption allowances are for uses exempt from the ODS phaseout and are only available since the United States' production and consumption is zero. Therefore, the amounts allocated for essential uses are in addition to the amounts otherwise allocated (*i.e.,* zero). By contrast, under the AIM Act, application-specific and essential use allocations are not exemptions from the cap but rather receive priority within the cap.

nominal timeline for the Agency to grant or deny a request.

One commenter disagreed with the requirement that the allowances for production or import must be in the same calendar year as the RACA. Further they requested that EPA allow producers and importers to net out their exports annually rather than periodically request a refund. EPA agrees that documenting that the production or import of the subsequently exported HFCs all occurred in the same calendar year is unnecessary. Such a requirement would hinder exports in the early part of the year as the HFCs would first have to have been produced or imported. EPA recognizes through managing the ODS phaseout that exports occur all year and what matters from the perspective of requesting an additional consumption allowance is when the export occurs, not the production or import. EPA is maintaining the requirement that both the export and the RACA occur in the same year and that any refunded allowances must also be expended in that same calendar year. This is necessary to ensure that the statutorily defined production and consumption reduction targets are met each year.

The exporter must submit certain information for EPA's review to verify that the regulated substances were in fact exported. This information includes: (i) The identities and addresses of the exporter and the recipient of the exports; (ii) the quantity (in kilograms) and names of regulated substances exported; (iii) the source of the regulated substances and the date purchased; (iv) the date on which, and the port from which, the regulated substances were exported from the United States or its territories; (v) the country to which the regulated substances were exported; and (vi) a copy of the bill of lading and the invoice indicating the net quantity (in kilograms) of regulated substances shipped and documenting the sale of the regulated substances to the purchaser. The full list of required information in a RACA can be found at § 84.17.

C. What is the process for issuing application-specific allowances?

This section discusses how EPA will implement subsection (e)(4)(B)(iv) of the AIM Act, which directs the Administrator to allocate allowances necessary to meet HFC demand for six specified end uses, or ''applications.'' The Act directs EPA to issue ''the full quantity of allowances necessary, based on projected, current, and historical trends.'' The Act also includes a limitation on application-specific allowances in subsection (e)(4)(B)(iii). This provision reinforces the requirement in subsection (e)(2)(A) that a person receiving an allocation may not produce or consume a quantity of regulated substances that exceeds the number of allowances held by them. Further, (e)(4)(B)(iii) reinforces that application-specific allowances are to be part of the annual production and consumption caps. (See subsection (e)(2)(B))

To carry out this statutory direction, EPA is creating, as proposed, a category of allowances called ''application-specific allowances'' that can be expended to either produce or import HFCs. These allowances may be used for either produced or imported HFCs because end users in the statutorily identified applications may not know in advance how they will procure HFCs, and this method provides flexibility to ensure that end users receive the ''full quantity of allowances necessary.'' To ensure that these application-specific allowances are provided from within the overall annual production and consumption caps, EPA is subtracting the amount of application-specific allowances allocated from both the production and consumption general allowance pools as discussed previously.

As part of the docket to the NODA that preceded this rule, EPA released reports characterizing the Agency's understanding of the market for five of the six applications (86 FR 9059; February 11, 2021). EPA updated the reports for the proposed rule and provided data on projected, current, and historical trends for the use of HFCs in each application. They provide an overview of the applications (other than mission-critical military end uses) and EPA has again updated them to incorporate comments received on the proposal. The most recent versions are in the docket for this final rule.

1. Who is EPA issuing application-specific allowances to?

The Act does not specify who should be issued application-specific allowances, so the Agency considered allocating either directly to the entity manufacturing the product listed in the application (end user) or to the producer or importer who supplies the bulk HFC to that entity. EPA proposed to issue application-specific allowances to the end user of the HFC who is manufacturing the product listed in subsection (e)(4)(B)(iv) of the Act or the DOD, in the case of mission-critical military end uses.

Commenters were generally in support of allocating allowances directly to the end user, with some commenters agreeing with EPA's rationale that doing so would allow end users the flexibility to change suppliers when necessary. Some commenters disagreed with this proposal and suggested that EPA instead allocate to the HFC producer, with one arguing this would be consistent with the rest of the proposed rule. This commenter expressed concern that allocating to the end user would result in end users importing HFCs directly from manufacturers outside of the United States and that this would negatively affect domestic manufacturing, could slow growth of the semiconductor industry due to difficulty in new facilities receiving raw materials, and would be challenging for EPA to obtain a complete list of end users (as compared to obtaining information from the few HFC producers), which may result in EPA being unable to provide sufficient allocations.

EPA is finalizing the proposed approach of allocating application-specific allowances to the end users in the statutorily listed sectors. EPA has experience under the essential use exemption, as implemented under title VI of the CAA, with issuing allowances directly to end users. In that instance, EPA issued essential use allowances directly to MDI manufacturers, for example, who then conferred those allowances to a company for the production or import of a specified regulated substance. One advantage of this system was that it ensured that those companies manufacturing MDIs had the allowances needed and they could choose which producer or importer they would confer their allowances to. This allowed the MDI manufacturers to make a competitive choice in a more open market for the material and price best suited to their needs, or import the material directly themselves. Another advantage was that it helped to ensure that the allowances would be expended only for an essential use.

Congress's expressed intent is to provide entities operating in these sectors with the regulated substances ''necessary.'' EPA can best meet this intent by allocating directly to the end user and providing them the flexibility to determine the best source of HFCs for their application and flexibility to switch suppliers. End users should also be the best positioned to estimate projected future needs for their company, and therefore EPA will work with end users in determining allocation levels to provide necessary

levels of regulated substances. There is nothing in the statute to suggest that these end users should be encouraged to obtain domestically manufactured HFCs, just that EPA ensure they were able to access ''necessary'' amounts of regulated substances.

EPA is also addressing comments on streamlining the process of conferring allowances to decrease disruption to the current supply chain, regardless of whether the HFCs used in these applications are currently produced or imported.

EPA has modified the definition of ''confer'' in recognition that there may be multiple steps in the supply chain between the producer or importer and the end user issued the allowances. Allowances may be re-conferred as needed through the chain. For conferrals of application-specific allowances, the conferrer must include a signed document from the conferee certifying that HFCs produced or imported with these allowances will only be conferred for the same application they were initially allocated for.

EPA notes the commenter's concern that the semiconductor industry could have difficulty receiving raw materials. However, several semiconductor manufacturers and industry associations representing semiconductors did not share this concern. In fact, some from the semiconductor manufacturing industry expressed support for EPA's approach of allocating directly to the end user. Most end users that commented on this point supported receiving the allowances directly.

EPA also notes a limited number of commenters' concern that EPA would experience challenges in obtaining a complete list of end users to provide sufficient allocations, but through stakeholder outreach, requests for information, and information provided historically to the GHGRP, EPA has been able to identify end users in the application-specific industries. EPA listed all identified end users for each of the applications listed in subsection (e)(4)(B)(iv) of the Act during the NODA and proposed rule stages. EPA also held five workshops on March 11–12, 2021, focusing on five of the six applications (not including mission-critical military end uses). In response to this proposal and continued outreach efforts, EPA received data from more than 30 entities that appear eligible and the DOD. EPA has reviewed the data and to the extent it has been verified intends to issue application-specific allowances for 2022 to eligible companies by October 1, 2021. Companies provided data indicating approximately 1–3 MMTEVe of HFCs were purchased annually for non-mission-critical military end uses between 2018 and 2020. EPA intends to issue allowances by October 1 to those companies. EPA expects there may be additional companies eligible for application-specific allowances. To the extent EPA has missed any end users, such entities would be eligible to seek allowances through the set-aside pool or procure HFCs through the open market similar to how they are acquiring HFCs now. EPA intends to continue reaching out to companies that may be eligible and associations that may represent them.

Several commenters asked EPA to expand the scope of the applications for which EPA gives the ''full quantity of allowances necessary.'' For MDIs, one commenter stated that the application of HFC use as a propellant in metered dose inhalers should be amended to encompass all medical devices. EPA is not accepting this recommendation. The statutory language in subsection (e)(4)(B)(iv) directs the Agency to provide necessary allowances for ''exclusive use'' as ''a propellant in *metered dose inhalers*'' (emphasis added). EPA notes that if the commenter believes there is another end use that should be eligible to receive allowance levels ''necessary,'' there is a process by which entities can petition the Agency under (e)(4)(B)(ii).

As discussed in Section V, EPA is amending the final definition of ''onboard aerospace fire suppression'' to include some military aircraft because they may be built using commercial aircraft designs that are modified for military use or built to commercial specification and then modified for military use (''commercial derivatives''). In the situation of these commercial derivatives, it may be impractical to provide allowances that distinguish between military and civilian use. EPA acknowledges that under this approach, manufacture of military aircraft (and their onboard aerospace fire suppression systems) may be eligible for application-specific allowances from mission-critical allowances or the onboard aerospace fire suppression allowances. Where such overlap exists, EPA intends to only provide a single set of application-specific allowances necessary to cover manufacture of military aircraft, to prevent double-allocating the ''necessary'' amount under both mission-critical and aerospace application-specific allowances.

For structural composite preformed polyurethane foam for marine use and trailer use, some commenters supported a broad and inclusive definition of trailer use but did not explain what that means in the context of this rule. For this application, EPA considers trailers to be refrigerated trailers for transportation of perishable goods, including either refrigerated intermodal containers transported on trailers or insulated cargo space designed with a refrigeration system in a truck or trailer-mounted system.

As noted previously in this section, EPA will allocate application-specific allowances to the end user. The end user generally refers to the entity manufacturing the product listed in the application, but this may look different for each application and is not limited to products. EPA is clarifying these entities here:

- Defense sprays: The end user is the entity manufacturing or contracting out the manufacturing of defense sprays. This would generally be the company filling the defense spray with an HFC propellant or paying another manufacturer to fill the defense spray on their behalf.
- Structural composite preformed polyurethane foam: The end user is an entity that manufactures structural composite preformed polyurethane foam for use in boats and trailers.
- Propellants in MDIs: The end user is the entity manufacturing or contracting out the manufacturing of MDIs using HFCs. This would generally be the company filling the MDI with an HFC propellant or paying another manufacturer to fill the MDI on their behalf.
- Onboard fire suppression: The end user is the entity manufacturing, servicing, or paying someone else to perform servicing (whether it is in cash, credit, goods, or services) of onboard aerospace fire suppression equipment. This would include the company manufacturing a self-contained fire extinguisher, such as a handheld unit, or servicing, including testing and recharging, of such self-contained fire extinguishers, as well as the company filling the pressurized system cylinder that is an integral part of a total flooding fire suppression system, such as lavatory trash receptacle fire suppression systems, or the company servicing, including testing or recharging, of such system cylinders.[49]
- The etching of semiconductor material or wafers and the cleaning of

[49] EPA notes that in the case of total flooding systems, the Agency is allocating to the company filling a specific type of bulk container (*i.e.,* a pressurized fire suppression cylinder). These cylinders may be made by the same company making the rest of the fire suppression system used for onboard aerospace applications and are intended to be connected to the fire suppression system when fully assembled.

chemical vapor deposition chambers within the semiconductor manufacturing sector: The end user is a semiconductor manufacturer that uses HFCs in the etching of semiconductor material (including cleaning of wafers) and the cleaning of chemical vapor deposition chambers within the semiconductor manufacturing sector.

- Mission-critical military end use: EPA is directly allocating application-specific allowances to the DOD for mission-critical military end uses.

2. How is EPA addressing transfers of application-specific allowances?

EPA is allowing limited transfer of application-specific allowances, as proposed. Specifically, end users within a specific application may transfer their allowances only with another end user that will use the application-specific allocation for that same application. These could be viewed as ''intra-application transfers.'' EPA is prohibiting transfers with companies in other applications. EPA received many comments supporting the proposal to allow limited transfer of application-specific allowances only among end users within the same application and did not receive comments from those opposed.

Section (e)(4)(B)(iv) of the AIM Act states that application-specific allowances are provided ''for the exclusive use'' of HFCs ''in an application solely for'' those in the statutory list. These transfer provisions help to ensure that, after EPA allocates the full quantity of allowances necessary for each application, the full quantity remains available to fully supply that application and ensure that the application-specific allowances are being exclusively used solely for one of the six listed applications.

EPA is also prohibiting the transfer of application-specific allowances back into the larger market for production and consumption allowances, as proposed. The AIM Act specifies that the allocation is for the exclusive use of one of the listed applications. It follows that an application-specific allocation cannot be transferred to produce or import HFCs for a use that was not enumerated.

EPA is establishing similar restrictions to the sale of HFCs acquired by expending application-specific allowances, as proposed. HFCs produced or imported by expending application-specific allowances must be used solely for the application it was produced or imported for. EPA is therefore also prohibiting the sale of that HFC for use in a different application from the one that was intended. This is an outgrowth of the statutory restriction placed on application-specific allowances that they be for the exclusive use in the application for which the allowance is provided. If an entity could procure HFCs with the application-specific allowance, but then freely sell that HFC on the open market, that would seem to create a loophole to the restriction placed on the use of the application-specific allowance. EPA is allowing the intra-application sale of material (*i.e.,* among companies within the same application), since such a sale would be consistent with the exclusive use limitation.

3. What criteria is EPA using to evaluate application-specific allowance requests?

This section explains how EPA will evaluate application-specific allowance requests for five of the six applications: Propellants in MDIs; defense sprays; structural composite preformed polyurethane foam for marine use and trailer use; etching of semiconductor material or wafers and the cleaning of CVD chambers within the semiconductor manufacturing sector; and onboard aerospace fire suppression. The approach for mission-critical military end uses is discussed in the next subsection of this notice. As discussed earlier in this section, EPA has been collecting information from entities that use HFCs in the applications listed in the AIM Act, including a detailed description of how the HFCs are used so EPA can determine whether the use is consistent with the definition of the application. EPA will use that information to determine the full quantity of allowances necessary, based on projected, current, and historical trends, for the production or consumption of HFCs for the exclusive use of the regulated substance for each application, on a company-specific basis. Starting with allocations in October 2022 for calendar year 2023, and in further future years, a company's calculated use in a given year would be based on the quantities acquired in that year for application-specific purposes minus amounts sold to or transferred to another entity for their application-specific use plus the decrease (or minus the increase) in inventory for application-specific uses from the prior year. For the initial five years after enactment of the AIM Act, EPA is finalizing its proposed approach of issuing application-specific allowances by multiplying the company's HFC use in the prior year by the higher of:

—the average growth rate of use for the company over the past three years; or

—the average growth rate of use by all companies requesting that type of application-specific allowance (*e.g.,* for MDIs) over the past three years.

As discussed further below, EPA is taking a slightly different approach for the initial allocation in 2022. For companies that experienced negative growth based on their submitted data from 2018 to 2020, in an application that also experienced a negative growth rate, the Agency will allocate allowances equal to the highest quantity of HFCs reported over the three years from 2018 to 2020. As further explained later in this section, EPA is also finalizing its proposal to allow for consideration of individual circumstances factually documented to the Agency (*e.g.,* when a company projects growth due to acquiring another company or it installs new manufacturing capacity that will open in the following year). EPA also took comment on whether to consider gross domestic product or United States population growth rates in determining allocation levels.

One commenter from the defense spray industry stated that the information request for 2018–2020 data gave an incomplete picture of their usage history and would not accurately depict their usage over the next five years. They requested instead that EPA consider the time period of 2015–2020 as it is more representative of historical and future HFC usage. EPA responds that for EPA's final approach, allocation requests will be considered annually based on the most recently available data and the Agency will consider certain individual circumstances that are factually documented. This approach will provide a more accurate estimate of future growth than relying on five years of data to support projections for future growth. Combining a three-year timeframe with consideration of individual circumstances provides a more accurate projection as it reflects change in near-term growth and will be more sensitive to changes in growth than a longer time horizon.

Several commenters, particularly from MDI, semiconductor, and structural composite preformed polyurethane foam manufacturers, stated that consideration of only gross domestic product or population growth would not fully capture the different types of growth within each of the applications. The commenters requested that EPA also consider company-specific factors or individual circumstances. Specifically, comments from semiconductor manufacturers stated

that historical linear growth does not account for unique growth patterns. Some of these commenters referred specifically to increased demand, construction of new fabrication plants, expansions at existing facilities, and newer and more complex semiconductor technologies that increase HFC usage on a per-wafer production basis. MDI manufacturers commented that EPA should consider broader factors such as disease prevalence.

As stated previously, EPA proposed that it could consider individual circumstances factually documented to the Agency. The Agency agrees with the commenters that supported this approach and is finalizing the proposal that EPA may consider individual circumstances when allocating application-specific allowances. This will inherently be a fact-driven and case-specific inquiry. EPA is establishing the following circumstances as potentially meriting an increased allocation to an individual company beyond historical growth rates: (1) Additional capacity will come on line in the next year, such as a new manufacturing plant or expanded manufacturing line; (2) a domestic manufacturer or some of its manufacturing facilities has been acquired; and (3) a global pandemic or other public health emergency increases demand for use of HFCs in an application, such as an increase in patients diagnosed with medical conditions treated by MDIs. These scenarios could provide reasons to increase allowance allocations to affected companies in the affected years. If a company wants to make a claim that it is deserves individualized treatment due to one of these exceptional circumstances, those circumstances must be shown to the Agency with sufficient documentation. Ultimately, accommodating individual circumstances that are fully documented and proven will help the Agency fulfill Congress's mandate that EPA ''allocate the full quantity of allowances necessary.''

A couple of commenters asserted that EPA's proposed approach to issuing application-specific allowances seems overly generous. The comments suggested that EPA should not over-allocate, and instead consider releasing any unused application-specific allowances as set-aside allowances for heating, ventilation, air conditioning, and refrigeration (HVACR) uses that may have trouble transitioning to reduced HFC use and consider unused allowances in the evaluation of future allowance allocations to the six application-specific uses. EPA agrees that it should not over-allocate application-specific allowances, but, for the reasons provided elsewhere in this section, has determined that the approach being finalized in this rule is appropriate to meet the Congressional directive to allocate the amount necessary for these applications based on historical, present, and future needs. EPA recognizes that it is possible that companies could be eligible for general pool and application-specific allowances. To avoid overallocation, EPA will take into account any allowances a company receives from the general allowance pool when issuing application-specific allowances. If a company historically imported HFCs for its own use in an application listed in subsection (e)(iv)(B) of the AIM Act, EPA would decrease the number of application-specific allowances allocated to that company by an amount equal to their general pool allowances. This process helps to ensure companies are not overallocated allowances for application-specific use.

Since application-specific allowances will be allocated on an annual basis, it is not feasible to collect and reissue ''unused'' allowances or place those in a set-aside pool. If an application-specific end user does not use all allowances allocated to them, those allowances will expire at the end of the calendar year. To the extent that an end user does not use all allowances allocated, or has regulated substances for application-specific use stockpiled in inventory at the end of the calendar year, EPA intends to take these factors into account in the following year's allocation. Further, if all companies within the same application have a negative growth rate over the prior three years (with the exception of the initial allocation), the company's allocation would decrease.

One commenter asked that EPA create a separate additional pool of allowances that would be available only to the semiconductor manufacturing sector to accommodate growth, new mid-year entrants, and under-allocation of application-specific allowances. EPA responds that an additional set-aside is unnecessary because the Agency is allocating the full quantity of allowances necessary, based on projected, current, and historical trends, for the production or consumption of HFCs in each of the statutorily identified applications. The Agency is basing application-specific allowances on the average annual growth of a company or sector multiplied by the use of HFCs in the prior year, as well as accounting for unique circumstances. Over-allocating or setting additional allowances aside just in case reduces the allowances available to general allowance holders and will reduce how much HFC can be imported or produced if there are unexpended allowances. As noted above, one of EPA's considerations when establishing the allocation system is to avoid issuing allowances to companies that cannot or will not use them. EPA is finalizing a reasonable approach to provide amounts necessary based on historical, current, and future trends.

With regard to the concern about under-allocations, EPA responds that the Agency is allocating allowances annually, rather than over multiple years, and based on a company's annual submissions of purchase and inventory data. This reduces the risk of under-allocating in comparison to projecting needs over longer periods, in which the impact of inaccurate growth rates would grow each year. EPA can also learn from the implementation of this program and can consider adjusting its methodology for subsequent application-specific allocations if the Agency has determined it has taken either an overly generous or restrictive approach. Further, there is nothing prohibiting a company from accessing HFCs from the open market and then requesting allowances for the next year. If a company did use more HFCs in a given year, that increased use would be reflected in the next year's allocation.

Some commenters requested a process that gives companies an opportunity to challenge EPA's application-specific allowance allocations if they believe the Agency has erred in its calculation or made an improper allocation. One commenter asked EPA to establish a process for companies to quickly challenge (and for the Agency to reconsider) any application-specific allocation. Another commenter asked that EPA automatically grant all allocation appeals and then work with those companies to ensure that all appeals are supported with reasonable data.

EPA intends to issue application-specific allowances on October 1 of each year, including allocating application-specific allowances for 2022 on October 1, 2021, which is the same day the Agency will allocate general pool allowances. This timing is consistent with the statutory timeframe for determining the quantity of production and consumption allowances for the following calendar year and is intended to provide all companies with sufficient notice of their allocation levels before the start of the calendar year. EPA has proposed, taken comment on, and is

now finalizing the process by which it will determine the allocation level ''necessary'' for each application-specific company. Entities have the opportunity for judicial review of this framework methodology if they file a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit. If an application-specific end user disagrees with how EPA applies that framework in a future individual allocation determination, that individual allocation is also subject to judicial review. EPA disagrees with the commenter that suggested EPA should allocate to each application-specific user whatever they ask for, and later determine how to support that allocation with data. Congress charged EPA with determining what is necessary for the statutorily identified end uses, and EPA is using its discretion to establish the reasonable approach described in this rule for making those determinations.

EPA will endeavor to provide companies with ''necessary'' levels of allowances according to the framework provided in this section, but if unforeseen events occur such that EPA's determination is inaccurate, companies can obtain application-specific allowances through other means, such as through transfers. If a company's actual demand for HFCs exceeds the amount of application-specific allowances allocated to them, any company that uses HFCs in one of the six listed applications has other avenues for acquiring HFCs. The company may acquire application-specific allowances or HFCs from another application-specific allowance holder in their end use. If a company still seeks additional HFCs beyond the application-specific amounts, the company can also acquire calendar-year allowances from the general pool or purchase HFCs produced or imported with calendar-year production or consumption allowances. EPA is requiring reporting of additional material purchased beyond the amounts associated with application-specific allowances so that future year projections and allowances will reflect that historical use. EPA will make application-specific allocations on an annual basis, so each company's allocation will be revisited each year and may be adjusted upward (or downward) as appropriate.

With regard to the semiconductor industry, some commenters requested a ''loss allowance'' or multiplier to adjust for HFC losses during the purification process. Commenters provided different estimates of how much regulated substance is lost in the purification process, which ranged from five to 10 percent. EPA agrees that such a multiplier is appropriate for allocations to semiconductor manufacturers. Semiconductor manufacturers will need to confer their allowances up a supply chain, and it is appropriate for them to have sufficient allowances to cover the full amount of regulated substances that must be imported or produced such that after the purification process (during which a certain percentage of the regulated substance is lost) the semiconductor manufacturer is given the amount of regulated substances necessary for their manufacturing process. Such an approach would allow semiconductor manufacturers to receive the ''full quantity of allowances necessary.'' Therefore, EPA is finalizing a 10 percent purification loss allowance, the higher end of the range, to ensure they receive the amount that is necessary. This purification process is unique to the semiconductor industry and therefore a similar multiplier is not needed for the other applications listed in the AIM Act.

EPA requested comment on whether the Agency should distinguish between misuse and proper use when evaluating ''the full quantity of allowances necessary'' for defense sprays. Recent news reports indicate there may be use that is inconsistent with the labeling in the product (*i.e.,* use of bear spray on people instead of bears).[50] One commenter stated that allowances provided for defense sprays should be limited to an amount sufficient only for ''appropriate uses.'' Another commenter acknowledged news reports indicating potential product misuse of bear sprays, but stated that this misuse cannot be addressed through this rulemaking. EPA is not finalizing an approach to allocating application-specific allowances for defense sprays that bases estimates of ''necessary'' allowance levels only on proper use, as it does not have sufficient information on misuse of defense sprays in order to adjust the allocation approach at this time. EPA will continue to monitor this issue and will consider whether use inconsistent with the labeling can be better documented and accounted for when allocating allowances for this application.

For the initial 2022 application-specific allocations, EPA is finalizing the following approach to issuing application-specific allowances to companies: For companies that experienced positive growth based on their submitted data from 2018 to 2020, the Agency will (1) calculate a company's growth rate from 2018–2019; (2) calculate a company's growth rate from 2019–2020; (3) average the growth rates calculated from steps 1 and 2; (4) multiply the average growth rate by the company's 2020 purchases of EVe-weighted regulated substances for application-specific use to determine an estimated level of allowance need for 2021; and (5) multiply the estimated level of 2021 need by the average growth rate to estimate need for 2022. The number calculated in step 5 will generally be used to allocate application-specific allowances to a company for 2022. EPA determined a company's historic HFC usage based on responses to EPA information requests, invoices, sales records, GHGRP reporting, supplier data, and other information available to the Agency. This amount was used to estimate both the growth rate and 2020 purchases of regulated substances for each company. For companies that experienced negative average annual growth based on their submitted data from 2018 to 2020, in an application that also experienced a negative growth rate, the Agency will allocate allowances equal to the highest quantity of HFCs on an EVe-weighted-basis reported over the three years. EPA also took into account information provided on individual circumstances (*e.g.,* public health emergency). EPA will use this approach for 2022 because the Agency recognizes that 2020 was an unusual year given economic disruptions due to the global pandemic. For 2023–2025, EPA will use the approach detailed at the top of this section for all companies requesting application-specific allowances. Under this approach, if a company and all the companies that apply for allowances in that application experience negative growth, a company would receive fewer allowances than in the prior year.

For the calculation of average growth rate, EPA will use the average annual growth rate formula, which is the growth rate between the first and second year plus the growth rate between the second and third year, divided by two. EPA will look at growth rate by using purchase data for application-specific uses for the initial allocation given that the Agency received disparate numbers on company use data. In the future, EPA intends to adjust for net change in inventory from purchase data as the Agency is requiring reporting on annual inventory data prospectively.

Some commenters cautioned against allocating allowances based on

[50] Briley, John. ''Bear Spray Is Showing up at Protests and Riots. Here's Why, and How It Affects Humans.'' *The Washington Post,* 19 Mar. 2021. Available at *www.washingtonpost.com/lifestyle/wellness/bear-spray-pepper-riot-dangerous/2021/03/19/053c3870-87fb-11eb-bfdf-4d36dab83a6d_story.html.*

unsubstantiated data. EPA has gone through a rigorous process to verify data that will be used for 2022 allocations and intends to continue to verify data used to determine application-specific allocation levels. If future information reveals a company applying for application-specific allowances has provided false, inaccurate, or misleading information, EPA reserves the right to adjust allowances downward (in the same year or a subsequent year) at a greater level than the number of application-specific allowances allocated, prohibit companies from receiving future allowances if it has made false, inaccurate, or misleading statements to the Agency or there is noncompliance with relevant legal and regulatory requirements, and pursue any other appropriate enforcement action. One commenter asked EPA to clarify that a company submitting false data is also subject to criminal liability and to make clear that the Agency can prohibit a company submitting false information from receiving future allowances. If a company has made false, inaccurate, or misleading statements to the Agency, EPA can apply administrative consequences consistent with the discussion in Section IX.A. Regardless of whether or not EPA applies an administrative consequence, EPA may also pursue any and all appropriate enforcement action.

4. How is EPA issuing application-specific allowances for mission-critical military end uses?

EPA proposed to issue application-specific allowances for mission-critical military end uses directly to DOD. EPA also stated in the proposal that the approach described earlier in this section would be for the other five applications covered by subsection (e)(4)(B)(iv), recognizing an inherent difference with the way the regulation would apply to mission-critical military end uses. EPA requested information from DOD on its preliminary estimates of annual usage quantities of HFCs for mission-critical military end uses including historical and projected trends in usage, to the extent this information is available. DOD's response to that letter was included in the docket for the proposed rule and states that due to the Armed Forces' multiple sources of supply for HFCs used in mission-critical applications, there is no consolidated and comprehensive HFC usage data for DOD. The different sources of supply include Defense Logistics Agency industrial gas support contracts; contractor-supplied material from numerous acquisition, procurement, maintenance, and repair contracts; and local purchases from commercial sources. The letter further provided information on historical estimates of mission-critical annual usage and preliminary estimates of projected need over the next five years, and noted that DOD would continue collecting information to close data gaps, reduce data uncertainty, and identify any additional HFCs that may have been missed in the initial data collection.

EPA is finalizing its proposal that all mission-critical military application-specific allowances will be allocated to DOD. Therefore, only DOD may request allowances for such uses, unless the use is covered by one of the other five application-specific uses authorized in subsection (e)(4)(B) of the AIM Act. EPA did not receive adverse comment on this proposal. EPA is also clarifying that while the allowances would be allocated to DOD, those allowances may be conferred to DOD's contractors and, in the case of Direct Commercial Sales, companies manufacturing military equipment. In addition, DOD may confer application-specific allowances for a mission-critical military end use to another agency of the Federal Government responsible for national defense *for that agency's mission-critical military end use* without being subject to the offset required of transfers of allowances in that section.

Given the complex nature of the way DOD sources and uses HFCs for mission-critical applications, EPA's proposed approach for the other applications would not be appropriate for DOD. DOD's April letter identified mission-critical refrigerant and fire suppression uses spanning multiple services. The use occurs at multiple sites and by multiple entities (*e.g.,* at federally run and contractor facilities). This network of use is significantly larger and more complicated than for the companies that are eligible for application-specific allowances in other end uses.

Additionally, DOD's data on historical uses is less robust and more complicated to compile than for companies in the other end uses. DOD will need to track and manage its use of HFCs more comprehensively going forward, but basing its allocation on growth over the past three years is not feasible at this time. There are also national security implications that may necessitate a different approach (*e.g.,* if there is an unexpected conflict where equipment using HFCs is needed).

Recognizing these factors, EPA is finalizing a different approach to determining the number of allowances needed for mission-critical military end uses. EPA is requiring that DOD request allowances annually on the same timeline as other application-specific allowance holders. DOD needs to provide the amount of HFCs needed for mission-critical military use by chemical and specify the broad categories of use similar to what they provided in their April 7, 2021, letter. EPA and DOD will work together to ensure the amount necessary is available for mission-critical military applications, discuss key drivers for any change in the amounts needed, and understand DOD's plans for managing inventory and deploying recycled and/or reclaimed HFCs in mission-critical military end uses, where appropriate. EPA is also finalizing different auditing and recordkeeping and reporting provisions to account for DOD-specific considerations, including potential national security concerns. A full discussion of auditing requirements can be found in Section IX.D, and a full discussion of recordkeeping and reporting requirements can be found in Section X.

D. What are the provisions for transferring allowances?

Subsection (g) of the AIM Act directs EPA to issue rules that govern the transfer of allowances. EPA is establishing transfer provisions in § 84.19 as proposed.

In order to transfer allowances, the transferor must first provide EPA with a transfer claim setting forth the following: The identities and contact information of the transferor and the transferee; the type of allowances being transferred (*i.e.,* production, consumption, or application-specific allowance); the quantity (in EVe) of allowances being transferred; the total cost of allowances transferred; the remaining quantity of allowances held by the transferor; and the quantity of the offset. For transfers of application-specific allowances, the transferor must also include a signed document from the transferee certifying that HFCs produced or imported with these allowances will only be used for the same application they were initially allocated for.

EPA will then certify with records in its possession that the transferor has unexpended allowances sufficient to cover the transfer claim. Based on comments received on the proposed administrative consequences (see Section IX.A), EPA will also ensure that both parties to the transfer are not subject to an administrative consequence that would preclude them from transferring or receiving

allowances. EPA will issue either an objection notice or non-objection notice to the transferor and transferee within three working days of receiving a complete transfer claim. The transfer cannot proceed until EPA issues a non-objection notice. If after issuance of a non-objection notice the Agency finds that the transferor did not have sufficient unexpended allowances to cover the transfer and required offset, the transferor and transferee, where applicable, will be held liable for any violations of the regulations of this subpart that occur as a result of, or in conjunction with, the improper transfer.

In cases where EPA issues an objection notice disallowing the transfer, either the transferor or transferee may file a notice of appeal, with supporting reasons, with the relevant Agency official within 10 working days after receipt of the objection notice. The official may affirm or vacate the disallowance. If no appeal is filed electronically by the tenth working day after notification, the disallowance shall be final on that day.

EPA does not intend to broker transactions but rather confirm that the transferor has sufficient allowances to cover the transfer and neither party is disallowed from engaging in transfer activity. As proposed, EPA is collecting information on the price of allowances transferred to inform future analyses of rule costs and provide additional insight into the market when assessing potential regulatory changes and future allocation options. As discussed in Section X.C.2, EPA will not release individual or transactional price data.

Subsection (g)(2) of the Act requires that the regulations the Agency is required to promulgate governing the transfer of allowances ''ensure that the transfers under this subsection will result in greater total reductions'' in the production or consumption ''of regulated substances in each year than would occur during the year in the absence of the transfers.'' In other words, the transfer of allowances must result in less overall production or consumption than would have occurred absent the transfer. The AIM Act specifies that the transferor's allowances be reduced by an amount greater than the amount of allowances being transferred. EPA is finalizing use of a mandatory offset on all transfers to accomplish this statutory directive.

EPA proposed to allow transfers of allowances for HFCs provided the transferor's remaining allowances are reduced by the amount it transferred plus five percent of the amount transferred (*i.e.,* an offset). EPA took comment on a range of offset values from one percent to 10 percent for the transfer of production and consumption allowances. Some commenters recommended that EPA maximize the environmental benefit of this provision by establishing an offset of 10 percent. Others commented that the offset should be 1 percent or 0.1 percent so as to not restrict the trade of allowances as determined by the market. Some said that the added ''tax'' or ''fee'' on transferring allowances could lead to fewer tolling agreements and thus less efficient production of HFCs. Some commenters suggested these lower values are appropriate because they follow past practice with transfers of ODS.

EPA is finalizing a five percent offset as proposed on the transfer of production and consumption allowances. The AIM Act provides significant discretion to EPA in choosing an appropriate offset level. EPA has considered the public comments on this issue and has determined that five percent is the right value to balance the interest from some commenters in a net environmental benefit without implicating other commenters' concerns of creating an overly burdensome requirement that would discourage trading necessary to meet market demands. A 10 percent offset could result in less net environmental benefits than a five percent offset by discouraging trading because an offset could be so high that no trading occurs and thus no allowances are offset.

As discussed in the proposal, an EPA analysis of HCFC inter-company transfer data for 2010 through 2018 found that between five percent and 30 percent of consumption allowances were transferred each year. If this level of transfer activity holds under this allowance allocation program, a five percent offset would likely result in a reduction in the total allowances in the general pool by 0.25 percent to 1.5 percent. Given that small size, EPA's consideration for the size of the offset, at this time, pertains more to the effect on an individual company and less on the impact to the market overall. As the phasedown progresses, EPA may revisit the size of the offset.

EPA disagrees with the reasons raised by commenters for using a lower offset level. While commenters made broad claims that a five percent offset requirement would be overly burdensome on trades or cause market disruptions, such claims were unsubstantiated, and EPA received no data from commenters that a five percent offset will prevent an allowance holder from engaging in the transfer of allowances. Allowances are issued to companies at no cost; transferors retain 95 percent of the value of something provided for free if they choose to transfer those allowances. Furthermore, allowances are not a property right of the allowance holder and EPA has been directed by Congress to require an offset if companies choose to transfer those allowances. EPA is sensitive to the concern that this could negatively impact tolling agreements. Existing tolling agreements are already reflected in the allocation because the allocation is based on what a company produced, irrespective of whether it was produced for the producing company or as part of an arrangement (*e.g.,* tolling agreement) with another company. EPA will continue to monitor whether there is an impact on future tolling agreements as the market shifts to a different mix of lower-GWP HFCs.

With regard to the comment that EPA should use 1 percent or 0.1 percent since those were the offsets in the ODS phaseout, EPA responds that looking at past practice under the CAA is informative, but not controlling for a rulemaking under the AIM Act. The AIM Act does not specify a percentage nor does it provide criteria for establishing the offset. EPA has considered the effects of HFCs on public health and welfare, the impact of offsets on the transferring parties, and the impact of offsets on the supply of HFCs to the market, and finds that a five percent offset is reasonable. Further, unlike the chemical-specific allocation system for HCFCs, EPA is issuing allowances on an exchange value-weighted basis thereby negating the need to transfer allowances between regulated substances. This is an important distinction from the ODS phaseout, where such transfers were required to repurpose allowances across chemicals regardless of whether the allowance transfer took place within a company or with another company.

EPA proposed to establish a lower offset level for application-specific allowances, given that these allowances are intended to be allocated based on end users' need. EPA intends to provide application-specific end users with the level of allowances ''necessary'' in the initial allocation, but in the event an entity needs to transfer away or acquire additional application-specific allowances, EPA has determined that it is appropriate to allow that to happen with a lower offset level. Therefore, EPA is finalizing as proposed an offset of one percent for transfers of application-specific allowances.

Commenters stated that application-specific uses should have no offset or an

offset of 0.1 percent given the importance of these end uses. EPA agrees that the AIM Act prioritizes these end uses, but also interprets subsection (g) to apply generally to all transfers of allowances. EPA does not have the ability under the statutory language to allow application-specific allowance transfers to occur without any offset transfer. An offset of 0.1 percent would not provide sufficient environmental benefit while a 1 percent offset would while also not being so burdensome as to discourage trading. Because EPA is issuing the full quantity of allowances necessary to each end user, the Agency anticipates that the amount of allowances transferred will be minimal.

One commenter asked EPA to allow for transfers of application-specific allowances without an offset in the event a subsidiary spins off of a parent company and continues to use HFCs in a specific application. EPA agrees that requiring a transfer and an offset in such a situation would not be needed. EPA's experience is that this type of activity is rare. Historically, under CAA title VI, the Agency treated this type of situation as a change in company name and/or ownership. An authorized official at the company transferring the allowances would have to make a formal request to EPA for the transfer. This approach would apply for any change in company ownership. However, EPA retains discretion to deny such requests based on the circumstances of the particular request or to request additional information before granting the request. Circumstances where EPA would consider denying such requests include but are not limited to if a company requests this treatment more than rarely, if the new company has overlapping ownership, if the allowance holder receives allowances consistent with this final rule as a new market entrant, or if there are indications of fraud. As discussed, application-specific allowances can be conferred to an importer, producer, or intermediaries in the supply chain without any offset. The conferral of allowances is not a transfer but rather an actualization of the allowance (*i.e.,* a use of the allowance for production or consumption) by an end user that is not a producer or importer. Because Congress made clear in subsection (e)(4)(B)(iv) of the Act that the statutorily listed applications should receive the amount of allowances necessary, based on projected, current, and historical trends, EPA is allowing these conferrals as part of the inherent process of ensuring end users can receive the necessary amount of HFCs.

E. How is EPA establishing the set-aside pool of allowances?

EPA proposed to establish a small set-aside pool of allowances for a limited set of end users and importers that would not otherwise qualify for allocations, in light of the relatively new and novel nature of the HFC allocation phasedown framework established in this rulemaking. While it is reasonable for this initial allocation period to largely allocate allowances to companies that are currently in the market of producing or importing HFCs, this approach could be a barrier to new market entrants. In addition, the AIM Act is still relatively new legislation and not all entities already operating in the HFC market, particularly those that have not been historically required to report to the GHGRP, may have been immediately aware of Congress's direction to begin regulating the HFC market. These entities may not have responded to EPA's multiple data requests. It is therefore appropriate, as a transitional measure, to establish a set-aside pool of consumption and production allowances as proposed.

EPA proposed to issue 5 to 15 MMTEVe of allowances for this set-aside pool. Based on comments and review of submitted data, EPA is finalizing a set-aside pool of 7.5 MMTEVe (less than 3 percent of allowances to be allocated for 2022) to accommodate the potential requests for application-specific allowances that were not timely received and the high level of interest in allowances for new market entrants. As noted previously, EPA is establishing an allowance allocation framework in this final rule for 2022 and 2023, but will promulgate another rulemaking for allowances for 2024 and beyond based on the Agency's experience implementing this rule and stakeholder feedback.

1. Who is eligible for allowances in the set-aside pool?

The set-aside pool is restricted to three groups of companies: (1) End users in applications identified for allocations under subsection (e)(4)(B)(iv) of the AIM Act that EPA has not identified for the initial allocation of allowances (*i.e.,* the allocation called for by October 1, 2021); (2) importers of HFCs that have not been required to report through the GHGRP under 40 CFR part 98, where EPA has not learned of their past imports in time to issue allowances as part of the general pool despite the Agency's best efforts; and (3) importers that are new market entrants.[51] EPA is finalizing its proposal not to establish a set-aside pool for companies looking to newly enter as producers of HFCs because the Agency does not wish to encourage the construction of new HFC production capacity in light of the statutory HFC phasedown.

Multiple commenters supported the set-aside generally and one commenter opposed the general concept of a set-aside pool of allowances, in particular a pool of allowances for new market entrants. The commenter asserted that a set-aside pool is neither authorized by the AIM Act, nor was EPA's rationale for its creation supportable. The commenter stated that implementing the AIM Act in a similar manner to title VI of the CAA would provide for a seamless transition, and that EPA's rationale for a set-aside where a distinction can be drawn between a phaseout under title VI of the CAA and a phasedown under the AIM Act is incorrect, as there are certain exemptions available under title VI of the CAA that in practice, do not demonstrate a phaseout. The commenter concluded that if EPA were to promulgate a set-aside pool, that it should be limited to no more than 5 MMTEVe as a one-time allocation and limited in scope and duration.

As noted elsewhere in this notice, Congress provided broad authority to EPA to establish an allocation system to phase down HFC production and consumption, and EPA concludes that creating a limited set-aside pool is within the scope of its discretion under the Act to determine a reasonable approach for allocating allowances. While EPA has noted in many instances that it is appropriate to rely on and build from the Agency's experience in implementing the ODS phaseout under title VI of the CAA, there is nothing in the AIM Act to suggest that EPA is required to create an identical allowance allocation system. For reasons explained previously, it is appropriate in this first implementation phase to allocate the majority of allowances to producers and importers that are currently in the HFC market. However, for the reasons discussed in this section, it is also reasonable to set aside a small quantity of allowances for those who may have been caught unawares or are new market entrants. Long term, EPA will revisit whether additional set-asides are needed in future years. After reviewing comments on the creation of a set-aside pool of allowances, EPA is finalizing the set-

[51] EPA proposed that new market entrants must be small businesses as defined by the Small Business Administration. For reasons explained later in the preamble, the Agency is broadening the eligibility criteria for new market entrants.

aside pool for these three types of entities.

a. Application-Specific End Users

EPA is finalizing the proposal to provide priority access to the set-aside pool to end users in the applications identified in subsection (e)(4)(B)(iv) of the Act. Not all end users may be aware of EPA's regulatory activity regarding HFCs, and providing a set-aside pool will help end users in the statutorily identified applications access the necessary allowances. EPA did not receive any comments that opposed providing priority access to application-specific end users to the set-aside pool of allowances. Therefore, EPA is finalizing the structure that provides priority access to companies operating within one of the application-specific uses. EPA will calculate a company's allocation of application-specific allowances from the set-aside pool in the same manner as the allocation of application-specific allowances from the general pool as shown in Section VII.C. EPA will issue only 2022 allowances to these application-specific end users from the set-aside pool. EPA expects these entities to apply for 2023 application-specific allowances in the same manner as all other application-specific allowance holders.

b. Previously Unidentified Importers

EPA explained in its proposed rule that the Agency would provide second priority access to allowances from the same set-aside pool to importers that currently import HFCs, but were not previously required to report to GHGRP and were not identified in time to be included in the general allowance pool. EPA proposed to not include producers because all HFC producers were required to report to the GHGRP. EPA did not receive significant adverse comments against its proposal, so is finalizing the creation of a set-aside pool from which allowances may be issued for these previously unidentified importers of HFCs to the extent EPA can verify their historical import levels. Similar to the application-specific allowances, allowances for these importers from the set-aside pool will be allocated in a level equivalent to what the importer would have been eligible to receive through the general pool of allowances in accordance with Section VII.B. Consistent with the proposal for general pool allowances, companies that did not import in 2020 will not be considered under this group. However, they can apply to be a new market entrant. EPA will issue only 2022 allowances to these importers from the set-aside pool. These entities will receive allocations through the general pool for 2023 in a manner and level that is consistent with other general pool allowance holders.

c. New Market Entrants

After allocations to the two previously discussed groups, EPA proposed to provide access to any remaining allowances in the set-aside pool to new market entrants seeking to import HFCs in line with the criteria described later in this subsection. EPA is finalizing the approach of establishing a set-aside pool and granting tertiary access to consumption allowances to new importers of regulated substances. EPA proposed to limit the set-aside pool of allowances to owners of companies, not operators or designated agents, and that businesses applying to be a new market entrant cannot be a subsidiary of or have any common ownership stake or familial relationship with another allowance holder. One commenter suggested that EPA expand the subsidiary, common ownership stake, and familial relationship exclusion proposal for new market entrants to cover companies that were recently affiliated with existing allowance holders, as this would prevent existing allowance holders from attempting to unfairly manipulate the system by re-acquiring a new market entrant. EPA agrees and is finalizing this criterion alongside the others described in this paragraph.

EPA proposed that allowances will be issued to these new market entrants for both 2022 and 2023 at the same time in the same quantity for both years. EPA is clarifying that allowances will be issued on October 1, 2022 for calendar year 2023. As noted elsewhere, EPA intends to revisit the overall process for allocating allowances for 2024 and beyond.

As explained previously, EPA recognizes that in allocating the vast majority of allowances based on historical activity in the HFC market, EPA may inadvertently create market barriers to companies looking to newly enter the HFC market. There is no prohibition in general on a new entity importing HFCs, but they would need to have an allowance in order to do so. EPA is providing these allowances free of charge to historical HFC market participants for 2022 and 2023, but absent a set-aside pool, new entrants would need to acquire a transferred allowance, which they would likely have to purchase. During the HCFC phaseout, EPA heard from some small businesses that they had been unable to source material from domestic suppliers in sufficient quantity and/or at a competitive price. EPA heard similar concerns from small and large businesses during the comment period. To mitigate the potential for similar challenges and allow businesses experiencing such challenge to import HFCs directly without the additional step of purchasing allowances, EPA proposed to establish a new market entrant set-aside pool. Given that the AIM Act contemplates continued production and consumption of HFCs following the mandated phasedown of HFC production and consumption in the United States, EPA finds that it is appropriate to facilitate participation by new market entrants in the HFC import business, at least at this early stage as the HFC market transitions to the Congressionally mandated phasedown. However, it is also reasonable to facilitate participation only by entities who show a demonstrated interest and ability to make use of allowances.

Several commenters expressed support for, and an interest in, applying to EPA's new market entrant set-aside pool. One commenter noted that in certain niche end uses, such as fire suppression, access and supply of necessary HFCs with higher GWPs from producers or importers may be unavailable and/or prohibitively expensive as the phasedown continues. The commenter stated that qualifying as a new entrant would provide the flexibility to import needed HFCs directly and ensure future availability.

EPA proposed limiting access to the new market entrant set-aside pool to small businesses, but is not finalizing this limitation. All types of businesses that are new entrants and meet the other criteria being finalized here will be eligible to apply for allowances from the set-aside pool. EPA reviewed comments received on this issue and did not see a strong basis in the record to limit access to small business participants. One commenter noted that they would be interested in applying to the new market entrant set-aside pool but were not a small business so they would not be eligible under EPA's proposed approach. EPA has determined that it is not appropriate, at this time, based on public comments received, evidence available in the record, and the Agency's knowledge of the HFC market, to limit access to the new market entrant set-aside pool to only businesses that meet certain characteristics. However, the Agency will continue to monitor the HFC market and if there are distortions or barriers to entry for certain types of businesses or individuals, EPA retains the discretion to target allowance allocations more narrowly in the future.

To support the proposed rulemaking, EPA conducted a preliminary review of HFC importers and HCFC allowance holders (available in the docket) and solicited comment on whether any individuals have experienced structural barriers inhibiting their earlier access to the HFC import market, including if there was difficulty entering the HFC import market based on criteria such as business location, employment of socially or economically disadvantaged individuals, or other criteria related to business ownership, employee characterization, or business location. As explained in the proposal and reiterated here, the Agency is concerned that certain businesses historically have and could continue to experience difficulty entering the HFC market because of barriers in the form of systemic racism or sexism, and the Agency continues to be interested in collecting the information requested in this paragraph to better understand whether such issues are affecting entry into this market and to explore future opportunities to ensure a more equitable marketplace. In reviewing comments received during the public comment period, EPA has not identified records that would indicate that certain businesses have historically and could continue to experience difficulty entering the HFC market as a result of structural barriers or social or economic inequities.

Broadening the eligibility for new market entrants seeking to import HFCs does not mean that EPA is dismissing certain groups and/or giving deference to other groups. Consistent with our position in the proposed rule, EPA encourages applications from businesses that had challenges entering the HFC import market due to systemic racism, market-access barriers, or other challenges particularly faced by minority- and woman-owned small businesses. EPA is mindful of the Executive Order on Tackling the Climate Crisis at Home and Abroad (Executive Order 14008), which calls for ''undertaking robust actions to mitigate climate change'' and ''developing programs, policies, and activities to address the disproportionately high and adverse human health, environmental, climate-related, and other cumulative impacts on disadvantaged communities, as well as the accompanying economic challenges of such impacts. . . .'' (86 FR 7619, February 1, 2021). EPA will monitor and evaluate the market dynamics of the set-aside pool in 2022 and 2023, and if it appears that certain potential participants are experiencing barriers in accessing the new market entrant pool, or if information is identified and/or provided documenting such structural barriers specific to the HFC market, the Agency may revisit additional eligibility criteria for new market entrants in subsequent rulemakings.

In the proposed rulemaking, EPA sought comment on whether the Agency should limit new entrants to companies that have never previously imported HFCs. Several commenters provided suggestions on how EPA should define a ''new'' entrant. Some commenters urged EPA to consider new entrants as those who began importing HFCs after 2016, and others requested that EPA treat any company that had not imported for at least three full years prior to 2020 as new entrants. EPA responds that the provisions for new market entrants are, in part, intended for companies that are seeking to import HFCs for the very first time or only began or restarted importing HFCs after January 1, 2020. As explained elsewhere, EPA is allocating allowances for the general pool to companies based on the average of three high years in EVe from 2011–2019, provided that the company was still active in 2020. EPA's treatment of partial or incomplete years of data is explained in Section VII.B. A lack of a full three years of imports does not by itself indicate that the company is a new market entrant for purposes of access to the set-aside pool.

Several commenters urged EPA to exclude companies that had exited the import business that are now trying to re-enter via the set-aside pool, noting that allowing such companies to participate as new market entrants would be contrary to the goal of supporting entities that had not previously imported HFCs. One commenter recommended that EPA evaluate what it means to exit the market on a case-by-case basis. For example, a company may not have been actively importing in 2020 but may have still been in business and operating from previous inventory. Based on a number of factors, EPA is determining that a new market entrant seeking to import HFCs may also be one that had previously imported HFCs in any prior year but exited the business by 2020 and who did not otherwise qualify to receive allowances (*e.g.,* from the general pool). The factors supporting this determination include: The general eligibility criteria for company ownership and relationships; the 0.2 MMTEVe limit on allowances per new entrant (discussed in section VII.E.2. below) that effectively prevents a specific company or specific type of company from importing a disproportionate amount of HFCs; and the information required as part of the new entrant application process, including an HFC import plan with a named prospective foreign exporter.

EPA received comment expressing concern about allowing new entrants who may have no experience with U.S. environmental or customs laws. They note that new entrants have proliferated in Europe and that there are administrative challenges associated with tracking their imports and monitoring their compliance. EPA recognizes these concerns and is requiring that among other information, the company submit a plan for importing in its application, as well as provide the name and contact information for the prospective foreign exporter that the company intends to work with (see Section VII.E.4 for full discussion). Since these elements are required as part of the application process for new market entrant allowances, companies without a detailed import plan and a prospective foreign exporter will not be eligible to receive new market entrant allowances from the set-aside pool. EPA is also requiring companies include in their applications a certification that the information they have submitted is complete, accurate and truthful and companies must certify that they understand the regulatory requirements established in this rule and will comply with those requirements. Companies participating in the new market entrant pool will be subject to all the same requirements as other importers (*e.g.,* third-party independent auditing by a Certified Public Accountant (CPA), recordkeeping and reporting requirements, administrative consequences, batch testing and labeling requirements for imported HFCs, data transparency).

d. Suggested Additional Entities Eligible for Set-Aside Allowances

Some commenters urged EPA to create additional set-aside pools of consumption allowances, up to 50 MMTEVe, to incentivize environmentally and/or climate friendly businesses. While multiple commenters made this point to EPA, none of them clearly defined the range of entities or activities that would meet this suggested new category other than being reclaimers and/or low-GWP refrigerant blenders.

Other commenters asserted that the proposed rule failed to satisfy the Agency's statutory obligations under the AIM Act in that EPA had not meaningfully considered ways to increase opportunities for reclaiming

HFC refrigerants, which commenters claimed was required by subsection (h)(2)(A) of the Act. Commenters suggested that EPA could fulfill its obligations, in part, by creating a separate set-aside pool of consumption allowances accessible only to reclaimers with specific suggestions for how those allowances should be managed and distributed. As explained in previous sections, EPA has determined that it is appropriate to allocate the majority of allowances to historical producers and importers in the HFC market with a small set-aside available to facilitate new entrants to the HFC import market. There are several reclaimers that import HFCs and thus are included in the general pool, while other reclaimers would be eligible for the new market set-aside pool. The commenters did not explain why it would be appropriate to take a significant share of allowances away from the general pool, and EPA is concerned that adopting this suggestion would inevitably lead to significant and potentially adverse disruptions in the HFC market. Abruptly shifting a large quantity of allowances from companies that are in the business of producing and importing HFCs to those that are not will strand existing supply chains, at least temporarily. While it is clear Congress has determined it is appropriate to phase down HFC production and consumption in the United States, it also opted to do so under a gradual schedule, presumably to allow the market time to transition into substitute chemicals.

EPA disagrees with some commenters' characterization of the language in AIM Act subsection (h)(2)(A) that the provision places a mandatory duty on EPA to prioritize helping reclaimers' needs over all others. The statutory language notes that ''[i]n carrying out this section, the Administrator shall *consider* the use of authority available to the Administrator under this section to increase opportunities for the reclaiming of regulated substances used as refrigerants'' (emphasis added). The Agency need not determine in this rulemaking whether this provision applies to this action—much less whether it establishes a requirement that may apply to other actions taken under the AIM Act—because even assuming that the commenters are correct that this provision creates a statutory obligation that applies to this rulemaking, the Agency has undertaken such consideration throughout this rulemaking process. Nothing in this statutory language requires that the Agency reach a certain result or use a certain mechanism; rather, it requires no more than that the Agency consider the potential to increase opportunities for reclamation of regulated substances used as refrigerants—and the Agency has done that in the context of this rulemaking, including in its consideration of these comments and potential responses to them. EPA notes that the HFC phasedown in and of itself will result in an increased reliance on reclaimed HFCs, regulated substances or blends with lower exchange values, as the volume of newly manufactured or imported HFCs continues to reduce consistent with the Congressionally mandated schedule. In particular, reclaimed material can be acquired through the expenditure of potentially zero allowances, given the AIM Act excludes reclamation from the definition of ''produce.'' Creating other set-asides, whether for reclaimers, Original Equipment Manufacturers (OEMs), or others, would also require determining details about scope, eligibility, and implementation that EPA does not have sufficient information at this time to consider such requests. The Agency is not prepared to do so without explicitly requesting comment—and receiving public input—on these topics. The Agency intends to evaluate further how it could continue to increase opportunities for reclamation under the AIM Act's authority in subsection (h)(2)(A) in future actions. EPA expects that it would evaluate options for increasing the supply of recovered HFCs for reclamation, as well as the demand for reclaimed HFCs. EPA will also review actions related to reclamation that are underway in California to see if similar types of regulation could be appropriate nationwide. In light of all of these considerations, EPA has determined that it is not appropriate at this time to create additional set-aside pools.

2. How large is the set-aside pool, and what are the applicable limits for applicants?

EPA based the proposed size of the set-aside pool on an analysis of new market entrants in 2017–2019 compared to 2011–2013. EPA stated in the proposal that it would be appropriate to establish a pool that roughly estimates the market shifts EPA has seen over this timeframe with additional allowances to accommodate for businesses that would have met EPA's criteria to be eligible for general or application-specific allowances, but were not identified in time. Accordingly, EPA proposed to establish a set-aside pool of 5 MMTEVe of consumption allowances taking comment on a range up to 15 MMTEVe for 2022. EPA also proposed to set aside 1 MMTEVe of production allowances, which can be used as application-specific allowances, for 2022.

Some commenters supported the concept of a set-aside pool of allowances but urged EPA to either retain the proposed 5 MMTEVe of consumption allowances, or decrease it to 3 MMTEVe. The latter suggestion was provided by a commenter as fully meeting the needs of the eligible applicants, while also providing additional stability to companies in the general pool. Many commenters requested that EPA expand the set-aside pool of consumption allowances to 15 MMTEVe. EPA has considered two related factors for informing our final decision. Based on information and data received from companies in the application-specific end uses, EPA may have underestimated the number of companies that were unaware of the HFC regulatory landscape and did not have an opportunity to submit relevant data in time for the Agency to consider for 2022 allowance allocations. In conjunction with the number of comments received on the proposal from companies that would be eligible as new HFC importers, EPA anticipates greater participation in the set-aside pool than initially contemplated. To improve the utility of the set-aside pool of allowances in meeting the objectives to accommodate the needs in order of priority for application-specific end users, previously unidentified importers, and new market entrants, EPA is finalizing the set-aside pool of consumption allowances at 7.5 MMTEVe. Given the number of companies that may be eligible for application-specific allowances, the Agency is also finalizing 2.5 MMTEVe of production allowances in the set-aside pool as EPA anticipates a higher number of application-specific allowances may be needed for 2022. EPA did not have data to support expanding the level of the pool further, and the Agency does not want to unnecessarily remove allowances from the general pool that will not be used. While some commenters suggested expanding the pool to 15 or even 50 MMTEVe, those commenters generally also suggested expanding the eligibility criteria to participate in the set-aside pool or creating multiple set-aside pools. As explained elsewhere in this section, the Agency is only allowing access to the pool for the following entities: (1) Application-specific end users not identified in time for the initial allowance allocation; (2) historical importers not previously

required to report to GHGRP that would have been eligible for an initial allocation, but were not identified in time for the initial allowance allocation; and (3) new market entrants.

As previously discussed, EPA is first issuing allowances within the set-aside pool to end users that are eligible for application-specific allowances in an amount equal to what EPA determines that end user would need. Second, EPA will issue allowances to historical importers that were not required to report to the GHGRP previously and would have been eligible for general pool allowances according to the formula shown in Section VII.B. Companies receiving allowances under this component of the set-aside will receive allowances as if they were in the general pool.[52] While anyone requesting allowances under this condition must have been below the 25,000 $MTCO_2e$ reporting threshold, there is not a discrete numerical cap on allowances that will be allocated for these companies per se, unless the full set-aside is exhausted by application-specific requests, which is unlikely. For the new market entrants of the set-aside pool, EPA proposed that each would be eligible for up to 0.2 MMTEVe in allowances. This value is based on the aggregated median quantity of AIM Act-regulated HFC imports (highest of 2017–2019 for ''new'' importers that did not also import in 2011–2013) reported to the GHGRP and scaled based on a common HFC blend, in $MMTCO_2e$. EPA sought comment on whether it should finalize a higher limit for companies other than those seeking application-specific allowances, up to 1 MMTEVe. While several commenters requested that EPA increase the maximum amount that new market entrants would be eligible for to the full 1 MMTEVe, or remove the limit altogether, EPA did not receive analysis or data that would reliably support a rationale to increase the maximum amount. A 0.2 MMTEVe consumption allowance limit should help to prevent any specific company or type of company from taking an undue share of the allowances available in the new market entrant pool and should retain a balance of allowances as available for several new market applicants. As noted earlier, EPA also wants to ensure that it is only allocating allowances to entities that are able to actually make use of the allowances in the quantity provided. Given that these entities are all new to the HFC import market, keeping their allowance allocation relatively modest is appropriate. Therefore, EPA is finalizing, as proposed, that each new market entrant in the set-aside pool would be eligible for consumption allowances of either 0.2 MMTEVe, or if the number of applications would lead to an exceedance of the remaining amount of allowances available, each applicant would receive consumption allowances on a pro rata basis. EPA notes again that nothing precludes entities from obtaining regulated HFCs that may be needed or desired from the open market or receiving transferred allowances from another entity.

3. How will transfers and unused allowances be treated in the set-aside pool?

EPA proposed a restriction that allowances issued from the set-aside pool are nontransferable, but is clarifying that this provision applies only to new market entrants. The Agency proposed this to ensure that applicants to the set-aside pool only request allowances they are able to use, and do not simply participate in the pool in order to sell the allowances on the open market. Some commenters voiced general support for the proposal, while others suggested that application-specific allowances should not be transferable, but previously unidentified importers and new market entrants should be allowed to participate in allowance trading, just like the general allowance holders.

EPA will allow application-specific allowance holders and previously unidentified companies that imported HFCs in 2020 and were not required to report under 40 CFR part 98 to transfer their allowances consistent with other application-specific and general pool allowance holders, respectively. The criteria for transfers are discussed further in Section VII.D.

There were also commenters that recommended EPA allow for transfer and sale of allowances from the set-aside pool for new market entrants, citing that having a restriction on sales or transfers would have two unintended consequences: Small businesses may try to immediately purchase HFCs to capitalize the value of allowances before they expire, and small businesses may have to purchase and stockpile HFCs for future use before cashflow may justify it. EPA responds that an allowance is a temporary privilege for production and/or consumption. The purpose of the set-aside for new market entrants is to issue allowances to companies that wish to import HFCs and would not otherwise receive allowances under the general pool. EPA strongly encourages companies to request a quantity of allowances that they can successfully import by December 31, 2022. While EPA appreciates that importing would likely be new for these companies, that is why the Agency is requiring prospective new market entrants provide a detailed plan for importing HFCs and name a prospective foreign exporter that those companies intend to work with. Companies will have to consider the lead time, cost, and overall investment needed to import HFCs prior to submitting an application. Further, EPA is not reducing allowances to new market entrants in 2023 for failing to use all the allowances issued in 2022. Allowing for transfers for new market entrants on the other hand, would create an opportunity for a company to request allowances with the sole interest of selling them to another company, and not entering the import market. That outcome would be completely inconsistent with the purpose of the proposed set-aside for new market entrants, and therefore EPA is finalizing, as proposed, that allowances for new market entrants are not transferable.

EPA also proposed that if there were fewer applicants for allowances such that 2022 allowances remain in the pool, EPA would redistribute them to the general pool of existing allowance holders on a pro rata basis by March 31, 2022. Alternatively, EPA stated in the proposed rulemaking that it could auction the remaining allowances by March 31, 2022.

Several commenters opposed an auction approach and cited that an auction system would represent a disproportionate burden on smaller allocation holders who may already be at a competitive disadvantage, and that an auction system could raise legal issues. On the other hand, several commenters supported an auction approach, citing that an auction system promotes transparency and ensures that all interested parties have an equal chance of access to unused allowances. EPA continues to be interested in how an auction structure for distributing allowances could potentially be integrated into future rulemakings. However, the cumulative efforts and resources that would be necessary to build, test, and successfully administer and implement an auction system by March 31, 2022, are not feasible. As a result, EPA is finalizing that any remaining allowances in the set-aside

[52] In the general pool, each company will receive the same percentage reduction from their high-year average determined in section 84.11. For set-aside allowances, EPA will determine each company's high value based on the approach described in Section VII.B and will then apply the same reduction percentage that all other general pool allowance holders receive from their high value to companies who are eligible from this component of the set-aside pool.

pool will be redistributed to the general pool of existing allowance holders on a pro rata basis by March 31, 2022.

4. What is the deadline to apply for allowances from the set-aside pool, and what information is required?

EPA proposed that companies would have until November 30, 2021, to apply for allowance allocations from the set-aside pool. The proposal also prescribed that entities that fall within the six statutorily identified applications in subsection (e)(4)(B)(iv), but did not initially receive application-specific allowances from EPA, would need to apply to EPA in the same manner as other application-specific end users by November 30, 2021. Similarly, EPA proposed that unidentified importers of HFCs who imported in 2020 and were below the GHGRP threshold of 25,000 $MTCO_2e$ would have to report their historical import and export, if applicable, data to the electronic Greenhouse Gas Reporting Tool (e-GGRT) by November 30, 2021.[53]

EPA proposed that new market entrant applicants must submit the following: (1) Name and address of the company and the complete ownership of the company (with percentages of ownership); (2) contact information for the owner of the company; (3) the date of incorporation and state in which the company is incorporated and state license identifier; (4) a plan for importing HFCs; and (5) a prospective foreign exporter that the applicant anticipates working with.[54] To prevent fraud and to ensure that these allowances go to new entrants in the HFC import business, EPA sought comment on whether there are other data it should request. EPA did not receive comments during the public comment period to support a record to alter our proposed provisions and requirements, and therefore the Agency is finalizing, as proposed, the information necessary to apply for allowances in the set-aside pool as a new market entrant.

EPA proposed that if future information reveals a company provided false, inaccurate, or misleading information or did not disclose financial or familial relationships between a new entrant and another allowance holder, EPA reserves the right to revoke allowances and require the company to retire a greater number of allowances than those received through the set-aside pool. EPA is finalizing this proposal, adjusting what it means to provide false information, consistent with the discussion in Section IX.A. As noted earlier, EPA is expanding the subsidiary, common ownership stake, and familial relationship exclusion for new market entrants to cover companies that were recently affiliated with existing allowance holders. Therefore, any future false, inaccurate, or misleading information, or not disclosing financial or familial relationships between a new market entrant and a recently affiliated allowance holder, could also result in EPA revoking allowances and requiring the company to retire a greater number of allowances than those received through the set-aside pool.

Recognizing that there may be some delay between signature of this final rulemaking and publication in the **Federal Register**, and that publication in the **Federal Register** serves as the official record and notification to potentially affected parties, EPA is finalizing that the deadline for applications to the set-aside pool of allowances is November 30, 2021. Consistent with the proposal, EPA is also finalizing the process that will allow the Agency to review all relevant data, conduct follow-up verification as needed, and issue allowances to applicants that meet the applicable criteria for each program no later than March 31, 2022.

VIII. What other elements of the AIM Act is EPA addressing in this rulemaking?

A. How is EPA addressing international trades or transfers of HFC allowances?

Subsection (j) of the AIM Act, titled ''International Cooperation,'' addresses the trade or transfer of production allowances between entities in the United States and foreign countries.[55] International transfers of production allowances allow for the production of a chemical to be consolidated at fewer plants in order to achieve economies of scale as demand shrinks and the HFC phasedown progresses. To implement this subsection, EPA must determine whether a country has ''enacted or otherwise established . . . the same or similar requirements or otherwise undertaken commitments regarding the production and consumption of regulated substances as are contained in'' the AIM Act. Under subsection (j)(4), EPA is required to promulgate a rule carrying out this subsection by December 27, 2021, and to review that rule at least annually and, if necessary, revise it.[56]

The statute uses the terms ''trade'' and ''transfer'' with respect to allowances in many parts of both subsections (g) and (j). While EPA has considered whether Congress intended ''trade'' and ''transfer'' to signify different actions with respect to allowances in these provisions, neither term is defined in the AIM Act and EPA cannot discern a consistent difference in how the terms are used in this context. EPA is therefore interpreting them as being used interchangeably.

In most instances, subsections (g) and (j) use ''transfer'' (either exclusively or alongside the term ''trade'') to describe the exchange of allowances between two entities. Subsection (j) uses the phrase ''trade or transfer'' throughout the subsection. However, (j)(2) and (3) exclusively use ''transfers'' in the paragraph titles, while using both ''trade or transfer'' and ''transfer'' in the text of both paragraphs. For example, (j)(2) permits the ''trade or transfer of a production allowance . . . if, at the time of the transfer'' certain conditions are met. There is one instance in subsection (g)(2)(C) where the AIM Act references trade alone in requiring that EPA's rule provide for ''the trading of consumption allowances in the same manner as is applicable [for] the trading of production allowances.'' In all other places in subsection (g), the term ''transfer'' is used exclusively, for example in (g)(1), which requires EPA to issue a rule that ''governs the transfer of [production] allowances.'' As Congress uses the term ''transfer'' more frequently when only one term appears in subsections (g) or (j), EPA finds it to be appropriate to use the term ''transfer'' in the AIM Act implementing regulations for all instances where the AIM Act contemplates ''trades'' or ''transfers.'' Hereinafter, EPA refers to ''trade or transfer'' as used in subsection (j) of the AIM Act as ''transfers'' for simplicity.

In relevant part, subsection (j)(1) of the Act prohibits any company subject to the AIM Act's requirements from transferring a production allowance to a company in a foreign country that, as determined by EPA, has not established the same or similar requirements within a reasonable time from the Act's

[53] Forms available at *https://ccdsupport.com/confluence/display/help/e-GGRT+and+HFC+Data+Reporting+related+to+AIM.*

[54] EPA also proposed to include demographic data related to the ownership and employees at the company. EPA is not finalizing these requirements.

[55] Subsection (j)(1) also addresses exports. In particular, after January 1, 2033, it prohibits the export of a regulated substance to a person in a foreign country if EPA determines that the country has not undertaken certain actions regarding the production and consumption of regulated substances. Given the timing of this prohibition, EPA does not address this aspect of subsection (j)(1) in this rulemaking.

[56] These reviews will be completed through an internal procedure, but EPA would engage in notice and comment rulemaking to revise the regulations.

enactment or otherwise undertaken commitments regarding the production and consumption of HFCs as are contained in the Act. Subsection (j)(2) describes specific conditions that must be satisfied for a company in the United States to transfer a production allowance to—or from—a company in a foreign country. Such a transfer to a company in a foreign country may occur if at the time of the transfer EPA revises the number of production allowances for the United States so that the aggregate national production of the regulated substance to be transferred is equal to the least of three different levels, which are described below. Similarly, such a transfer may occur from a company in a foreign country to a company in the United States if, at the time of the transfer, EPA finds that the foreign country has revised its domestic production limits of the regulated substance in the same manner. EPA also has discretion under subsection (j)(3) to reduce the United States' production limits as a prerequisite to a transfer to a company in a foreign country, or to increase the United States' production limits to reflect production allowances transferred from a company in a foreign country to a company in the United States.

The regulations that EPA is finalizing to implement the AIM Act's international transfer provisions are structured similarly to the provisions governing international transfers under the ODS phaseout (see 40 CFR 82.9(c) and 82.18(c)). When a transfer request is submitted, EPA will review whether the foreign country where the foreign company is located meets the conditions of subsection (j)(1) and is therefore eligible to participate in transfers of production allowances to or from the United States.[57] If the foreign country does not meet the conditions in subsection (j)(1), EPA would notify the requestor in writing that no transfers to or from the country can occur.

If EPA determines that the foreign country meets the conditions in (j)(1) of the Act, it will consider whether the applicable requirements in subsection (j)(2) of the AIM Act are met. For transfers to a foreign country, a company in the United States may engage in the transfer under subsection (j)(2)(A) if at the time of the transfer EPA revises the number of production allowances such that the aggregate national production of the regulated substance to be transferred is equal to the lesser of three values listed in subsection (j)(2)(A)(i)–(iii):

- The maximum production level permitted under the AIM Act for the applicable regulated substance in the year of the international transfer minus the production allowances transferred;
- the maximum production level for the applicable regulated substances that are allowed under applicable law minus the production allowances transferred; or
- the average of the actual national production level of the applicable regulated substances for the three years prior to the date of the transfer minus the production allowances transferred.

In relevant part, subsection (j)(2)(A)(i)–(iii) of the AIM Act refers to the ''applicable regulated substance'' and ''applicable regulated substances,'' such as in the phrase ''the maximum production level permitted for the applicable regulated substance in the year of the transfer . . . , less the production allowances transferred.'' Since EPA is issuing allowances as an exchange value-weighted amount and not as a chemical-specific quantity, allowance holders could use all their allocated production allowances for any one chemical. As such, if a company transfers production allowances to a foreign country, EPA considers the ''maximum production level permitted for the applicable regulated substance in the year of transfer'' to be the same as the maximum allocation listed in § 84.7(b), which is an exchange value-weighted amount. EPA will take the same approach of weighting amounts based on exchange values when considering the levels consistent with (j)(2)(A)(ii) and (iii). As the production allowances transferred would also be accounted for in terms of the exchange value-weighted units, the reduction would be appropriately reflected in the total.

EPA is finalizing the process wherein a company in the United States seeking to transfer allowances (*i.e.,* the ''transferor'') must provide EPA with a signed statement requesting that EPA revise the number of production allowances consistent with the requirements of subsection (j)(2)(A)(i)–(iii). EPA will determine which is the lesser of the three values. The transferor also needs to submit information on the contact person and foreign country authorizing the transfer; the chemical and quantity being transferred; documentation that the foreign country possesses the necessary quantity of unexpended production rights; and the calendar year for that transfer.

EPA sought comment on whether it should additionally require approval by a foreign country or some other documentation from the foreign country verifying it can increase allowable production in the relevant calendar year if EPA approves the transfer, or whether an application for such reduction or other official government communication from the foreign country's embassy in the United States is sufficient. For these transfers, the allowance revisions for the company in the United States would be reflected at the individual transferor level, which would have the effect of revising the number of allowances for production under subsection (e)(2) of the Act for the United States, and which reflects EPA's interpretation of requirements under subsection (j)(2)(A). EPA received one comment in favor of requiring prior approval from the foreign country to ensure the country is informed and avoid what the commenter called environmental dumping. EPA responds that the Agency will not require prior approval of an official representative of the foreign country because there are some countries that require EPA to make a decision before they consider the request. EPA disagrees that the foreign country will not be informed of the transfer as an official representative at the foreign embassy in the United States must approve of the transfer.

In reviewing submissions for transfers to a company in a foreign country, EPA will consider whether the transfer and revised production limits meet the requirements in subsection (j), as discussed above. EPA is also defining other factors the Agency could take into account in considering whether to approve such transfers. Under the CAA title VI implementing regulations in 40 CFR part 82, subpart A, EPA has the discretion to take factors into account relating to possible economic hardships created by a transfer, potential effects on trade, potential environmental implications, and the total amount of unexpended allowances held by entities in the United States. For the AIM Act regulations, there is value in having discretion to consider the environmental implications, since there could be an environmental benefit or cost associated with the international transfer that could influence EPA's decision making. EPA is finalizing its proposal to consider environmental benefit and the total unexpended allowances held by entities in the United States, given that EPA cannot

[57] In the ODS context, EPA developed a list of countries that had domestic regulatory requirements in place regarding the production and consumption of ODS. Given the limited number of international transfers of production allowances that EPA saw under CAA title VI, EPA does not presently anticipate that a list will be necessary to implement these provisions. EPA may consider whether to implement such a list at a future time, such as when the Agency starts implementing the January 1, 2033, export prohibition in subsection (j)(1).

approve a transfer if there were insufficient allowances to transfer.

Two commenters urged EPA to include the same considerations as in title VI of the CAA when making a decision to approve an international transfer of production allowances and one recommended that consideration of at least economic hardships and environmental implications be mandatory and not discretionary. One of those commenters, expanding on environmental considerations, suggested that EPA limit transfers to where production capacity is consolidated (*e.g.,* a specific production line turned off in location A and capacity increased from an existing production line in location B). Nor, the commenter said, should EPA allow the transfer of excess HFC allowances from a country exceeding its phasedown schedule into the United States as that would lead to an overall increase in production. EPA responds that it is finalizing regulatory text giving the Agency discretion to consider, as appropriate possible economic hardships created by a transfer, potential effects on trade, potential environmental implications such as the ones raised by the commenter, and the total amount of unexpended allowances held by entities in the United States. EPA is retaining its discretion to consider these factors rather than making them mandatory as they may not all be appropriate in all circumstances.

For transfers from a foreign country, subsection (j)(2)(B) of the Act provides that the company in the United States may engage in the transfer if EPA finds that the foreign country has revised their domestic production limits of the regulated substances in the same manner as for transfers by a company in the United States. Accordingly, EPA is finalizing its proposal to require the company to submit a signed document from an official representative in that country's embassy in the United States stating that the appropriate authority within that country has revised the domestic production limits for that country equal to the least of:

- The maximum production level permitted under the AIM Act for the applicable regulated substance in the year of the international transfer minus the production allowances transferred;
- the maximum production level for the applicable regulated substances that are allowed under applicable law (including the country's applicable domestic law) minus the production allowances transferred; or
- the average of the country's actual national production level of the applicable regulated substances for the three years prior to the date of the transfer minus the production allowances transferred.

Consistent with subsection (j)(2)(B) of the Act, these three situations are intended to align with the provisions in subsection (j)(2)(A)(i)–(iii) of the Act. As noted above, subsection (j)(2)(A)(i)–(iii) of the AIM Act refers to the ''applicable regulated substance'' and ''applicable regulated substances,'' such as in the phrase ''the maximum production level permitted for the applicable regulated substance in the year of the transfer . . . , less the production allowances transferred.'' As proposed, if the country uses an exchange value-weighted system similar to what EPA is finalizing in this action, this phrase should have the same meaning as for transfers from the United States to another country. If a foreign country has established chemical-specific production levels, this phrase is interpreted to mean the production level for the particular regulated substance involved in the transfer. In such a scenario, the production allowances transferred will be translated into exchange value-weighted amounts for purposes of tracking compliance with obligations under the AIM Act. EPA will take the same approach when considering the levels consistent with (j)(2)(A)(ii) and (iii). If the foreign country has established a different domestic regulatory approach, EPA will need to consider on a case-by-case basis how best to review this condition to ensure that requirements of the AIM Act are met.

Language in (j)(2)(A)(i) that establishes one of the thresholds for determining the reduction in production allowances refers to the maximum production level permitted ''under this section'' for the applicable regulated substance in the year of the international transfer. As proposed, EPA is interpreting this language as restricting international transfers from a foreign country to situations in which the country has revised their production limits to establish a phasedown schedule at least as stringent as that in the AIM Act. As noted above, under subsection (j)(2)(B), EPA must find that the country has revised the domestic production limits ''in the same manner'' as provided for transfers by a company in the United States to a company in a foreign country for the transfer to occur. One requirement for such transfers to a foreign country in (j)(2)(A) is that the number of allowances for production under subsection (e)(2) of the Act must be revised downward such that national aggregate production is equal to the lesser of one of three values, one of which is the maximum production level permitted ''under this section'' for the applicable regulated substance in the year of the international transfer. EPA is finalizing its proposed interpretation that subsections (j)(2)(A) and (j)(2)(B) be read together to mean that Congress intended for the international transfer provisions only to apply to countries that have revised their production limits to establish a phasedown schedule at least as stringent as the AIM Act's. All commenters on this topic agreed that in order to meet the environmental goals of the AIM Act, transfers must only be with countries that have phasedown schedules that are the same or more stringent than in the AIM Act.

For international production allowance transfers to a company in the United States, the company must provide EPA with a request that includes: The contact person and foreign country authorizing the transfer; the chemical and quantity being transferred; the calendar year for that transfer; and a signed statement describing whether the increased production is intended to allow the company in the United States to serve the export market or to serve the United States market. This information is helpful to EPA because once the transfer is complete, the Agency will treat production allowances transferred from a foreign country the same way as all other production allowances issued by EPA. As such, a production allowance and a consumption allowance must be expended for each unit of HFC produced, though if the amounts are later exported, the consumption allowances may be reimbursed.

For both transfers from and to foreign countries, EPA, following review, will notify the requestor in writing that the appropriate production allowances were either granted or deducted and specify the affected year(s), provided EPA determines the request meets the required conditions. In approving an international transfer, EPA will notify the transferor in writing of the appropriate revisions to a transferor's allowance balance at the time of approval. For transfers from a foreign country, the Administrator will notify the requestor in writing that the allowances of that company are revised to equal the unexpended production allowances held by the company plus the level of allowable production transferred from the foreign country. EPA will not adjust available allowances until the foreign country's representative has confirmed the appropriate number of allowances were deducted in the foreign country.

The AIM Act does not limit the quantity of production allowances that may be transferred to a foreign country. EPA sought comment on whether to include a provision like the one used under the implementing regulations for international transfers for ODS under CAA title VI giving the Administrator the option to disapprove the proposed transfer if the transfer is not consistent with domestic policy. EPA also sought comment on what policies might be relevant in this context. Additionally, EPA proposed that it would deny the transfer if the transferor did not possess sufficient allowances to permit the necessary reduction in aggregate domestic production to be reflected in the transferor's revised production limits. EPA did not receive comments on these points and is finalizing provisions allowing EPA to disapprove the proposed transfer if the transfer is not consistent with domestic policy or if the transferor does not possess sufficient allowances.

If EPA approves the proposed transfer, EPA will establish revised production limits for the transferor so that the aggregate national production permitted reflects the effect of the transfer of production allowances. In certain circumstances, following a transfer of allowances to another country, the AIM Act requires that the total United States production of the HFC to be transferred be reduced by an additional amount beyond a simple deduction of the number of allowances transferred to another country. For instance, if the average actual United States production during the three-year period prior to the date of the transfer is less than the total allowable United States production for that substance under § 84.7(b), then by the time of the transfer, United States production would need to be revised downward to equal the three-year average minus the amount transferred. This additional reduction would also need to be reflected in the revised production limit.

EPA requested comment on whether there are any other scenarios where a greater reduction would be needed. EPA did not receive comments on this point. Thus, EPA is finalizing as proposed to conclude that it would be appropriate for the required reduction in United States production to be allocated among all the transferors participating in international transfers in the same calendar year in proportion to the number of allowances transferred by each entity. This approach is fair, as it treats every company equally based on the total number of allowances transferred. To ensure EPA does not need to revise allowances if companies submit their requests at different times, *e.g.,* one company submits a request by February 1 and another on September 1, EPA is finalizing its proposal that all requests for international transfers of production allowances be submitted by October 1 of the year prior to the year the transferred allowances would be usable. If there is only one transferor, the reduction will be applied exclusively to that company. EPA will notify each transferor of the revised production limit before January 1 and the allowances will be usable as of January 1 for the full calendar year. The transfers will be deemed to occur as of January 1, the date the transferor's production limit is revised and the allowances are usable, for purposes of determining the three-year period under this analysis. The transferor will then be able to make timely market decisions with the remaining production allowances. EPA will rely upon the three most recent calendar years' worth of data. For example, if a request were submitted by October 1, 2022, EPA will rely upon data from January 1, 2019, through December 31, 2021, to determine the average of the actual national production level over the last three years (as specified in subsection (j)(2)(A)(iii)). While the AIM Act states the Agency should use the average production level for the ''three-year period ending on the date of the transfer,'' such data for the year ending on the date of transfer would generally not be reported until 45 days after the end of the quarter, and then would need to be reviewed by EPA for accuracy. Further, EPA does not know the timing for the availability and/or release of another country's data. Thus, EPA is implementing this provision through the three most recent calendar years' worth of data.

To determine the transferor's balance of production allowances after a transfer to a company in a foreign country, the Administrator will determine which of the values under (j)(2)(A) of the Act leads to the lowest value and adjust allowance balance(s) accordingly.

Given the discussion at the start of this section explaining how ''transfers'' is used in (g) and (j) of the Act, and that EPA is interpreting references to that term as synonymous with references to ''trade,'' the Agency is also applying the requirement in subsection (g)(2) to international transfers. Subsection (g)(2) of the Act specifies that EPA's regulations shall ensure that transfers ''will result in greater total reductions in the production of regulated substances in each year than would occur during the year in the absence of the transfer.'' The Agency concludes that it is reasonable to view (g)(2) of the Act as applying equally to all transfers. This is consistent with the requirement under (g)(1) that EPA promulgate a regulation that ''governs the transfer of allowances for the production of regulated substances under subsection (e)(3)(A)'' of the Act. As the international transfers under (j)(2) would affect the production allowances issued under subsection (e)(3)(A), it is reasonable to apply those requirements to international transfers as well. This approach will also result in an additional benefit for the environment than would occur absent the transfer, consistent with (g)(2).

B. What HFC destruction technologies is EPA approving?

The AIM Act in subsection (b)(7) defines the term ''produce'' to exclude the destruction of HFCs if the destruction occurs through use of a technology approved by the Administrator. This section lists destruction technologies that would be considered approved for purposes of the AIM Act.

Many destruction technologies previously approved by EPA to destroy ODS have also been found capable of destroying HFCs to a minimum destruction and removal efficiency (DRE) of 99.99 percent.[58] There are three broad categories of destruction technologies: Thermal oxidation (incineration), plasma, and conversion (other, non-incineration) technologies. EPA finds that technologies that destroy HFCs to a DRE of 99.99 percent are appropriate to list for approval under the AIM Act. As proposed, EPA is finalizing two lists of destruction technologies: One for HFCs other than HFC-23, and one for all HFCs including HFC-23 given that HFC-23 is harder to destroy than other HFCs. Commenters supported the creation of two lists, noting that not all destruction technologies need to be able to destroy HFC-23 as it is rarely contained in mixtures with other HFCs.

There are twelve destruction technologies capable of destroying HFCs other than HFC-23 to a DRE of 99.99 percent. They are:

- Incineration (6 technologies): Cement kilns, gaseous/fume oxidation, liquid injection incineration, porous thermal reactor, reactor cracking, and rotary kiln incineration.

[58] 2018 TEAP Report, Volume 2: Decision XXIX/4 TEAP Task Force Report on Destruction Technologies for Controlled Substances. March 15, 2021. Available *at https://ozone.unep.org/sites/default/files/2019-04/TEAP-DecXXIX4-TF-Report-April2018.pdf.*

• Plasma (3): Argon plasma arc, nitrogen plasma arc, and portable plasma arc.
• Conversion (3): Chemical reaction with hydrogen (H_2) and CO_2, gas phase catalytic de-halogenation, and superheated steam reactor.

Eight of those technologies are capable of destroying HFC-23 to a DRE of 99.99 percent. They are:

• Incineration (4): Gaseous/fume oxidation, liquid injection incineration, reactor cracking, and rotary kiln incineration.
• Plasma (2): Argon plasma arc and nitrogen plasma arc.
• Conversion (2): Chemical reaction with H_2 and CO_2 and superheated steam reactor.

These technologies provide a variety of technological options for the destruction of HFCs and are capable of either destroying HFCs at a DRE of at least 99.99 percent or converting them into non-regulated substances. The Agency intends to consider approving additional destruction processes in the future if further technologies are developed.

C. What is EPA requiring for HFC-23 emission controls?

As discussed in the Section V, the creation of a regulated substance beyond insignificant quantities inadvertently or coincidentally created in five specific circumstances [59] is considered ''production.'' Such production, whether intentional or unintentional, would generally require the expenditure of production and consumption allowances unless the regulated substance is timely destroyed. This subsection discusses narrowing this general approach for HFC-23. Specifically, as further explained in this section and the proposed rule, given the extremely high exchange value of HFC-23, EPA is exercising its significant discretion to determine that production and consumption allowances cannot be expended for HFC-23 production if that HFC-23 is emitted rather than being captured and either destroyed or sold for consumptive use. Put another way, if a facility produces HFC-23 and emits that HFC-23 onsite beyond the numerical standard established in this final rule, production and consumption allowances cannot be expended to cover the generation of the HFC-23, and the facility will be deemed to have undertaken production of HFC-23 without an accompanying expenditure of allowances in violation of the AIM Act and the regulations established in this rulemaking. Instead of being emitted, HFC-23 must be captured and controlled to a specific standard stated later in this subsection. Entities can either destroy the HFC-23 or expend production and consumption allowances to capture, refine, and sell it for consumptive uses.

One commenter noted that EPA is relying on its discretion as opposed to direct statutory language in the AIM Act for the HFC-23 controls being finalized here. EPA responds that the AIM Act itself provides EPA with discretion in how to establish an allowance allocation system. EPA is exercising this discretion to only allow production and consumption allowances to be expended for HFC-23 if the HFC-23 is refined and sold for consumptive uses, such as in semiconductor etching or refrigeration at very low temperatures. EPA understands that some HFC-23 is unintentionally created as a byproduct in chemical production processes and vented to the atmosphere.[60] EPA is finalizing its proposal that allowances created through the AIM Act cannot be expended for HFC-23 that is vented. The AIM Act makes clear in subsection (e)(2)(D)(ii) that a production allowance is a ''*limited* authorization for the production . . . of a regulated substance'' (emphasis added). An entity that creates HFC-23 would need to capture the HFC-23 and either (1) expend production and consumption allowances to sell that HFC-23 for consumptive uses or (2) destroy the captured HFC-23 using a technology approved by the Administrator. After reviewing public comments, EPA is finalizing this approach as proposed, and is not finalizing the alternative proposal.

This approach is consistent with Congress's intent for phasing down, maximizing reclamation, and minimizing the release of regulated substances under the AIM Act. Congress identified HFC-23 as a regulated substance under the AIM Act. In the Congressionally provided table in subsection (c) of the Act, HFC-23 is assigned the highest exchange value of any regulated substance (14,800), indicating that Congress was well aware of the potential impact of this substance and intended for it to be regulated on that basis. This exchange value is almost 5,000 more than the next closest regulated substance (HFC-236fa at 9,810). As further outlined in a memo to the docket, EPA has data available through the GHGRP indicating that there are at least four facilities that intentionally manufacture regulated substances or substances controlled under title VI of the CAA and emit HFC-23. Existing data suggest that absent control, there may be significant emissions of HFC-23 at facilities that incidentally generate HFC-23. A new production line or new chemical manufacturing process in the future could generate HFC-23, which absent regulation could be vented in an uncontrolled manner. Because HFC-23 has a significantly higher exchange value than any other regulated substance under the AIM Act, EPA is finalizing the prohibition on expenditure of production and consumption allowances on HFC-23 that is emitted.

EPA acknowledges that it is not possible for owners and operators to control their facilities such that no HFC-23 is emitted. EPA further understands that facilities that do not currently control their HFC-23 sufficiently will need time to install and calibrate necessary equipment to capture and control HFC-23 being produced on facilities' lines. Therefore, through this rule EPA is requiring facilities to control HFC-23 to what the Agency has determined to be a level and on a timeline that is practicable. As explained further in the supporting documentation provided in the docket, facilities that are anticipated to be covered by this regulatory requirement are already taking steps to control, capture, and/or destroy their HFC-23 emissions. As further documented in the memo to the docket, some facilities are already controlling at or below the standard EPA is requiring in this rulemaking. EPA used this real-world experience, in addition to conversations with the known affected facilities, analysis of available control technologies, and analysis of expected costs of controls provided in the RIA, to determine that the numeric emission standard finalized here is practicable. Specifically, EPA is finalizing a requirement that beginning on October 1, 2022, as compared with the amount of chemical intentionally produced on a

[59] EPA received comment that HFC-23 can be incidentally created at some semiconductor manufacturing facilities. EPA understands that the amounts of HFC-23 generated at semiconductor manufacturing facilities are very small and would meet the threshold of what EPA intended to exclude from production as an ''insignificant quantit[y].'' As explained further in that section, EPA is finalizing regulatory language that ''insignificant quantities'' of regulated substances inadvertently or coincidentally generated at semiconductor manufacturing facilities are excluded from the definition of ''production'' under the AIM Act.

[60] See, *e.g.,* ''Fluorinated Greenhouse Gas Emissions and Supplies Reported to the GHGRP.'' EPA, 24 Feb. 2021. Available at *https://www.epa.gov/ghgreporting/fluorinated-greenhouse-gas-emissions-and-supplies-reported-ghgrp#production.*

facility line, no more than 0.1 percent of HFC-23 created on the line may be emitted. Put another way, no more than 0.1 kg of HFC-23 may be emitted per 100 kilograms of the primary chemical produced by such facility line. After such point, emissions of HFC-23 byproduct that exceed the 0.1 percent will be treated as violations of an applicable emissions limitation in violation of federal law and subject to any appropriate enforcement action.

One commenter expressed confusion about how the chemicals would be measured to determine whether the emissions standard was met. EPA responds that the 0.1 percent allowable emissions standard is mass based, with the mass of the intentionally produced substance as the comparison point. In other words, if a line is intentionally producing 1,000 pounds of HCFC-22 over a certain time period, only one pound of HFC-23 could be emitted over that same time period.

One commenter suggested that EPA codify this numeric emission limitation by defining the specific chemicals that are intentionally produced along with the HFC-23 in its regulations. EPA responds that HFC-23 is unintentionally produced at a few different facilities that are intentionally producing different chemicals. It is also possible that in the future, HFC-23 could be produced during a currently unknown chemical manufacturing process. Therefore, EPA is keeping the requirement generic, and not limiting it to specific chemicals, in order to cover production of HFC-23 at any chemical manufacturing facility. For similar reasons, EPA is not adopting the commenter's suggestion that EPA provide a more specific metric for measuring the required level of emissions by using a standard based on relative measurement of emissions.

Another commenter suggested that EPA revise its standard to be based on a reduction in total emissions volume, as opposed to a standard that is related to intentional chemical production. The commenter noted that the orientation of the emission standard is such that the public may lack an ability to track and evaluate what is happening, based on EPA's historical approach to withhold data on chemical production. EPA responds that the Agency is finalizing the emission standard as proposed because if the emission limit was just framed in terms of a set reduction from a certain historical point, the facility could simply reduce production on a line to meet the emission target, as opposed to installing more stringent controls on the production line. Conversely, if a facility increased production of the intended chemical, they would not be limited in that production change by a much more stringent emission limit. Tying the limit to intentional chemical production should ensure the facility is held to a consistent standard regardless of whether production of the intended chemical increases or decreases in a given year. An emission reduction standard also would not address future facilities that may produce HFC-23 in future chemical manufacturing processes. As discussed further in Section X.C.1, EPA is making a determination that production data collected under the reporting requirements established in this rule is not entitled to CBI treatment. This should alleviate the commenter's concern about public access to the information needed to calculate whether facilities subject to the HFC-23 emission standard are meeting the requirements. Additionally, EPA will explore ways to provide data on its website to allow stakeholders to determine whether the HFC-23 standard finalized here is being met at all chemical manufacturing facilities that produce HFC-23.

EPA received a comment questioning what requirements would apply between January 1, 2022, and the emission standard compliance date, and whether allowances would be needed to cover HFC-23 produced and emitted before the compliance date. The commenter noted that the proposed rule was clear that allowances may not be expended for HFC-23 emissions, but still suggested that EPA allocate allowances to cover HFC-23 emissions between January 1, 2022, and the emission standard compliance date. EPA is not accepting the commenter's suggestion, and the Agency does not plan to provide allowances to cover HFC-23 emissions at any point. Such an approach is also counter to the Agency's prohibition on the expenditure of allowances for HFC-23 emissions. It would be impracticable to provide allowances from the general pool to cover such emissions given the incredibly high exchange value of HFC-23 and the very high level of historical emissions at the commenter's facility. The Agency's intent is that production and consumption allowances are not required—or even allowed—to be expended to cover HFC-23 that is generated and emitted until the emission standard compliance date. Put another way, starting January 1, 2022, production and consumption allowances must be expended for HFC-23 that is produced, refined, and sold for consumptive purposes (such as semiconductor etching and very low temperature refrigeration). Production and consumption allowances are not to be expended for any other HFC-23 produced. Starting October 1, 2022 (unless a compliance deferral is granted), HFC-23 emissions must be controlled to the specific numeric emission standard—as compared with the amount of chemical intentionally produced on a facility line, no more than 0.1 percent of HFC-23 created on the line may be emitted. A facility that meets these two requirements will be in full compliance with the AIM Act regulations being finalized in this rule.

As noted previously, HFC-23 that is captured can either be sold for a consumptive use after the producer expends necessary production and consumption allowances, or the HFC-23 must be timely destroyed (such that the producer would be exempted from needing to expend allowances for the HFC-23 production, as described in Section VIII.C). If a producer intends to be exempt from expending allowances because HFC-23 is destroyed, such destruction must occur using a technology approved by EPA as provided in section VIII.B. of this rulemaking and 40 CFR 84.29(b).

While October 1, 2022, should provide adequate time, circumstances could arise that make it impracticable for an individual facility to install and begin operating the necessary controls by October 1, 2022. Therefore, for companies that can sufficiently demonstrate to EPA that at the relevant facilities they have taken concrete steps to start to improve their HFC-23 control, capture, and destruction (such as purchase and installation of necessary equipment), are reporting under GHGRP, and provide information to EPA regarding their plans to meet the 0.1 percent HFC-23 emissions limit, EPA is finalizing that the Agency may grant a six-month deferral. EPA maintains the discretion to provide a one-time additional six-month extension, but anticipates granting a second deferral only in limited circumstances where a company has demonstrated immense hurdles in meeting the first deferral date. Companies must request a deferral by August 1, 2022, and EPA will make a determination on an application within 30 days. EPA's determination will be based on whether the company has demonstrated good-faith efforts to comply with the HFC-23 emissions reduction requirement, whether there are reasons that have necessitated compliance deferral, and whether there are clear plans for the company to come into full compliance by the deferred

date. If a company would like to seek a second deferral, such application must be received no later than February 1, 2022. A second deferral will be granted only in extreme circumstances. EPA intends to publicly announce any compliance deferrals granted under this process.

One commenter, who owns a chemical manufacturing facility that produces HFC-23 and currently has emissions above the standard being established in this rulemaking, expressed support for the extension approach EPA is finalizing here. Two commenters asked that EPA not provide any compliance date extensions, but did not provide sufficient technical analysis to explain why EPA providing extensions under the framework outlined was not justified or why it was improper to allow flexibility if a company experiences documented unavoidable delays in installing and calibrating control equipment. Therefore, the Agency is finalizing the deferral approach discussed in this section.

The destruction of captured HFC-23 is not required to occur at the same plant where the HFC-23 is generated. Destruction of HFC-23 may occur either at the plant where it is generated (onsite) or offsite at another plant. In instances where captured HFC-23 is destroyed offsite, transportation to and destruction at the offsite plant will be considered in calculating compliance with the 0.1 percent emissions standard.

One commenter suggested that EPA also prohibit the release of HFC-23 during the manufacture of HCFC-22 under CAA authority. The requirements finalized here relate to any production of HFC-23, whether it is produced alongside generation of another regulated substance or alongside generation of ODS, such as HCFC-22, or some other chemical in the future. The requirements flow from the production of HFC-23, which is a regulated substance under the AIM Act, and the emission standard finalized herein is not limited to instances where the chemical intentionally produced is also a regulated substance under the AIM Act. The EPA Administrator has signed a proposed rule with similar action to regulate HFC-23 emissions created during the production of HCFC-22 in a separate action using CAA authority. Any action EPA might take under the CAA is out of scope here.

IX. What enforcement and compliance provisions is EPA finalizing?

Based on EPA's experience with the ODS phaseout in the United States,[61] the global experience phasing out ODS,[62] and the recent experiences in countries that have begun phasing down HFCs,[63] the incentive to illegally trade HFCs will likely increase as HFC production and consumption become regulated and as allowances that authorize import and production of HFCs decline. It is EPA's intent to establish a comprehensive system of mechanisms that together and by themselves discourage and prevent illegal production, import, and subsequent sales of illegally produced or imported HFCs. EPA intends for, and has designed, these provisions to each stand independently from the others and to provide significant stand-alone benefits to deterring and identifying potential violations, while also recognizing that these separate provisions work together as a comprehensive system to deter noncompliance, incentivize future compliance, and ensure that companies that are complying with statutory and regulatory obligations are not put at a competitive disadvantage. These provisions also help to ensure the environmental benefits of the HFC phasedown are fully realized.

In developing these provisions, EPA reviewed in detail the challenges faced by the European Union (EU) in preventing illegal imports of HFCs. Assessments available in the docket from HFC producers, industry associations, and environmental non-governmental organizations provide evidence of significant noncompliance with the EU F-gas rule (Regulation (EU) No. 517/2014), which establishes a schedule to phase down HFC production and consumption over time, similar in concept to the HFC phasedown in the AIM Act, albeit on a different schedule. These assessments suggest that noncompliance in the EU occurs primarily through illegal imports, which can be grouped into two categories: (1) ''Open smuggling'' through the normal customs channels (*e.g.,* correct commodity codes without proper allowances to do so) and, (2) ''traditional smuggling'' where the importer seeks to avoid the typical customs channels altogether or where HFCs are concealed (*e.g.,* mislabeling). Reports show significant awareness in the industry of illegal activity. A 2019 report by the Environmental Investigation Agency (EIA) [64] provided results of surveys conducted with industry stakeholders in Europe. More than 80 percent of companies surveyed were aware of or suspected illegal HFC trade and 72 percent had seen or been offered refrigerants in disposable cylinders—a common feature of illegally imported HFCs given the EU requirement that HFCs be sold in refillable containers.

The review of European customs data presented in the EIA report and other studies support this perception. EIA found that ''bulk HFC imports in 2018 were too high for compliance with the 2018 quota.'' [65] EIA estimated that the amount of HFCs placed on the market in 2018 could be 16.3 $MMTCO_2e$ (or 16 percent) above the quota amount (*i.e.,* the amount allocated) through ''open smuggling of HFCs (*i.e.,* imports openly shipped through customs without quota).'' [66] Honeywell estimated that illegal imports were equivalent to more than five percent of the total CO_2-weighted quota in 2015. [67] The law firm

[61] See, *e.g.,* Goldberg, Carey. ''A Chilling Change in the Contraband Being Seized at Borders.'' *The New York Times,* The New York Times, 10 Nov. 1996. Available at *www.nytimes.com/1996/11/10/us/a-chilling-change-in-the-contraband-being-seized-at-borders.html* and ''Enforcement Actions under Title VI of the Clean Air Act.'' *EPA,* Environmental Protection Agency, 17 Dec. 2020. Available at *www.epa.gov/ozone-layer-protection/enforcement-actions-under-title-vi-clean-air-act#2011.*

[62] See, *e.g.,* Montzka, S.A., Geoff S. Dutton, G.S., Yu, P., Ray, E., Portmann, R.W., Daniel, J.S., Kuijpers, L., Hall, B.D., Mondeel, D., Siso, C., Nance, J.D., Rigby, M., Manning, A.J., Hu, L., Moore, F., Miller, B.R., and Elkins, J.W. (2018) ''An unexpected and persistent increase in global emissions of ozone-depleting CFC-11'' *Nature* 557: 413–417. Available at *https://www.nature.com/articles/s41586-018-0106-;2*; WMO (World Meteorological Organization), *Scientific Assessment of Ozone Depletion: 2014,* World Meteorological Organization, Global Ozone Research and Monitoring Project-Report No. 55, 416 pp., Geneva, Switzerland, 2014. Available at *https://www.esrl.noaa.gov/csd/assessments/ozone/2014/report.html*; Environmental Investigation Agency (EIA) (2018) Blowing It: Illegal Production and Use of Banned CFC-11 in China's Foam Blowing Industry. Available at *https://eia-global.org/reports/20180709-blowing-it-illegal-production-and-use-of-banned-cfc-11-in-chinas-foam-blowing-industry*; and Rigby, M. et al. ''Increase in CFC-11 emissions from eastern China based on atmospheric observations'' *Nature* 569 7757: 546–550. Available at *https://www.nature.com/articles/s41586-019-1193-4.*

[63] ''Doors Wide Open.'' *Eia-International.org,* Environmental Investigation Agency, Apr. 2019. Available at, *https://reports.eia-international.org/doorswideopen*; ''Resources.'' *Alliancepolicy.org,* The Alliance for Responsible Atmospheric Policy, 1 Nov. 2020. Available at, *www.alliancepolicy.org/ref-imports/resources-2.*

[64] ''Doors Wide Open.'' *Eia-International.org,* Environmental Investigation Agency, Apr. 2019. Available at *https://reports.eia-international.org/doorswideopen.*

[65] Ibid.

[66] Ibid.

[67] ''10m Tonnes of Illegal F-Gas Enters Europe.'' *Cooling Post,* 1 May 2016. Available at

King & Spalding, on behalf of the Alliance for Responsible Atmospheric Policy, found that reported imports to European customs officials exceeded the quota amount by 16 percent in 2019 and 33 percent in 2020.[68] The European FluoroCarbons Technical Committee (EFCTC) cited analysis of customs records performed by Oxera, which found a significant disagreement in trade data on HFCs shipped from China to the EU. Oxera created a database using data from the EU statistics agency Eurostat, the United Nations' trading statistics database Comtrade, and Chinese export data to calculate the amount of HFCs that were illegally imported (above the quota amount). They found that what was reported as exported from China alone was 16 percent higher than the amounts reported as imported into the EU during 2016, six percent higher in 2017, and 21 percent higher in 2018.[69]

These reports also indicate the likelihood of more covert smuggling activity, though the scale is not fully known. Reported seizures of illegally imported material in EU member states between 2018 and 2020 range from a few cylinders to more than 76 MT of HFCs.[70] These reports show significant growth in legal HFC imports from China into countries neighboring the EU. King & Spalding cites a 2020 report by Oxera showing a 40 percent increase in HFC exports from China to EU neighbor countries from 2016–2018.[71] They note the dramatic increase in 2018 coincides with a stepdown under the EU's HFC allocation program, and that the increase in legal imports to neighbor countries could be associated with smuggling HFCs into the EU. They also ''noted that various reports found smuggled imports [into the EU] were 20 to 30% of the quota.'' [72]

While not definitive, the reports note this growth may be because the HFCs are being illegally imported into the EU through neighboring countries, such as with fraudulent import declarations, disguised as something else, or through shipment in hidden compartments. The reports also note that illegally imported HFCs that are caught are shipped primarily in disposable cylinders. King & Spalding cites a report from an international investigation agency called Kroll, which was hired by the EFCTC to investigate HFC trade in the EU. In addition to finding that illegal HFCs travel through EU neighbor countries, illegal shipments are often sold through online market platforms or arrive through misdirected transhipments, allocation abuse, open smuggling, and counterfeit material.[73]

In summary, there is significant evidence of noncompliance with HFC quotas in the EU, which suggests that similar attempts will be made to evade legal requirements in the United States. By comparison, if the United States were to see similar noncompliance of 16 to 33 percent [74] of the total United States allocation, that would equate to 43–90 MMTEVe of additional consumption than should happen under the statutorily provided phasedown step for 2022 alone with accompanying long-term emissions and environmental and public health costs associated with that level of consumption. This level of noncompliance would put businesses complying with regulatory requirements at a competitive disadvantage and could inhibit companies from investing in research and development to identify new alternatives. In addition, illegal imports of HFCs have consequences for other federal agencies, such as CBP, that collect duties on imports of HFCs.

Consistent with the documented experience in the EU, EPA has also seen situations where material that appears to be illegally imported is advertised as one chemical, but the contents of the container are something different. EPA recently identified imports of CFCs that were advertised as ''Cool Penguin F-12'' (or CFC-12) in small cans for use in motor vehicle air-conditioners. [75] While the cans contained some CFC-12, they also contained an inconsistent mixture of numerous other chemicals, including R-40 (chloromethane) which is toxic and has the potential to explode. Given this experience with imports of fluorocarbons that are mislabeled, there are consumer and worker safety concerns.

Since the 1990s, there also have been important enforcement efforts to ensure the phaseout of ODS in the United States. Of note are two specific trade operations targeting illegal imports of CFCs and HCFCs: Operation Cool Breeze and Catch-22.

Operation Cool Breeze was designed to respond to the growing illegal trade of CFCs, after the 1996 phasout of certain CFCs listed under the CAA as class I ODS. EPA estimated that 7,500 to 15,000 MT of illegal CFC-12 were imported between 1994 and 1995. Operation Cool Breeze highlighted the importance of national coordination, cross-agency information sharing, customs trainings and awareness, and criminal prosecution. As a result, close coordination between EPA, CBP, and U.S. Department of Justice resulted in 44 prosecutions and the seizure of more than 862 MT of CFCs. The United States also relied on cooperation with counterparts in Mexico, Canada, China, and Russia to support international efforts to halt the illegal trade of CFCs.

Catch-22 was an outgrowth of Operation Cool Breeze. Catch-22 was an interagency trade operation to identify and prosecute those found to be illegally smuggling HCFCs into the United States. Similar to Operation Cool Breeze, Catch-22 relied on the cooperation and communication of several entities including EPA, CBP, DOJ, industry stakeholders, and counterparts in other countries. Catch-22 resulted in multiple criminal convictions including sentences of imprisonment, significant criminal fines, and forfeiture of illegal proceeds. Those prosecuted for knowing violations of federal law included bulk importers, wholesale purchasers, freight forwarders, importers of HCFC pre-charged appliances, as well as those falsely claiming import of reclaimed HCFCs.

The experience in the U.S. with regard to ODS, in the EU for HFCs, and the grounded belief that a similar scenario could come to fruition for HFCs in the United States calls for

www.coolingpost.com/world-news/over-10m-tonnes-of-illegal-F-gas-enters-europe.

[68] See King & Spalding, on behalf of the Alliance for Responsible Atmospheric Policy, Side Event presentation at COP12/MOP32 (November 23, 2020). Available in the docket and online at *https://www.alliancepolicy.org/site/usermedia/application/10/Bradford%20KS%20HFC%20Presentation%2023%20Nov%202020%20v4.pdf.*

[69] ''The Black Market for HFC Refrigerant Gas Is Thriving across Europe.'' Webinar on Illegal Trade of HFCs—2020.06.26, European Fluorocarbons Technical Committee, 17 Sept. 2020. Available at *www.youtube.com/watch?v=qqO8IuEt7eg* and *https://stopillegalcooling.eu/wp-content/uploads/Oxera-webinar-slides.pdf.*

[70] See EFCTC, Tracking, Training, Tracing: Trade Enforcement on Illegal HFC Imports, Side Event presentation at COP12/MOP32 (November 23, 2020). Available in the docket and online at *https://www.alliancepolicy.org/site/usermedia/application/3/Angelica%20Candido%20EFCTC%20Alliance%20Side%20Event%202020.pdf.*

[71] See King & Spalding (on behalf of Arkema Inc., The Chemours Company, Honeywell International Inc., and Mexichem Fluor Inc.), Comments Regarding Foreign Trade Barriers to U.S. Exports of Hydrofluorocarbons, submitted to the Office of the United States Trade Representative (October 26, 2020). Available in the docket.

[72] Ibid.

[73] See EFCTC, New Kroll findings reveal how illegal imports of HFCs continue to enter EU (April 15, 2020). Available in the docket and online at *https://www.fluorocarbons.org/wp-content/uploads/2020/04/2020-04-15_Press-release-Kroll_final_website-1.pdf.*

[74] Based on reports documenting potential noncompliance in the three most recent calendar years for which data is available (2018 through 2020).

[75] See Mobile Air Climate Systems Association (MACS), Safety Alert: Online Sales of Cool Penguin F-12 in Action (November/December 2020). Available in the docket.

robust enforcement, compliance, and transparency provisions to ensure EPA can meet the statutory directive in AIM Act subsection (e)(2)(B) that ''the Administrator shall ensure that the annual quantity of all regulated substances produced or consumed in the United States does not exceed'' the levels prescribed in the AIM Act. This directive, as well as the prescriptive schedule established in subsection (e) of the AIM Act and the inclusion of application-specific allowances within the overall cap, are indications that Congress intended for the statutorily required reductions in HFC consumption and production to occur. EPA is accordingly establishing comprehensive compliance and enforcement measures to help ensure that it can implement the allowance program so that it achieves these reductions.

EPA is finalizing strong enforcement and compliance measures at the outset of this new regulatory program to prevent and identify noncompliance, to ensure the Agency can meet the statutory directive in subsection (e)(2)(B), and to create a level playing field for the regulated community. Failure to prevent or identify illegal activity in the United States and ensure compliance with the obligations under the AIM Act could significantly harm the environment, the United States economy, and consumer and worker safety. These provisions were chosen to address specific challenges with enforcement and compliance experienced in the United States and abroad. While each provision functions independently from the other provisions, the requirements also complement and often reinforce each other to create a holistic approach to ensuring EPA can meet the statutory directive in the AIM Act. EPA is finalizing a multifaceted approach that utilizes a variety of tools to deter, identify, and penalize illegal activity. Each element is intended to complement the others to create a robust enforcement and compliance system. The key components of this system include:

- Administrative consequences for allowance allocations to deter noncompliance separate and in addition to traditional enforcement to address the impacts of noncompliance;
- Requiring use of refillable cylinders;
- Increased oversight of imports including requiring consumption allowances to import heels (residual amounts of HFCs remaining in containers used to transport such substances), petitioning to import regulated substances for transformation or destruction processes, reporting of transhipments, and prohibiting the import of virgin HFCs for disposal;
- Establishment of a comprehensive certification ID tracking system using QR codes to track the movement of HFCs, including requiring anyone that imports, sells or distributes, or offers to sell or distribute HFCs to be registered in the system;
- Recordkeeping and reporting;
- Third-party auditing; and
- Data transparency.

In the proposed rule, EPA stated its intention to work with CBP to establish an automated electronic mechanism to check in real-time if an importer has sufficient allowances for a particular shipment. EPA is working with CBP to develop such a mechanism and as discussed later in this section is finalizing complementary reporting provisions in this rule to allow for this to occur. EPA and CBP have established working relationships regarding the imports of various goods subject to domestic regulation, including ODS. To align with CBP's data systems, EPA intends to modify the Agency's electronic database monitoring HFC allowances such that the most current available information is up to date to allow for real-time or near real-time electronic confirmation for CBP of whether a company seeking to import HFCs is an allowance holder and has sufficient allowances for that specific import.

To support effective enforcement and compliance, EPA proposed to prohibit the sale or distribution, or offer for sale or distribution, of regulated substances that were illegally produced or imported. EPA is finalizing these prohibitions as proposed. These prohibitions are designed to curtail demand for regulated substances that were produced or imported in violation of the regulations and to meet the statutory directive to ensure that the annual quantity of all regulated substances produced or consumed in the United States does not exceed the levels prescribed in the AIM Act.

The prohibitions against selling or offering to sell illegally produced or imported regulated substances provide EPA with broad authority to hold any entity that substantially facilitates or contributes to bringing about or effectuating a sale of illegally produced or imported regulated substances liable. This includes, but is not limited to, parties who transfer ownership, transfer custody, advertise, facilitate online sales, or broker the sale of illegally produced or imported regulated substances. The prohibition against distributing illegally produced or imported HFCs into commerce also provides EPA with broad authority to hold any entity liable that engages in activity that is central to the products' distribution in commerce. Distribution is not confined to the actual transportation of illegally produced or imported HFCs, but includes the whole transaction of which such transporting is a part. A company that provides the means by which individuals are able to list and sell the prohibited products or that exerts control over these sales, including companies that own or operate platforms for eCommerce transactions, will be considered distributors under this rule.

The final rule also prohibits the sale or distribution, or offer for sale or distribution, of regulated substances that are contained in non-refillable cylinders or that do not meet the registration and certification identification (certification ID) requirements. When these prohibitions become effective, EPA will have the same broad authority to implement these prohibitions that the Agency has to implement prohibitions relating to the sale or distribution, or offer for sale or distribution, of regulated substances that were illegally produced or imported.

These prohibitions impose broad liability to encourage all regulated parties involved in the sale, distribution, and storage of regulated substances to take the steps to verify that the HFCs they sell, offer for sale, or distribute were legally produced or imported.

The AIM Act provides in subsection (k) that section 113 of the CAA applies to rules and regulations promulgated under the AIM Act as though the AIM Act were included in title VI of the CAA. Accordingly, EPA's enforcement authorities, including penalties, and associated regulations (*e.g.,* 40 CFR part 22) apply to this and any other AIM Act regulations.

A. What potential administrative consequences are available to EPA with respect to allowances?

The AIM Act makes clear in subsection (e)(2)(D)(ii) that a production allowance, consumption allowance, and application-specific allowance do ''not constitute a property right,'' and are a ''limited authorization.'' The AIM Act gives the Administrator significant authority to determine an appropriate allowance system, which EPA finds includes the authority to adjust allowance allocations at the discretion of the Administrator if EPA determines that a person failed to comply with

certain requirements relating to the HFC allowance allocation and trading program. Further, establishing a set of administrative consequences for allowances is an appropriate exercise of EPA's authority to define further how the limited authorization of allowances will be implemented. These administrative consequences do not supplant or replace any potential enforcement action taken under the AIM Act. Instead, such consequences would be in addition to any available enforcement action.

EPA proposed to retire, revoke, or withhold allowances as well as potentially ban a company from receiving future allowances as administrative consequences. In general, commenters supported strong enforcement of these regulations, including the proposal to adjust allowances. Some commenters raised concerns that the distinctions between retiring, revoking, and withholding allowances were unclear and potentially overlapping. These commenters requested EPA clarify what would trigger different administrative consequences. One commenter stated that EPA lacks authority to issue such enforcement measures nor does the Agency have discretion to invalidate allowances. The commenter also stated that it is unfair for EPA to issue consequences for alleged, rather than proven, violations.

In regard to the comment about the Agency's authority, these administrative consequences function as an adjustment to allocations that the Agency has made. Since EPA was given authority and discretion to create the allowance system, and EPA allocates all allowances initially, EPA also has the authority to alter allowance allocations if those holding the allowances have failed to comply with regulations relating to the HFC allowance allocation and trading program, have provided false or misleading information to the Agency to receive those allowances, or meet the other conditions described in this section.

EPA is clarifying in this final rule how the administrative consequences operate and what actions would trigger them. More specifics on the types of actions that warrant administrative consequences is included later in this section.

A withheld allowance is one that is retained by the Agency until an allowance holder that has failed to meet a requirement comes back into compliance, at which point EPA allocates it to the allowance holder. An example of when an allowance may be withheld is when a company fails to provide necessary reports. For example, if an allowance holder does not conduct an independent audit, EPA could withhold allowances until the Agency receives the audit results. This also applies to quarterly reports and other records requested or required consistent with implementation of the AIM Act. If an allowance holder fails to come into compliance by the date specified by EPA, the Agency could revoke and redistribute the allowances.

1. What are the administrative consequences?

Based on comments that the proposal was unclear, EPA is further explaining in this final rule how the different administrative consequences operate and what actions would trigger them. The three ways that EPA may adjust allocations as an administrative consequence are to retire, revoke, or withhold allowances. A retired allowance is one that must go unused and expire at the end of the year. A revoked allowance is one that EPA takes back from an allowance holder and redistributes to all the other allowance holders. A withheld allowance is one that is retained by the Agency until an allowance holder that has failed to meet a requirement comes back into compliance, at which point EPA allocates it to the allowance holder. A withheld allowance could become a revoked allowance if the allowance holder fails to come back into compliance.

EPA also proposed that there may also be circumstances where the potential administrative consequence could be a ban on a company and/or its owner(s) receiving future allowances. EPA is finalizing this proposal. In this scenario, the company and/or its owner(s) would not be eligible to receive or obtain allowances by way of allocation or transfer, and such a ban would effectively render the company and/or owner(s) unable to produce or import HFCs. If EPA were to ban the company, any allowances that the company has already received would be revoked and redistributed on a pro rata basis to the general pool. If EPA were to ban the owner(s), any remaining allowances that the owner(s) has already received, either through the company at fault or a different company, would be revoked, and any allowances that the owner(s) might have otherwise received in the future, either through the company at fault or a different company, would be withheld and redistributed on a pro rata basis to the general pool. This consequence serves as a deterrent to prevent illegal production and import, as well as a method to ensure that bad actors are removed from the HFC allocation system such that EPA can ensure production and consumption caps are met moving forward in line with the AIM Act's Congressional directive.

2. What action could merit an administrative consequence?

EPA has identified the following types of practices that could warrant the Agency exercising its discretion to adjust allowances as an administrative consequence: Submitting false, inaccurate, or misleading information; failing to disclose information that, if disclosed, would have barred a company from being an allowance holder; noncompliance with the AIM Act or prohibitions under § 84.5; and noncompliance with DOC and CBP relevant statutory and regulatory requirements affecting HFC trade. The following paragraphs provide examples of situations that could merit an administrative consequence. Depending on the severity of the noncompliance, EPA could also ban a company and its owner(s) from receiving future allowances for such practices.

a. Submitting False, Inaccurate, or Misleading Information

Submitting false, inaccurate, or misleading information may warrant allowance revocation or withholding. For example, if future information reveals that a company applying for application-specific allowances has provided false information, EPA reserves the right to revoke allowances and/or withhold allowances at a greater level than the number of application-specific allowances allocated. Similarly, failing to disclose relevant information as described in the preamble Section VII.E.4 could also warrant EPA revoking or withholding allowances. If the company receiving set-aside allowances is later determined to be ineligible for the set-aside program, EPA could apply these provisions regarding revoking, withholding, and retiring allowances as well as banning all the companies and owner(s) involved from receiving future allowances.

b. Noncompliance With the AIM Act

Unlawful production or import of HFCs, or attempts to unlawfully produce or import HFCs, may warrant EPA action to retire, revoke, or withhold allowances depending on whether that allowance holder currently has allowances or was anticipated to have allowances issued to them in the future. EPA can also ban a company and its owner(s) from receiving future

allowances for such action, depending on the severity of noncompliance.

This administrative consequence need not be contingent on an enforcement action. Instead, it would be based on information available to EPA, such as allowance availability at the time of production or import, evidence from the certification ID tracking system, or results from an independent audit that a company is selling material that was produced or imported without allowances.

These potential administrative consequences are designed to deter illegal production and import. Illegal production and import undermine EPA's ability to meet the AIM Act requirement that EPA ensure that HFC production and consumption in the United States do not exceed the statutorily defined cap. These administrative consequences are directly related to and support EPA's ability to meet the statutory obligation in subsection (e)(2)(B) of the AIM Act and further clarify how EPA views its role in adjusting allowances for failing to comply with 40 CFR part 84, subpart A. Under the AIM Act, some companies will face burdens and costs associated with the Congressionally mandated phasedown; those increased burdens and costs unfortunately create economic incentives to avoid compliance. That reality increases EPA's statutory and policy imperative to identify and apply tools that counter those incentives to increase the rate of compliance. Given the serious concerns about potential noncompliance and the undermining of Congress's directive to ensure reductions in production and consumption occur consistent with the statutory schedule, there is an imperative to use every reasonable tool at our disposal to ensure compliance and thus the objectives of the AIM Act. Retiring allowances also ensures there is an environmental benefit to account for noncompliance that could result in production and/or consumption above the permitted levels.

Additionally, any practice or combination of practices specified in the regulatory text, including in § 84.5 ''Prohibitions for regulated substances'' may warrant EPA exercising discretion to apply one or more administrative consequences for allowances. This could include, for example, the sale or use of HFCs produced or imported with application-specific allowances for a non-qualifying use.

c. Violating Department of Commerce and U.S. Customs and Border Protection Trade Laws

EPA is concerned about companies not complying with other similar HFC trade provisions, such as Anti-Dumping/Countervailing Duties, as violations of such provisions may create an unequal framework for fair distribution of HFC allocations under the AIM Act.[76] Dumping refers to ''when a foreign producer sells a product in the United States at a price that is below that producer's sales price in the country of origin (''home market''), or at a price that is lower than the cost of production.''[77] Foreign governments may subsidize industries by providing financial assistance to benefit the production, manufacture, or exportation of goods, thereby unfairly undercutting domestic producers. The DOC attempts to eliminate the unfair pricing or subsidies and the injury caused by such imports by imposing additional duties, termed countervailing subsidy duties. The amount of subsidies the foreign producer receives from the government is the basis for the subsidy rate by which the subsidy is offset, or ''countervailed,'' through these higher import duties. Anti-dumping and countervailing duties are two ways that the United States Government addresses dumping and unfair foreign subsidies. The United States Government can require that foreign companies involved in dumping and/or benefiting from subsidization are charged antidumping and/or countervailing duties collected by CBP each time they import products into the United States. This helps negate the value of the dumping/subsidization for foreign manufacturers and creates a fairer competition for manufacturers in the United States. In findings of dumping, DOC issues an order that requires importing entities to pay AD/CVD for goods covered by the order (*e.g.,* in this case, certain HFCs and HFC blends). EPA has placed a memo in the docket summarizing actions taken to date, as well as the HFC-relevant AD/CVD orders that it is aware of.

As proposed, any entity importing HFCs subject to an AD/CVD order issued by DOC that is receiving allowances for 2022 or 2023 must provide documentation of payment of the AD/CVD duties for HFCs imported from January 1, 2017, through May 19, 2021, the date of the proposed rule, or provide evidence that those imports were not subject to AD/CVD for those years. Companies that do not provide sufficient documentation may be subject to administrative consequences from EPA, such as withholding or revoking allowances. Also as proposed, EPA is not allocating allowances to companies in 2022 or 2023 that CBP determines are not in compliance with or are otherwise in arrears with payment of AD/CVD during those years. After an entity is issued allowances, including for 2022, if it has not paid the required AD/CVD within the required time frame, EPA may apply administrative consequences.

The Agency understands that there are two events related to AD/CVDs where there could be non-payment. The first is when an importer is required to pay a cash deposit at the time of entry as an estimate of AD/CVD duties. The second is liquidation, which is the final computation or ascertainment of duties on entries for consumption or drawback entries. The final amount of duties owed is not determined until Commerce conducts an administrative review to establish the final AD/CVD rates on past entries. In other words, the final duties are assessed retrospectively on prior entries. The final AD/CVD amount may increase, decrease, or remain unchanged from the AD/CVD cash deposit paid at the time of entry. After DOC sends instructions to CBP on the final AD/CVD rate for the entry, CBP will assess this final duty. CBP will issue a bill for any increase in duty plus interest or refund any overpayment plus interest as a result of a decrease of a duty. On average, this entire process, from the date of importation, takes approximately three years. Failure to pay on the timeline specified by CBP could result in EPA applying administrative consequences.

Because the time frame for payment of AD/CVD to CBP could occur after the year of import, after consulting with CBP, EPA may revoke or retire that company's allowances for the year payment is due (and not paid) or may reduce future allowance allocations. After consulting with CBP, EPA may also ban a company from receiving future allowances.

As proposed, EPA finds that the Agency has the discretion to revoke, retire, or withhold allowances for companies that fail to use the correct Harmonized Tariff Schedule (HTS) codes[78] with each shipment of HFCs or

[76] This rule does not change any obligation or liability that an entity may have under other laws and regulations, as applicable, such as requirements under U.S. customs law.

[77] ''U.S. Antidumping and Countervailing Duties.'' *Trade.gov,* International Trade Administration. Available at *https://www.trade.gov/us-antidumping-and-countervailing-duties.*

[78] For purposes of this regulation and the regulations established at 40 CFR part 84, subpart A, the terms ''Harmonized Tariff System code,'' ''HTS code,'' and ''commodity code'' have the same meaning and are used interchangeably.

HFC blends. Incorrectly declaring the HFC or HFC blend in a shipment is one way importers may attempt to illegally import HFCs without allowances or with fewer allowances. Likewise, findings of other violations of other laws, including but not limited to, the False Claims Act (31 U.S.C. 3729–3733), that govern the importation of goods into the United States, the making of false statements or claims to the United States, the collection of the revenue of the United States from imports, or the number of allowances needed, could also be subject to the administrative consequences finalized in this rule. EPA intends to work with CBP to institute an automated electronic mechanism to check in real-time if an importer has sufficient allowances for a particular shipment. Errors on Customs forms inhibit EPA's ability to conduct this cross-check to ensure accuracy in and compliance with EPA's allowance system. The Agency also has the discretion to ban a company or the company owner(s) from receiving future allowances if the company repeatedly misreports HTS codes.

These situations are not meant to be exhaustive, but instead are intended as examples of when EPA might exercise discretion to apply one or more administrative consequences for allowances. In response to the proposal's request for comment on whether there are additional non-compliant activities, one commenter recommended applying consequences to entities that have previously underreported HFC production or consumption under the GHGRP. EPA responds that the Agency is not retroactively applying consequences for behavior that occurred prior to the effective date of this rule. However, EPA has already discussed in this section that failure to report to EPA is grounds for an administrative consequence. Future non-reporting or underreporting to the GHGRP would be equivalent to not reporting under the AIM Act as EPA is working to align the two reporting systems for HFC reporting.

3. How would EPA apply the administrative consequences?

EPA proposed that it may exercise discretion to add a range of premiums (between 20 percent and 200 percent) based on the case-specific factors such as the egregiousness of the action and whether they are repeated. One commenter stated that EPA should only apply a 200 percent premium in cases of repeat or egregious violations and a 100 percent premium should be applied in all other instances in which a producer or importer exceeds their allowances.

The proposal did not specify how these premiums would apply under the different methods of adjusting allowances. Based on the comments and on the Agency's desire to streamline the implementation of administrative consequences, EPA is removing some discretion to adjust specifying in this rule the premiums for the first time a company is subject to different administrative consequences. EPA is retaining discretion to determine premiums for a company's subsequent actions triggering an administrative consequence.

An example of when an allowance may be retired is when a company exceeds their allocation. EPA is issuing allowances to new entrants for 2022 and 2023 through this rule. If that new entrant imported more HFCs than they had allowances for in 2022, EPA could require the company to retire some portion of their 2023 allowances. Those 2023 allowances could not be used, sold, or transferred, and EPA would not redistribute them to other allowance holders. Retiring allowances is an important outcome when an allocation is exceeded because it is a direct response to improper excess consumption of regulated substances.

EPA is finalizing a 50 percent premium in first instances where allowances are retired. In the example above, if a company has 100 allowances and imports 110 MTEVe that year, the amount of allowances retired in the next available year would be 15 MTEVe (*i.e.,* 150 percent of the exceedance).

An example of when an allowance may be revoked is when those allowances were acquired by providing false, inaccurate, or misleading information. EPA is issuing allowances based on historical 2011–2019 data through this rulemaking. If the Agency determines that those data were inflated, EPA could revoke the allowances acquired as a result of providing incorrect information to the Agency and redistribute them pro rata to other allowance holders. Revoking allowances is an important outcome when there are distributional effects of an allowance holder's action, as the allowances are redistributed. In situations such as where the Agency learns of new information after the allowances have been expended, EPA could revoke and then may redistribute the allowances that are to be allocated in the next year.

EPA is finalizing a 50 percent premium in first instances where allowances are revoked. In the example above, if a company gains 100 allowances through that false, inaccurate, or misleading information, EPA would revoke 150 allowances. If the company was not entitled to any allowances (*e.g.,* hid that a new entrant is owned by a company receiving calendar-year allowances from the general pool), EPA could revoke all of their allowances and may ban them from receiving future allowances.

Submitting false, inaccurate, or misleading information may warrant allowance revocation or withholding. If future information reveals that a company applying for application-specific allowances has provided false, inaccurate or misleading information, EPA reserves the right to revoke allowances and/or withhold allowances at a greater level than the number of application-specific allowances allocated. Similarly, failing to disclose relevant information as described in Section VII.E.4 could also warrant EPA revoking or withholding allowances. For example, if the company receiving set-aside allowances is later determined to be financially connected or have a familial relationship with another company receiving set-aside allowances or another allowance holder, EPA could apply these provisions regarding revoking, withholding, and retiring allowances as well as banning all the companies and owner(s) involved from receiving future allowances.

Administrative consequences could be applicable when an entity fails to comply with any provision in 40 CFR part 84, subpart A, including any practice or combination of practices specified in the regulatory text in § 84.5 ''Prohibitions for regulated substances.''

An example of when an allowance may be withheld is when a company fails to provide necessary reports. For example, if an allowance holder does not conduct an independent audit, EPA could withhold allowances until the Agency receives the audit results. This also applies to quarterly reports and other records requested or required consistent with implementation of the AIM Act).

For administrative consequences that would lead to the withholding of allowances, EPA is finalizing that it will hold back 20 percent of that allowance holder's allocation until the situation is corrected. In the example above, if a company has 100 allowances, EPA would withhold 20 allowances. EPA anticipates that these situations would be resolved quickly, but if not resolved within 30 days, EPA could revoke the allowances instead and redistribute them. Depending on the timing, those allowances could be revoked in the following calendar year.

4. What is the process for notifying and responding to proposed administrative consequences?

EPA proposed a process for implementing the administrative consequences provisions. A few commenters expressed concern that there is no ability to appeal an allowance adjustment. In response to the comment that EPA must provide an appeals process, EPA notes that the established process does include an opportunity for information exchange before the Agency makes a final decision on an administrative consequence. If EPA does ultimately determine to issue an administrative consequence, that would be a final agency action and as such would be subject to judicial review. EPA is not providing for a further administrative appeal process at this time.

EPA is finalizing the following process, which is largely as proposed. Upon evidence of practices including but not limited to the examples provided in this section, EPA would provide a company notice of the impending allowance adjustment or ban that would set forth the facts or conduct that provide the basis for the action. The notice would also state the specific administrative consequence triggered by the conduct. EPA will provide such notice no less than 30 days before the impending action. During this 30-day period the company will not be allowed to expend or transfer its allowances.

Any company that receives notice of an impending action may provide any information or data to support why EPA should not adjust allowances or prohibit the company from receiving or obtaining future allowances. The company must provide information within 14 days of the date of the Agency's notice. If EPA does not receive a response within 14 days, the impending action would be effective on the date specified in the notice, but not sooner than the expiration of the 14-day window.

After review of the supporting data or information provided by the company receiving notice, EPA could decide to rescind the notification, modify the notification, or continue with the allowance adjustment or ban. EPA's decision would occur within 30 days of the date of the Agency's notice. EPA could also decide it needs to gather additional data and extend the timeline for withholding or making a final decision. Should EPA rescind its notification, the company's allowances would be unfrozen; and, should EPA continue with its impending action, the company's allowances would remain frozen until the effective date of the retirement, revocation, withholding, or permanent ban. Once the Agency issues a final decision, there is no additional administrative appeal to modify the decision. A company would have the ability to challenge EPA's decision in court given it is a final agency action.

B. How is EPA transitioning to refillable cylinders?

EPA proposed to prohibit the sale of regulated substances contained in disposable cylinders, effective January 1, 2025. To facilitate the transition from using both disposable and refillable cylinders to only using refillable cylinders, EPA proposed to prohibit importing or filling disposable cylinders domestically beginning July 1, 2023, eighteen months before the prohibition on sales. This section discusses EPA's authority to prohibit disposable cylinders, describes how it will be implemented, and responds to some of the major comments on the proposal. After considering the public comments, EPA is providing additional time for the transition to using only refillable cylinders in the United States. EPA is finalizing the compliance date of January 1, 2025, for importing or filling disposable cylinders and January 1, 2027, for prohibiting the sale and distribution of disposable cylinders, thus allowing more than five years for this transition. This two-stage approach first prohibits additional disposable cylinders from being added to the market, and subsequently prohibits sales two years later. EPA is also making minor changes to accurately reflect how the prohibition will be implemented and is updating the RIA to account for data provided by commenters.

1. Background

Compressed gases such as HFCs can be stored and transported in a variety of different types of containers. These containers can hold as little as sixteen ounces or as much as a ton (or even more in the case of railcars and ISO tanks). The size and type of the container depend in large part upon the intended use of the regulated substance. OEMs and companies that prepare refrigerant blends often are supplied with HFCs from large containers. Fire suppression system cylinders tend to be smaller and are refillable. HFC refrigerant sold to technicians servicing existing equipment is predominantly contained in disposable cylinders certified to Department of Transportation (DOT) specifications. These cylinders are often called DOT–39 cylinders because the cylinders are certified to meet DOT specification 39 requirements.[79] A DOT–39 cylinder is designed for a single use and is strictly not refillable. As such, a DOT–39 cylinder tends to be less expensive and weigh less than refillable refrigerant cylinders. Disposable cylinders have their own unique shape and are also often shipped packaged in a box while refillable cylinders are not. Refillable refrigerant cylinders are more durable and can be used for up to 20 years. The two primary shapes of refillable refrigerant cylinders are akin to a propane tank or a cylindrical scuba tank and have a two-way valve that can be adjusted to allow pressurized gases in or out.

2. What is EPA's authority for prohibiting disposable cylinders?

The AIM Act charges the Agency in subsection (e)(3) to issue regulations that phase down the production and consumption of regulated substances through an allowance allocation and trading program. Inherent in this charge is not only the need to issue allowances and a system for their allocation, but also the responsibility to ensure that the statutorily required phasedown occurs. Subsection (e)(2)(B) states that ''the Administrator shall ensure that the annual quantity of all regulated substances produced or consumed in the United States does not exceed the'' prescribed phasedown steps. This Congressional direction provides the Agency authority to establish complementary measures such that the Agency can meet the statutory reduction steps and enforce the requirement that regulated substances may only be produced or consumed when the necessary allowances are expended. The direction to stand up the regulatory program in 270 days and in the first year to start by allocating allowances equal to 90 percent of the baseline rather than 100 percent indicates how urgent the phasedown of HFCs is to Congress.

As noted above, EPA is concerned about the significant potential for noncompliance with the HFC consumption limits established by Congress. EPA anticipates that there will be attempts to evade the requirement to expend a consumption allowance to import HFCs into the United States. Any level of illicit import of HFCs may cause the consumption limit to be exceeded as EPA is allocating the full amount of allowances to producers, importers, and application-specific allowance holders. EPA does not find it appropriate to hold allowances in reserve to accommodate

[79] See 49 CFR 178.65—Specification 39 non-reusable (non-refillable) cylinders.

HFCs that are imported illegally. If a similar level of noncompliance seen in the EU over the last three years were to occur in the United States, EPA estimates that 43–90 MMTEVe [80] of imports above the statutorily required phasedown step could occur. Imports on such a scale will have significant long-term environmental and public health costs and put businesses that are complying with regulatory requirements at a severe competitive disadvantage.

The prohibition on disposable cylinders is a strong component within the suite of enforcement and compliance tools that will deter illegal activity in the HFC market and allow EPA to enforce the program as directed by Congress.

Requiring the use of refillable cylinders has a proven track record of facilitating the detection and interdiction of illegal HFCs. The visual differences allow Customs officials and law enforcement personnel to easily distinguish a disposable cylinder from a refillable cylinder. Quickly identifying the type of cylinder is important because the vast majority of illegal imports of HFCs in other countries have been shipped in disposable cylinders. Disposable cylinders are favored for illicit trade because they are cheaper, easier to transport, and difficult to trace. Several studies have found that illegal HFCs are entering European markets in disposable cylinders.[81] EPA has placed a summary of some key studies and evidence into the docket, which include the following highlights:

- At least 500 incidents of illegal HFC imports have been reported to the Montreal Protocol's Ozone Secretariat from 2018–2020, and close to 90 percent of these instances are noted to involve the use of disposable cylinders; [82]
- there were 13 major seizures of illegal HFCs in Europe in 2020, the largest of which contained over 7,000 disposable cylinders; [83] and
- in July 2021, Greece customs officials in one port seized 1,352 illegal disposable cylinders containing 17,200 kg of HFC refrigerant.[84]

EPA has consulted with counterparts in the European Commission, Canada, and Australia, all of which have instituted similar prohibitions on disposable cylinders. Staff implementing the HFC phasedown in these governments confirmed that prohibiting disposable cylinders is an effective mechanism for identifying illegal HFCs. The review of the data reported to the United Nations Environment Programme (UNEP) is telling in that disposable cylinders make up the overwhelming number of cases taken against illegal imports. These documented enforcement actions, combined with feedback from other government representatives, demonstrate that prohibiting disposable cylinders is an effective mechanism for identifying illegal HFCs and therefore is an important mechanism to fulfill Congress's directive in subsection (e)(2)(B) to ensure that the phasedown limits are met. After the initial phase-in and transition from disposable cylinders to refillable cylinders is complete, a disposable cylinder will be a red flag to inspectors to further investigate an entity or to distributors to not purchase the material.

3. How is EPA implementing the transition to refillable cylinders?

EPA proposed a two-step process for implementing the transition to only refillable cylinders. EPA proposed to restrict the import and placement of HFCs in disposable cylinders by July 1, 2023, followed by a prohibition on the sale of HFCs in disposable cylinders January 1, 2025. EPA's reasoning was to stop the placement of disposable cylinders on the market and allow 18 months for any remaining inventory of disposable cylinders to be sold. EPA proposed to require that all refillable cylinders have a unique etched serial number. EPA also discussed establishing a limited sell-through provision that would allow for six more months of sale of remaining disposable cylinders so long as they are registered with EPA.

Based on the comments received and as discussed in the next section, EPA is providing additional time before prohibiting disposable cylinders. Importing or domestically filling disposable cylinders with HFCs will be prohibited as of January 1, 2025. This delay will address many of the points raised by commenters discussed below. EPA is retaining the two-step process as a mechanism to sell through inventory and is prohibiting the sale or distribution of HFCs in disposable cylinders effective January 1, 2027. EPA is not establishing a process for registering remaining disposable cylinders with EPA for continued sale after January 1, 2027. Delaying the prohibition on sale and distribution to more than five years from the date this rule is signed is a simpler way of ensuring inventory is sold than establishing a 6 month sell-through of registered cylinders.

The final rule also clarifies what actions are prohibited. The proposed rule stated that no person may ''import or place a regulated substance in a nonrefillable cylinder.'' EPA is finalizing the phrase ''import or domestically fill'' disposable cylinders to clarify what the Agency meant by placing a regulated substance in a disposable cylinder. Second, the proposed rule states that ''no person may sell or offer for sale'' regulated substances contained in a disposable cylinder. EPA is finalizing a broader prohibition to say that ''no person may sell or distribute or offer for sale or distribution'' regulated substances contained in a disposable cylinder. This addresses other types of transactions and movement in commerce, as described above, which the Agency has seen in the context of ODS.

4. What are the costs of prohibiting disposable cylinders?

A prohibition on the use of disposable cylinders will directly impact companies that sell, distribute, or repackage HFCs including producers, importers, exporters, reclaimers, fire suppression recyclers, blenders, repackagers, wholesalers, and distributors of refrigerants.

EPA initially estimated that transitioning from allowing both disposable cylinders and refillable cylinders to only allowing refillable cylinders in the United States would cost $18.2 million annually. If that annual cost were applied to every year from 2022–2050, total costs of transitioning fully to refillable cylinders are estimated to be $349 million at a 3 percent discount rate, in 2020 dollars, discounted to 2022. The Agency

[80] This range is based on recent reports documenting potential noncompliance with the production and consumption limits required by the EU F-Gas regulation in 2018 through 2020. Those reports, discussed earlier in Section IX, document a range of 16 to 33 percent potential noncompliance.

[81] ''Illegal Refrigerant Imports Could Be as Much as One Third of EU Market.'' *Fluorocarbons.org,* The European FluoroCarbons Technical Committee, June 26, 2020. Available at *www.fluorocarbons.org/wp-content/uploads/2020/09/EFCTC_Press-Release_EN-2.pdf.* ''Doors Wide Open.'' *Eia-International.org,* Environmental Investigation Agency, Apr. 2019. Available at *https://reports.eia-international.org/doorswideopen.*

[82] United Nations Environment Programme (UNEP), Information on illegal trade reported by the parties (2021). Available at *https://ozone.unep.org/countries/additional-reported-information/illegal-trade.*

[83] European Anti-Fraud Office (OLAF), *76 tonnes of illicit refrigerant gases detained in Romania thanks to OLAF intelligence* (2020). Available at *https://ec.europa.eu/anti-fraud/media-corner/news/05-08-2020/76-tonnes-illicit-refrigerant-gases-detained-romania-thanks-olaf_en.*

[84] Cooling Post, *10m Tonnes of Illegal F-Gas Enters Europe* (2016). Available at *https://www.coolingpost.com/world-news/over-10m-tonnes-of-illegal-f-gas-enters-europe.*

assumed that 4.5 million disposable cylinders of HFCs and HFC blends are sold each year in the United States, that refillable cylinders are three times as expensive as disposable cylinders, that each refillable cylinder is used 1.5 times per year (reducing the number of cylinders needed by a third), and that refillable cylinders are in use for 20 years. EPA also assumed twice as many trips for refillable cylinders as for disposable cylinders (*i.e.,* one trip from the producer/importer to the distributor/user and one trip back) and due to weight limits for each shipment, about 25 percent fewer cylinders could be shipped in each truckload.

EPA reviewed previous studies, including those referenced in comments, and consulted with other governments that require the use of refillable cylinders, and has updated the analysis in the RIA. After consideration of all comments, EPA's updated cost analysis, available in the docket, shows that the expected cost of the prohibition on disposable cylinders is $441 million (2020 dollars, discounted to 2022) at a three percent discount rate through 2050, including transportation costs of $104 million. Average annual costs during that timeframe are $22 million per year at a three percent discount rate. However, after 2027 when the requirements have fully phased in, EPA expects a net annual savings per year resulting from the need to purchase significantly fewer cylinders each year.

EPA revised its key assumptions as follows: That refillable cylinders are only sold once per year, that industry would need to build a fleet of cylinders twice as large as total annual sales (*i.e.,* 9 million refillable cylinders) to prevent shortages, that the cost of refillable cylinders is more than 5 times higher than disposable ones, and that cylinders are refurbished every five years as part of the recertification process. Additional sensitivity analysis is included in the RIA. EPA retained the assumption that 4.5 million disposable cylinders are sold in a year. While additional cylinders are sold currently, the Agency estimates those additional cylinders are filled with ODS and non-HFC alternatives. EPA also retained the assumption that fewer refillable cylinders would be shipped per truckload and that refillable cylinders can be reused for 20 years.

Further discussion of these costs can be found in the RIA. Comments related to the RIA can be found later in this section of the preamble.

5. What are the additional benefits of transitioning to only refillable cylinders?

There are secondary benefits of transitioning to refillable cylinders beyond preventing the import of HFCs outside of the allowance allocation and trading program. Disposable cylinders tend to release more of their contents into the environment than do refillable cylinders. Losses from cylinders can occur under a variety of circumstances during transport, storage, and disposal, the frequency and severity of which depend in part on the type of cylinder. HFC losses are most likely to occur and in the most significant quantities from disposable cylinders.

Every cylinder when ''empty'' still retains a residual amount of its contents, and some cylinders contain more than a heel if not all the contents are used. Removing this ''heel'' or remaining HFC requires the use of recovery equipment, like that used to recover refrigerant from an appliance. Unfortunately, that is not common practice. Technicians are instructed to dispose of an empty disposable cylinder by checking that the cylinder pressure is released to zero pounds pressure and then rendering the cylinder useless by puncturing the rupture disk or breaking off the shutoff valve. The intent of this disposal practice is to prevent the unsafe practice of reusing a disposable cylinder. Some HFCs in that cylinder are released to the atmosphere in that process and ultimately all are released when the cylinder is crushed for scrap metal recycling. Releases would also occur if a disposable cylinder is sent to a landfill instead of recycled for scrap metal. Even if not punctured, the seal on the cylinder will degrade over time and eventually break, resulting in emissions of whatever is left in the cylinder. Refillable cylinders avoid this disposal process by being returned, heel included, to the distributor. Technicians are incentivized through a deposit system to return cylinders rather than discard them.

Another difference between a refillable and a disposable cylinder that affects their emissions is the mechanism used when a cylinder is over pressurized. While not particularly common, a cylinder that is overfilled or overheated if left in the sun can develop unsafe internal pressures. Disposable cylinders have a rupture disk that will discharge the whole contents of the cylinder before the pressure reaches unsafe levels. Refillable cylinders have resealable safety release valves that relieve the pressure by releasing at most 20 percent of the cylinder contents.

EPA initially estimated that replacing disposable cylinders with refillable cylinders in the United States would prevent the release of up to 5.2 $MMTCO_2e$ of HFCs per year. EPA's assumptions were that 95 percent of disposable cylinders had a heel and that the heel was 5 percent of the full cylinder. EPA reviewed previous studies, including two done at Congress's behest and those referenced in comments, and has updated the analysis in the RIA. Based on revised assumptions, EPA estimates the prohibition on disposable cylinder use with HFCs would prevent the release of 29 $MMTCO_2e$ of HFCs between 2022 and 2050. These figures assumed that 4.5 million 30-pound disposable cylinders sold each year are replaced in a 2:1 ratio with refillable cylinders, and that HFCs are not recovered from the disposable cylinders 75 percent of the time. The Agency also assumed that the average residual heel is 4 percent, which is approximately the midpoint of the 2011 ICF study conducted for the California Air Resources Board (CARB). EPA includes additional sensitivity analyses in the RIA looking at higher and lower heel and recovery assumptions. While some companies may recover heels from cylinders, there is no evidence that this practice is widespread. The assumption that heels are released from 75 percent of disposable cylinders may therefore be an underestimate of the potential emissions reduction opportunity.

The reductions in emissions from transitioning to refillable cylinders is not a primary basis for EPA's action, nor is it a part of the fundamental rationale or related to the authority upon which EPA is relying. To the extent the reuse of HFCs in heels increases the supply of available HFCs in a given year, it would also decrease the cost of transition in that year.

6. How is EPA responding to public comments?

EPA received many comments on the proposal to prohibit the use of disposable cylinders. Comments generally pertained to the Agency's authority to prohibit disposable cylinders, the ability to source and/or produce enough cylinders to meet the proposed timeline, the environmental benefits, and the costs. Many of those comments are discussed here, and all other comments are addressed in the Response to Comments document, the RIA, and relevant technical memoranda in the docket.

Authority

Some commenters asserted that EPA lacks authority to prohibit disposable cylinders under either the AIM Act or the CAA. For the reasons discussed at the outset of this section, EPA disagrees. A program to control the production and import of HFCs is only achievable to the extent it can be enforced. Restrictions designed to deter and identify illegal imports, and enforce against those who are violating import controls, are a necessary component to such a program. The importance of compliance assurance is reflected in Congress's direction to EPA in subsection (e)(2)(B) that ''the Administrator shall ensure that the annual quantity of all regulated substances produced or consumed in the United States does not exceed the'' prescribed phasedown steps.

Under the AIM Act, some companies will face burdens and costs associated with the Congressionally mandated phasedown; those increased burdens and costs unfortunately create economic incentives to avoid compliance. That reality increases EPA's statutory and policy imperative to identify and apply tools that counter those incentives to increase the rate of compliance. Given the risk of noncompliance, there is an imperative to use every reasonable tool at our disposal to ensure compliance and thus the objectives of the AIM Act. Prohibiting the filling, import, and eventually sale of disposable cylinders is directly related to and supports EPA's ability to meet the statutory obligation in subsection (e)(2)(B) of the AIM Act. Specific reasons are discussed in more detail previously (*e.g.,* it provides a proven visual tool for Customs officials and other enforcement personnel to easily identify illegal material). Given the serious concerns about potential noncompliance, in particular but not exclusively from illegal imports, and the undermining of Congress's directive to ensure reductions in production and consumption occur consistent with the statutory schedule, prohibiting the use of refillable cylinders will support EPA's ability to effectively implement the statute.

Some commenters agreed that prohibiting the use of disposable cylinders would help identify HFCs that are entering the market illegally. Other comments asserted that requiring refillable cylinders does not prevent illegal imports, given the EU continues to see HFC imported in disposable cylinders a decade and a half after the prohibition was put in place. EPA responds that both commenters are correct. Data from the EU show that smuggling continues. The data also show that prohibiting disposable cylinders is an effective tool for identifying and prosecuting those who attempt to illegally import regulated substances. No single element of EPA's enforcement and compliance regime is more important than the others. Prohibiting disposable cylinders in and of itself will not end the illegal importing of HFCs, but no single action can. EPA's overall approach in establishing a broad array of enforcement and compliance tools throughout the allowance allocation and trading program is to have separate requirements that work in tandem to help ensure that the HFC phasedown targets are reached.

Other commenters cited articles showing that as a result of the EU's prohibition on disposable cylinders, importers operating outside of the quota system switched to low-quality refillable cylinders. The commenters asserted that these cylinders are leak-prone and therefore pose risks to the environment, and endanger the safety of technicians, homeowners, and workers. EPA acknowledges that the practices of illicit trade will evolve, potentially including moving to inexpensive and unreliable refillable cylinders. All cylinders must meet standards from the DOT [85] and awareness of that particular tactic allows EPA to work with DOT and CBP to monitor and address this potential issue. However, the pressure to use poor-quality refillable cylinders could also be affected by the availability of higher-quality cylinders that are compliant with domestic and international standards (*e.g.,* from a timeline for transition that is too short). In theory, a lack of compliant, higher-quality cylinders could lead to the purchase of poorer-quality ones simply because those are the only ones available. As discussed later in this section, some commenters expressed concern about the short 18- to 20-month transition timeline in the proposed rule and the challenges with producing enough DOT-compliant cylinders in that timeline. Part of the reason EPA is finalizing a later compliance date for prohibiting disposable cylinders is to allow sufficient time for the manufacture and purchase of refillable cylinders that comply with DOT requirements.

Cylinder Supply

Various comments were submitted on supply chain issues that could occur as a result of the proposed prohibition on disposable cylinders. Some commenters raised concerns that not enough refillable cylinders could be manufactured to accommodate the marked increase in the supply needed. As such, commenters were concerned that there would be shortages of HFCs in parts of the United States. Commenters stated that the United States may experience a surge in imports of lower-cost and lower-quality refillable cylinders which would be a financial harm to the domestic manufacturer of cylinders. Commenters allege that lower-cost imported cylinders would result in financial injury.

EPA recognizes the concern raised by commenters that not enough refillable cylinders will be ready before the proposed July 1, 2023, date for the prohibition on filling disposable cylinders. For this reason, among others discussed in this section, EPA is delaying the compliance dates for this provision to January 1, 2025. The adjusted compliance date allows for a more gradual approach to mitigate concerns about the supply of cylinders. This additional time will also allow for companies to develop a plan to transition to refillable cylinders and allow companies to adjust their storage and management practices to account for empty cylinders on their way back to the original filler. EPA also acknowledges comments on the availability of potential lower-cost refillable cylinders (concerns about lower-quality cylinders have been discussed previously). The Agency is not limiting who may supply refillable cylinders in this rule. Any refillable cylinders that meet safety and other applicable standards can be used for storing and transporting regulated substances.

Environmental Benefits

Many commenters discussed the Agency's analysis of the environmental benefit of the disposable cylinder prohibition. Some organizations supported the analysis, while a few noted that the heels in disposable cylinders may be upwards of 10 percent. Other commenters asserted that EPA's estimate that up to 8 percent remains as a heel is based on outdated data or is a worst-case scenario that assumes that there have been no mitigating actions taken prior to disposal. Some commenters cited data from studies that the average heel left in a disposable cylinder is closer to 3 percent and may be less than 1.5 percent, and attributed this lower estimate, in part, to technicians recovering the heels because of the monetary value of the remaining

[85] See 49 CFR Subpart C—Specifications for Cylinders.

HFC as well as complying with the venting prohibition under section 608 of the CAA.

EPA responds that there may be variations in how much HFCs remain in a disposable cylinder at its end of life. EPA used 5 percent as the amount of heel in the proposal, not 8 percent, to be conservative. EPA has reviewed multiple studies and is reanalyzing the emissions benefit using a 4 percent heel for the final rule. EPA has no evidence to support an average heel of 1.5 percent and, based on experience with compliance under CAA section 608, doubts the practice of recovering heels is widespread.

Several commenters suggested that the increased transportation and freight requirements necessary to distribute, service, and return a fleet of refillable cylinders would harm the environment. Commenters cited factors such as the increased weight per cylinder, the increased size of refillable cylinders resulting in an increased number of trips, and the travel associated with refilling cylinders as reasons why overall emissions would increase. Commenters referenced a study conducted for CARB by ICF in 2011 [86] estimating that in certain parts of the country, the transportation costs and annual distance traveled could approximately double. Commenters also noted concern that prohibiting disposable cylinders for HFCs could result in imports of refillable cylinders to meet demand, which would result in increased transportation-related emissions compared to domestically sourced cylinders.

The Agency has considered added transportation costs in its analysis. EPA had considered the study estimating that travel distances for refillable cylinders would be double that of disposable cylinders at the proposal stage and has revised its estimates. Several commenters cited the study conducted for CARB in 2011, noting that the review indicated that there were limited environmental benefits associated with transitioning to refillable cylinders. EPA responds that the 2011 CARB analysis assumed full compliance with California's requirements to evacuate refrigerant from cylinders. The report notes that ''[i]n reality, compliance with [CARB's] Refrigerant Management Program is highly uncertain and difficult to enforce. Under a scenario of noncompliance with this program, net GHG emissions avoided by transitioning to refillable cylinders would be approximately 14 $MMTCO_2e$, and cost effectiveness would be $\$14/MTCO_2e$ for HFCs only'' by 2050.[86] Given there is no similar national standard on recovery (it is not required under EPA's CAA section 608 regulations), this higher estimate would be more appropriate as a comparison point than the value cited by commenters.

Some commenters suggested that EPA employ other measures to achieve the same environmental outcome as a prohibition on disposable cylinders. They suggested, among other things, implementing end-of-life practices for disposable cylinders and extending existing regulations, such as the venting prohibition in section 608 of the CAA, to disposable cylinders.

EPA responds that the measures proposed by the commenters could provide environmental benefit relative to the status quo, but none of the suggestions address the primary reason EPA is prohibiting the use of disposable cylinders. Prohibiting disposable cylinders provides an easy mechanism for the flagging of potential illegal HFC activity on the border and within the United States. The environmental outcome EPA is seeking is to ensure that the statutorily directed phasedown in HFC production and consumption occurs. EPA is presenting the additional environmental benefit, and additional financial costs, of prohibiting disposable cylinders as part of the overall RIA.

Costs and Related RIA Assumptions

Commenters raised concerns with the costs of transitioning to refillable cylinders and stated that EPA's estimates for the conversion were too low. Several commenters cited a figure generated by the sole domestic refillable refrigerant cylinder manufacturer that converting the entire fleet to refillable cylinders would cost $2 billion, which does not factor in additional costs from converting the transport fleet, visually inspecting and testing new equipment to ensure their suitability for service, and establishing a reverse distribution system. The same refrigerant cylinder manufacturer provided an annualized cost estimate of approximately $521 million for switching to refillable cylinders. This figure was premised on the following parameters: (i) Producing refillable cylinders requires retooling costs at the specific cylinder production facilities; (ii) EPA's estimate of the number of refillable cylinders needed was too low; (iii) EPA neglected to account for periodic cylinder inspection and refurbishment costs; (iv) EPA used incorrect cylinder and valve costs; and (v) EPA overestimated the number of refillable cylinders that can fit in a truckload. Other commenters extrapolated figures from the 2011 CARB report estimating that a nationwide refillable cylinder system would be at least $340 million (in 2011 dollars) more expensive to implement between 2011 and 2050 than a similar disposable cylinder system. Some commenters also asserted that the necessary monetary investment would adversely affect every point in the supply chain, including but not limited to packagers, distributors, contractors, individual technicians, and consumers.

Several commenters disagreed with EPA's assumption that refillable cylinders can replace disposable cylinders on a one-to-one basis. Several commenters described the need for four times as many refillable cylinders to create the closed-loop system that is needed. Commenters stated that one refillable cylinder is at each of the following locations at any given time: A job site with a technician or installer; in transit between filler, reclaimer, or distributor; storage with an end user or distributor; and, in the process of being filled, refurbished, or recertified. Commenters also asserted that EPA's estimate that 4.5 million disposable cylinders are sold annually in the United States is low. Instead, commenters estimated that six to seven million disposable cylinders are used annually, based on consultation with various industry stakeholders. Commenters calculated that the total number of refillable cylinders needed to replace the disposable cylinder fleet would therefore be 26 million, not including another 2.6 to 3.9 million new cylinders needed per year to replace cylinders that are damaged, lost, or at their end of life (10 to 15 percent of the fleet size).

EPA responds that the Agency's estimate of 4.5 million cylinders is limited to the number of cylinders needed for annual sales of HFCs and blends containing HFCs. This figure does not include cylinders needed for HCFCs, HFOs, or other alternatives as this rule does not affect those substances. EPA is confident in its estimate and has not adjusted this number in the final RIA. In regard to the comment that EPA underestimated the ratio of refillable to disposable cylinders, EPA acknowledges that its initial assumption of 1 refillable cylinder for every 1.5 disposable cylinder is likely an underestimate. EPA does not agree with comments that four times as many refillable cylinders are needed relative to the number of disposable cylinders sold in a given year

[86] See ICF International, ''Lifecycle Analysis of High-Global Warming Potential Greenhouse Gas Destruction,'' (2011). Available at *https://ww2.arb.ca.gov/sites/default/files/classic//research/apr/past/07-330.pdf.*

currently to determine the total fleet size needed. In practice, a 4:1 ratio for the full fleet of cylinders compared to current cylinder sales in a closed-loop system assumes that each cylinder is only sold once resulting in a 4-year cycle on average for one cylinder to make it from the point of filling to the next time it is filled. While this could occur for some cylinders, this is counter to experiences in other countries where each cylinder is filled 1.3 to 4 times per year. A 4-year cycle would be a very inefficient distribution chain. EPA expects that companies would deploy deposit and return systems, as companies in other countries have done, or use other mechanisms to incentivize returns at a more efficient pace than only cycling ¼ of the cylinder fleet through the supply chain each year. EPA acknowledges that the Agency may have underestimated the ratio and has updated the estimates in the RIA to be 2:1. Thus, EPA estimates 9 million refillable cylinders may be needed to replace the current fleet of disposable cylinders. This estimate is lower than those provided by several commenters. However, this estimate aligns with at least one commenter, who estimated 7–10 million cylinders would be needed for the United States market, and reflects the longer lead time. The ratio required in the near term would be higher if EPA required all disposable cylinders to be replaced at once. In this final rule, EPA is instead providing five years for the transition to occur. While there will be an upfront cost with establishing a fleet of only refillable cylinders, long-term costs associated with the cylinders will likely be below current costs due to the long lifetimes of properly maintained cylinders. As noted above, some amount of the fleet needs to be replaced each year. Feedback from EPA's counterparts in the government in Australia indicates less than seven percent of the cylinder fleet is lost, retired, or damaged each year, yet few cylinders are ever beyond the ability of repair. They estimate less than two percent of cylinders are lost each year, but the cost of those cylinders is typically covered by deposit and therefore has no cost to the distributor. EPA has assumed that 5 percent of cylinders are retired each year and that every cylinder needs to be recertified (and in some cases refurbished) every five years.

7. Treatment of Small Cans With Self-Sealing Valves

EPA proposed to allow the continued sale of HFCs in certain disposable containers, such as small cans of refrigerant with a self-sealing valve that meet the requirements in 40 CFR 82.154(c)(2). These containers have a mechanism in place to reduce emissions, so there would not be the same environmental benefit from their prohibition as EPA perceives in prohibiting other disposable cylinders. For a more complete discussion of the ways self-sealing valves reduce emissions of refrigerant, see 81 FR 82272 (November 18, 2016).

One commenter supported EPA's proposal to allow the continued sale of HFC refrigerants in small cans with a self-sealing valve meeting the requirements contained in 40 CFR 82.154(c)(2), noting that the development of those regulations was a joint process between one industry and state and federal regulatory bodies that resulted in success for consumers, industry, and the environment. Another commenter provided several reasons for why EPA should prohibit small cans including: Small cans of refrigerant are a public safety and environmental hazard; devices that can circumvent the self-sealing valves are readily available to consumers and void the intended effects of the valves; and, the end users of small cans may not be limited only to the do-it-yourself community. The commenter also provided an alternative to the proposed exemption for small cans with self-sealing valves, whereby the filled cans contain reclaimed refrigerant, and a limit of one can per customer is enacted.

After considering these comments, EPA is finalizing, as proposed, the provision that allows the continued sale of HFCs in certain disposable containers, limited to small cans of refrigerant with a self-sealing valve that meet the requirements in 40 CFR 82.154(c)(2). EPA has previously determined that these self-sealing valves reduce emissions of refrigerant after use (see 81 FR 82272) and the commenter did not provide sufficient data to suggest that EPA's previous finding was incorrect. In addition, EPA explicitly did not propose prohibiting small cans in the proposal. Further, some of the suggestions offered, *e.g.,* purchase limits and composition requirements, are outside the scope of the proposal.

8. Compliance Dates

EPA proposed implementing the prohibition on disposable cylinders in two stages. First, it would be unlawful to import or fill disposable cylinders containing HFCs, effective July 1, 2023. This first stage prevents new disposable cylinders from entering the market. Second, EPA proposed to prohibit the sale or offer for sale of HFCs in disposable cylinders, effective January 1, 2025. This second stage allows time for disposable cylinders already on the market to be sold.

Regarding the first deadline, one commenter suggested an earlier compliance date of January 1, 2023, to ensure that existing stock can be sold prior to January 1, 2024. All other commenters concurred that July 1, 2023, was too short to implement such a transition. Commenters cited various reasons that the deadline is unachievable, many of which have been discussed earlier, including but not limited to costs, infrastructure and distribution requirements, and supply chain considerations. Commenters suggested a range of alternative dates ranging from January 1, 2024, to three or more years. Regarding the second deadline, commenters asserted that EPA's assumption that all inventory can be sold in 18 months was unsupported by any data, and in fact, some inventory can be maintained for multiple years.

Based on the factors cited above EPA is also finalizing a later compliance deadline than the proposed July 1, 2023, date for the prohibition on the import or placement of HFCs in disposable cylinders from, namely January 1, 2025. EPA expects that the adjusted compliance date will assist with a gradual and phased-in approach that will contribute substantially in mitigating the supply chain issues identified in public comments and reducing the need for a larger than necessary fleet of cylinders. EPA is also finalizing a later compliance date for the prohibition of the sale or offer for sale of regulated substances in disposable cylinders (January 1, 2027, as compared to the proposed date of January 1, 2025), to accommodate for inventory sell-through.

EPA proposed to prohibit the import of HFCs in cylinders designed to hold 100 pounds or less of a regulated substance intended for use in a process resulting in their transformation or destruction. As discussed in Section IX.E of this preamble, feedstock HFCs may be imported without expending consumption allowances. This minimum size restriction is intended to prevent the submission of false information that a particular shipment of HFCs in cylinders does not require allowances because they are for transformation or destruction processes. EPA does not anticipate this proposal would affect current business practices as these HFCs are typically imported and used in large volumes at specific facilities. Commenters, including companies that import feedstock HFCs, were supportive of this proposal. One commenter requested an exemption for

HFCs used for research and development purposes as these are typically needed in smaller quantities. EPA responds that the Agency does not have sufficient information to say that these research and development applications qualify as transformation or that these small quantities could not be sourced domestically.

C. What are the labeling requirements?

EPA proposed to require that all containers that contain a regulated substance in bulk (*e.g.,* ISO tanks, drums, cylinders of any size, or small cans) must have an affixed label or other marking that indicates the specific HFC(s) in that container. Specifically, the proposed label must state, legibly and indelibly, in numbers and letters at least ⅛ inch high, the common name of the HFC or HFC blend contained, and the composition and ratios of the HFCs if a blend. This font size is consistent with the DOT–39 labeling standards (see 49 CFR 178.65). EPA also requested comment on whether the label should include the quantity of HFC in the container.

Many commenters expressed concern that an EPA labeling requirement would be duplicative of existing labeling requirements. Commenters suggested that EPA defer to the labeling requirements in DOT, Occupational Safety and Health Administration (OSHA), and DOC regulations. One commenter suggested that the presence of an American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) number on a cylinder or can is sufficient to determine the composition.

EPA responds that the intent of the proposed labeling requirement was to allow EPA to take an enforcement action if an EPA or Customs official discovers an unidentified cylinder or suspects that a cylinder is misidentified. EPA is seeking to avoid contradicting the DOT, OSHA, or DOC labeling requirements. As such, EPA is not finalizing the specific lettering size requirements or the requirement that the cylinder have a serial number.

EPA also understands from comments that containers must be labeled with technical names of the contents if the proper shipping name does not specify the chemical name. EPA is finalizing a requirement that the container specify either the name of the regulated substance, the ASHRAE designation (where applicable), or the percentage composition of the regulated substances it contains.

As discussed in the proposed rule, companies without allowances have attempted to evade import restrictions by misidentifying in the Customs documentation or on the cylinders that the imported regulated substance is a different compressed gas. ODS refrigerants have been falsely labeled as HFCs, since allowances were not required to import HFCs at that time. EPA can also conceive of allowance holders or others attempting to evade import restrictions by similarly misidentifying an HFC or blend that has a high EVe as a blend with a lower EVe, thereby reducing the number of allowances needed to be expended for the import. Under this method of illegal import, once the unidentified or misidentified regulated substance enters the United States, a domestic counterpart who knows the true identity of the compressed gas would have to relabel the cylinder with the correct substance to be commercially useful. Consistent with the proposal, EPA considers repackaging material that was initially unlabeled or mislabeled to be a knowing violation of this subpart. Preventing these violations helps EPA to meet the directive of subsection (e)(2)(B) that EPA ''ensure that the annual quantity of all regulated substances produced or consumed in the United States does not exceed'' the statutorily prescribed phasedown schedule.

To provide a way to check the accuracy of the label, EPA proposed to require producers and importers to batch test their product and retain records indicating the results of the batch testing. EPA received two comments on this proposal, both of which were supportive of this requirement. One commenter stated that the use of batch testing is already a common industry practice among both producers and importers and that it is a mechanism that can be used to reinforce accurate labeling of HFC content. EPA is finalizing the requirement for batch testing of all HFCs produced and imported. Records would need to be maintained to document the results of the batch testing.

EPA requested comment on whether to require that containers purporting to contain a specific HFC or an ASHRAE designated blend with an HFC component meet the specifications in Appendix A to subpart F of part 82—Specifications for Refrigerants. Currently, under the CAA section 608 regulations, reclaimed refrigerant is required to meet specifications based in large part on the AHRI 700–2016 standard for purity before it can be released into the market. Based on input from industry, EPA is now aware that virgin material potentially could include impurities or that the ratio of components in a blend may not match that required of the blend.[87] Multiple commenters supported including a requirement that all companies (not just reclaimers) comply with AHRI Standard 700 where relevant. To ensure the quality of the refrigerant entering the U.S. market is to industry specifications and to ensure the HFCs being imported and produced match the amount of allowances being expended, EPA is finalizing a requirement that all HFCs imported, filled in containers domestically, and sold as refrigerants meet the specifications in Appendix A to subpart F of part 82—Specifications for Refrigerants.

EPA is finalizing as proposed that if the bill of lading or other evidence suggests that cylinders contain HFCs but the cylinder itself is not labeled or the labeling is illegible, EPA will presume that the container is completely full of HFC-23, unless the importer verifies the contents with independent laboratory testing results and fixes the label on the container before the container is imported. As such, a company would have to expend the requisite allowances to import HFC-23 to be able to legally import the unlabeled HFCs . The company can also choose to have the shipment held at the port or in a bonded warehouse until they can arrange for testing to identify the contents and relabel the container. Only the importer may repackage (including relabeling) a container of regulated substances if it is unlabeled or the labeling is illegible. The goal of this presumption is to deter illegal activity and promote accurate and clear labeling, while also simplifying the process for EPA, in coordination with CBP for imports, to deduct a sufficient number of allowances at the point of import. HFC identifiers and a certified laboratory to verify the contents of a container may not be available at a port, so providing a clear presumption that could be used in such circumstances would facilitate compliance and enforcement efforts. This also reduces the safety risk of shipping and storing unlabeled cylinders and the potential to damage equipment resulting in the release of refrigerant and harm to the environment.

Under the AIM Act, some companies will face burdens and costs associated with the Congressionally mandated phasedown; those increased burdens and costs unfortunately create economic

[87] See Air Conditioning, Heating, and Refrigeration Institute (2013). Reports of R-134a Contaminated with R-40 and Other Refrigerants [White paper]. Available at *https://www.ahrinet.org/App_Content/ahri/files/News%20Room/Press%20Releases/2013/AHRI_R_40_Contamination_white_paper.pdf.*

incentives to avoid compliance. That reality increases EPA's statutory and policy imperative to identify and apply tools that counter those incentives to increase the rate of compliance. These provisions, alongside the other provisions described in this rule, improve the enforceability of this rule and compliance with the statutory phasedown. Given the risk of noncompliance, as described throughout this section, there is an imperative to use every reasonable tool at our disposal to ensure compliance and thus the objectives of the AIM Act. Requiring limited labeling and testing requirements to ensure material imported, produced, and sold matches the label is directly related to and supports EPA's ability to meet the statutory obligation in subsection (e)(2)(B) of the AIM Act. Given the serious concerns about potential noncompliance and the undermining of Congress's directive to ensure reductions in production and consumption occur consistent with the statutory schedule, proper labeling and testing to verify that labeling will support EPA's ability to effectively implement the statute.

D. What is EPA requiring for auditing?

EPA proposed to require external audits that are performed by CPAs on an annual basis for all producers, importers, exporters, reclaimers, and entities issued application-specific allowances.[88] [89] EPA proposed that the scope of the audit be of records necessary to verify that the reports provided to EPA are accurate. EPA proposed that the audits be sent directly to EPA by the auditor before the results were shared with the auditee.

To ensure the integrity of the allocation program, EPA is finalizing a requirement for annual third-party audits of producers, importers, exporters, reclaimers, and companies issued application-specific allowances. These entities affect compliance with the phasedown caps under the AIM Act or generate certification IDs. The Agency is providing additional detail on the types of certification statements that must accompany an audit report when submitted to EPA. These requirements are based on similar requirements under the Renewable Fuel Standard (40 CFR part 1090), which have helped to confirm the accuracy of reported information. EPA is also adding recyclers of HFCs used for fire suppression to the list of companies that must be audited. This is appropriate since they will be required to request certification IDs associated with the HFCs they recycle and resell in bulk. The Agency has also added reporting requirements for these companies. EPA is also amending the proposed auditing requirements for the DOD by requiring an internal annual review rather than requiring third-party auditing. EPA is extending the compliance date by a year and requiring the first audit be conducted in 2024 on calendar year 2023 data. More detail is provided below about auditing requirements for specific entities.

As noted elsewhere in Section IX, under the AIM Act, some companies will face burdens and costs associated with the Congressionally mandated phasedown; those increased burdens and costs unfortunately create economic incentives to avoid compliance. That reality increases EPA's statutory and policy imperative to identify and apply tools that counter those incentives to increase the rate of compliance. As described below, auditing is one of those compliance tools, as it provides an independent check on a company's reports and has a well-documented record of fostering compliance. The audits will also review records that are not routinely sent to EPA. Given the risks of noncompliance described in this rule, EPA must use every reasonable tool at our disposal to ensure compliance and thus the objectives of the AIM Act.

Many economic studies have found that third-party auditing improves company and individual compliance with the law.[90] [91] [92] [93] EPA has used third-party auditing since at least the reformulated gasoline regulations were promulgated in 1994 (59 FR 7716, February 16, 1994). In the Renewable Fuel Standard, which uses third-party auditing, EPA noted expert consensus that well-implemented third-party auditing is a good use of limited enforcement and oversight resources (79 FR 42080, July 18, 2014).[94] Independent and objective audits are a valuable tool to improve compliance and accuracy among all companies, not just those with covert malicious intent to be inaccurate in their reporting. Given that EPA is establishing a new program, it is likely that there will be inadvertent reporting errors. Audits will also assist EPA in understanding where there may be common areas of confusion among industry participants that the Agency can improve upon in subsequent rulemakings.

Commenters from environmental organizations and state agencies expressed support for the proposed auditing requirement, because they agreed that third-party auditing improves compliance with environmental rules. Several HFC importers also expressed support, although at least one such commenter requested more time to meet the requirement.

Many commenters objected to the proposed auditing requirement based on concerns for the potential cost. One commenter said that annual audits could cost them between $40,000 and $60,000 annually, not including auditee staff time or time required for the auditor to compile the report. Another expressed concern about the cost of third-party audits, relative to the low

[88] In the proposed rule, EPA inadvertently used the term ''allocation-specific allowances'' in some places when it meant application-specific allowances. However, the text at proposed 40 CFR 84.33 is clear that the intent of the proposal was to cover ''[a]ny person receiving . . . application-specific allowances,'' (see 86 FR 27222–27223).

[89] Entities that import HFCs for the sole purpose of destroying those HFCs will be exempt from the auditing requirement described in this section. Entities that import HFCs for the sole purpose of transforming those HFCs will not be exempt from the auditing requirement. See regulatory text for details.

[90] Esther Duflo, Michael Greenstone, Rohini Pande, and Nicholas Ryan, ''Truth-Telling by Third-Party Auditors and the Response of Polluting Firms: Experimental Evidence from India,'' *Journal of Economics* (2013), 1499–1545. Available at *https://doi.org/10.1093/qje/qjt024.*

[91] Henrik Kleven, Martin Knudsen, Claus Kreiner, Søren Pedersen, and Emmanuel Saez, ''Unwilling or Unable to Cheat? Evidence From a Tax Audit Experiment in Denmark.'' *Econometrica,* 79: 651–692. (2011). Available at *https://doi.org/10.3982/ECTA9113.*

[92] Marcelo Bérgolo, Rodrigo Ceni, Guillermo Cruces, Matias Giaccobasso, and Ricardo Perez-Truglia, ''Tax Audits as Scarecrows: Evidence from a Large-Scale Field Experiment,'' *NBER* Working Paper No. 23631 July 2017, Revised January 2020 JEL No. C93, H26, K42.

[93] Keshav Choudhary and Bhanu Gupta, ''Third-party Audit and Tax Compliance—Evidence from a Notched Policy in India.'' (2019). Available at *https://www.isid.ac.in/~epu/acegd2019/papers/BhanuGupta.pdf.*

[94] Other government programs with third party audits include Food and Drug Administration's imported food programs (see *https://www.fda.gov/food/importing-food-products-united-states/industry-resources-third-party-audit-standards-and-fsma-supplier-verification-requirements*) and medical device inspection program (see *https://www.fda.gov/medical-devices/third-party-inspection-devices/inspection-accredited-persons-program*); the Consumer Product Safety Commission's children's product safety rule (see *https://www.cpsc.gov/Regulations-Laws--Standards/Rulemaking/Final-and-Proposed-Rules/Third-Party-Conformity-Assessment-Bodies*); and the Federal Communication Commission's Telecommunications Certification Bodies (see *https://www.nist.gov/standardsgov/telecommunications-certification-bodies-tcb-application-information*). Another comprehensive discussion of third-party programs conducted by the Administrative Conference of the United States is available at *https://www.acus.gov/sites/default/files/documents/Third-Party-Programs-Report_Final.pdf.*

volume of HFCs that some of its members purchase. Similarly, several commentors asked that EPA exempt smaller companies from the annual third-party auditing requirement. At least one commenter expressed concerns about companies' ability to furnish third-party audits during the first allocation period, which the commenter viewed as too tight a turn-around.

Based on the quantitative information that commenters submitted, EPA has updated its estimated recordkeeping and reporting costs in the RIA. Recognizing that the cost of an audit for each company will differ depending on the quantity and number of HFCs it acquires in a given year, the size of the business, and the amount of records that would need to be reviewed, EPA has increased the estimated average cost for an audit from approximately $2,500 to approximately $11,000 by adding in additional time for company staff and for the third-party auditor's time. The updated cost of the auditing requirement is still reasonable given the substantial benefit auditing has been proven to provide for overall compliance. In response to public comment, EPA is extending the compliance date by a year with the first audits due by May 31, 2024 (for calendar year 2023), rather than by May 31, 2023 (for calendar year 2022), as proposed. EPA will require auditors to review a representative sample of five percent of or 10 batch testing records, whichever is higher, rather than all records as proposed.[95] EPA has also lessened the amount of records from reclaimers that will be required to be audited (see below). These changes reduce burden while still maintaining a rigorous independent audit. Some commenters questioned the need for auditors to be CPAs, citing concerns about the cost as well as their potential lack of industry-specific knowledge. Commenters noted that it would take time to train an auditor on how this industry works, which would contribute to the cost and difficulty associated with the auditing requirements. A few comments questioned the value of independent audits and/or requested that EPA allow companies to self-audit.

EPA considered these comments but maintains that CPAs are best suited to conduct annual compliance audits of a regulatory program. CPAs are licensed by the states to ensure their independence, competency, and adherence to ethical standards. CPAs are also trained to be able to work across varied industries and understand accounting frameworks and recordkeeping obligations across sectors, and have conducted thousands of audits (called attest engagements) under the CAA fuels regulations over the last 25 years. EPA is delaying the auditing requirement by one year, for which should help give companies time to find qualified CPAs and for CPA firms to develop the industry-specific expertise. EPA disagrees with the suggestion to allow companies to self-audit as this would effectively be redundant with companies' annual and quarterly reports. Self-audits do not have the proven benefits for compliance and correcting errors as shown by third-party audits.

At least one commenter expressed concern about auditors' ability to keep their data private. EPA responds that the auditing profession has ethical norms and practices that prevent the release of confidential information learned in the course of an audit. Auditees also have the option to enter additional non-disclosure agreements with auditors. Both safeguards should provide additional assurance that CBI will be protected during audits.

One commenter asked that entities that import HFCs solely to transform them be exempted from the proposed auditing requirement. EPA disagrees with the commenter that auditing should not apply to such entities. HFCs used for transformation are regulated substances and could be a way for material produced or imported without allowances to be diverted for non-excepted uses. Anyone importing HFCs for transformation would need to have a third-party independent audit conducted by a CPA.

Some commentors asked that entities issued application-specific allowances not be subject to the proposed auditing requirements, especially if those allowance holders would confer their allowances up their supply chains to an HFC producer or importer. These commenters provided two concerns. The first concern was the difficulty of tracing their allowance conferrals up their supply chains, since they may not know how allowances are re-conferred through the supply chain. The second concern was the potentially duplicative nature of these audits, because application-specific allowances would often be ultimately conferred to producers or importers, which are already subject to annual auditing. One commentor said that tracing their allowances could involve delving into DOD contracts, and asked that if EPA requires audits of application-specific allowances, DOD should conduct the audits themselves because of the potential complexity and security concerns involved.

EPA is finalizing different provisions regarding auditing of application-specific allowances conferred by DOD for mission-critical military end uses (see below). Regarding concerns about an application-specific allowance holder not knowing all the entities in the supply chain, EPA is not requiring entities that are issued application-specific allowances to know the activities of all the other companies in the supply chain; this information would not be covered by an audit. These audits would not be duplicative, even if the ultimate conferee of the application-specific allowance was a producer or importer as the focus is to verify data reported to EPA (*e.g.,* allowances conferred, quantities purchased, and inventory for application use). With the exception of mission-critical military end uses, audits of application-specific allowance holders would need to review records documenting their conferral to the most immediate company in the supply chain. EPA is establishing a reporting requirement to track conferrals for all applications other than mission-critical military end uses and will determine in the future if additional audits of application-specific supply chains are needed (see Section X for a full discussion).

As noted above, EPA is finalizing different auditing requirements for mission-critical military end uses. EPA is allocating all mission-critical application-specific allowances to the Department of Defense and therefore will rely on internal monitoring and review procedures run by DOD instead of requiring the audit be conducted by a third party. Such an approach is appropriate given that DOD is a federal government agency, and many uses of regulated substances for mission-critical needs may implicate sensitive national security information.

Producers, importers, exporters, reclaimers, fire suppressant recyclers, exporters, and entities issued application-specific allowances, aside from allowances for mission-critical military end uses, must have auditors review the reports they provide to the Agency, and the inputs for developing those reports, to ensure that they were complete and accurate. The records subject to audit will differ depending on the type of entity being audited but at a minimum, auditors should review what is listed below.

[95] If a company engages in multiple types of HFC-related activity (*e.g.,* importing, reclaiming, etc.) then a random sample must be taken for each activity. So if a company both imports and reclaims HFCs, auditors must review a five percent random sample of the import records and, separately, a five percent random sample of the reclamation records.

Producers, importers, and exporters:
- The amount of production and consumption allowances received from EPA;
- The amount of allowances transferred and/or received via transfer;
- Records documenting the amount of application-specific allowances received from EPA and/or received by conferral from other companies;
- Records documenting the amount of HFCs imported, exported, produced,[96] destroyed, transformed, reclaimed, and/or recycled or sent to another entity for such purpose;
- Records documenting the amount of HFCs produced with application-specific allowances and amount sold or distributed for such purpose;
- The dates and the ports from which HFCs were imported or exported, as well as the relevant HTS codes, invoices, and bills of lading;
- The number and type of railcars, ISO tanks, individual cylinders, drums, small cans, or other containers used to store and transport imported HFCs;
- The inventory of regulated substances as of the end of the prior calendar year;
- A random sample (5 percent or 10, whichever is higher) of batch testing results;
- A random sample (5 percent or 10, whichever is higher) of certification IDs requested and generated and where the associated HFCs are sold and distributed; and
- All other reports submitted to EPA under 40 CFR part 84, subpart A.

Companies issued application-specific allowances by EPA:
- Records documenting the amount of application-specific allowances received from EPA;
- The amount of allowances transferred and/or received via transfer;
- Records documenting the amount of allowances received by conferral and/or conferred to other parties;
- Records documenting the amount of HFCs received from each allowance conferral (whether in bulk or a manufactured product);
- The total amount of HFCs purchased for the application-specific end use, and the amount of HFCs sold to another company for application-specific use;
- The inventory of regulated substances for application-specific uses as of the end of each reporting period in the prior calendar year (*i.e.,* December 31 and June 30);
- All other reports submitted to EPA under 40 CFR part 84, subpart A.

Reclaimers and Fire Suppressant Recyclers:
- The quantity of HFCs received for reclamation or recycling, including a random sample (5 percent or 10, whichever is higher) of records documenting the names and addresses of persons sending them material and the quantity of the material (the combined mass of refrigerant and contaminants) by HFC sent to them;
- Records documenting the quantity of HFCs reclaimed;
- A random sample (5 percent or 10, whichever is higher) of batch testing results;
- A random sample (5 percent or 10, whichever is higher) of certification IDs requested and generated and where the associated HFCs are sold and distributed; and
- All other reports submitted to EPA under 40 CFR part 84, subpart A.

The lists above may overlap in the types of records reviewed if a company fits into more than one category. As proposed, third-party auditors must electronically submit the results of their audit to EPA through e-GGRT before sending the results to the auditee. Results from the audit of a prior year's records are due to EPA no later than May 31st. EPA finds that May 31st allows sufficient time after the last report of the prior year is due to conduct an audit.

Regarding the Department of Defense and allowances issued for mission-critical military end uses, EPA is not requiring an independent third-party audit by a CPA due to the potentially sensitive nature of some DOD applications. DOD has long monitored its use of ODS and has internal controls to ensure the regulatory requirements are followed. EPA understands that DOD intends to build on that 25-year history to establish internal controls and monitoring for HFCs. EPA is establishing a requirement that DOD data and reports for application-specific allowances for mission-critical military end uses shall be subject to internal DOD monitoring and review for accuracy as prescribed by the Office of the Secretary of Defense. The results of this review shall be reported electronically to EPA by May 31 of the year following the compliance period. This report should not include national security sensitive details. Similar to the annual application, EPA and DOD would meet to discuss the report's findings to ensure accountability.

E. Petitions To Import HFCs as a Feedstock or for Destruction

All bulk imports of HFCs into the United States either require the expenditure of consumption allowances or authorization granted by EPA through a non-objection notice. This section discusses the petition process for requesting EPA authorization to import HFCs without expending allowances. There are two types of shipments addressed in this subsection: (1) Virgin HFCs that are imported for use in a process resulting in their transformation (*i.e.,* as feedstocks) or destruction; and (2) used HFCs that are imported for purposes of disposal at a destruction facility using an approved destruction technology.

The definition of ''produce'' in section (b) of the AIM Act excludes the manufacture of a regulated substance that is used and entirely consumed (except for trace quantities) in the manufacture of another chemical. The process is known as transformation and the regulated substances used and consumed are called feedstocks in this rulemaking. Feedstock HFCs are exempt from production, and therefore consumption, and do not require allowances to be produced or imported. Companies typically generate feedstocks for use within the same facility, but some feedstocks can be transported from another location or imported from abroad. EPA is calling this second-party transformation. These provisions of the rule address the risk of unlawful behavior associated with transporting and importing feedstock HFCs.

Used HFCs may need to be destroyed when they are contaminated beyond the point that reclamation is economical. Providing a pathway to import used HFCs for proper disposal within the United States can benefit the environment and the domestic destruction industry. To keep this process narrowly tailored to minimize a potential pathway for illegal imports, EPA is limiting this petition process for destruction to used HFCs. Importing virgin HFCs, even for disposal, requires the expenditure of consumption allowances. Similarly, and consistent with the discussion in section VII.A. and the proposal, importing used HFCs, including those that have been reclaimed or that are bound for reclamation, also requires the expenditure of allowances unless they are being imported for transformation or destruction consistent with § 84.25.

EPA based the proposed petition process in large part on the ones in 40 CFR 82.13(g)(5) and 82.24(c)(6) for the import of used ODS for destruction. EPA proposed that the importer of HFCs for feedstocks or destruction submit a petition to EPA at least 30 working days before the shipment's departure from the foreign port. EPA proposed the

[96] These records include records and reports related to the control of HFC-23 emissions.

petitioner submit the following elements to verify that these imports will in fact be transformed or destroyed: (i) Name, commodity code, and quantity in kilograms of each regulated substance to be imported; (ii) name and address of the importer, the importer ID number, and the contact person's name, email address, and phone number; (iii) name and address of the consignee and the contact person's name, email address, and phone number; (iv) source country; (v) the U.S. port of entry for the import, the expected date of import, and the vessel transporting the material; (vi) name and address of any intermediary who will hold the material before the HFCs are transformed or destroyed; (vii) name, address, contact person, email address, and phone number of the responsible party at the transformation or destruction facility; and (viii) an English translation, if needed, of the export license, application for an export license, or official communication acknowledging the export from the appropriate government agency in the country of export. If at the time of submitting the petition the importer does not know the U.S. port of entry, the expected date of shipment and the vessel transporting the material, and the importer receives a non-objection notice for the individual shipment in the petition, the importer is required to notify the relevant Agency official of this information prior to the date of importation [97] of the individual shipment into the United States.

EPA proposed that within 30 working days of receiving a complete petition EPA would send either a non-objection notice or an objection notice to the petitioner. The Agency may object to the petition if the petition provides insufficient information or if it contains or is suspected to contain false or misleading information. A petitioner may re-petition once if the Agency indicated ''insufficient information'' as the basis for the objection notice.

EPA received three comments on the proposed petition process, all of which were opposed to the requirement to petition the Agency for importing ODS to be transformed. The commenters stated that the petition requirements and timeframe for transformation are not logistically feasible or commercially practical. One of the commenters stated that they do not have full information requested in the petition until three days prior to departure, with other data elements being known only 14 days before departure. The commenter proposed a one-time notification to EPA for each shipment at such time as all requested information is finalized prior to export from the foreign port.

In this final rule EPA is maintaining the requirement to petition the Agency and the information requirements of the petition as proposed with two changes. To support the prohibition on importing HFCs for feedstock in cylinders designed to hold 100 pounds or less of a regulated substance (see Section IX.F.3), EPA is requiring that the petition provide (ix) the capacity of the container. To support real-time review of imports, EPA is also requiring that the importer report (x) the unique identification number of the container used to transport the HFCs as part of the petition. Given the logistical realities described by the commenters EPA is not finalizing a requirement that the petition be submitted to EPA 30 working days before leaving the foreign port. Rather, EPA is requiring that the petition be submitted at least 30 days before arriving at the U.S. port. This timing will allow the importer to provide all the necessary information and will not hold up the normal flow of imports. For companies that can submit complete information earlier, they would be able to submit once all requested information is finalized prior to export from the foreign port. EPA will issue a non-objection or objection notice within 21 days of the submission of the petition. Some companies will face burdens and costs associated with the Congressionally mandated phasedown; those increased burdens and costs unfortunately create economic incentives to avoid compliance. That reality increases EPA's statutory and policy imperative to identify and apply tools that counter those incentives to increase the rate of compliance. EPA has determined that petitions for importing material that is exempt from the definition of production is one of those compliance tools and will help along with the other tools described in this rule to ensure material imported into the U.S. either is imported with an allowance or has prior authorization.

EPA also proposed that HFCs imported for transformation or destruction be transformed or destroyed, as applicable, within 60 days of being imported into the United States. EPA took comment on whether it is appropriate to allow longer timeframes, up to 12 months. EPA received three comments on these timeframes. With regard to the timeline for transformation, commenters stated that 60 days is impractical. One recommended 120 days while a few others recommended 12 months. One commenter also noted that it may not be possible to identify when a specific molecule of imported HFC is transformed. For the reasons provided by the commenters EPA agrees that 60 days is too limited for transformation. EPA is finalizing a requirement that the material be transformed within one year of being imported.

EPA also received two comments that it may not be possible to destroy HFCs within the proposed 60-day timeframe. One commenter noted that the destruction of HFCs has to be carefully controlled to avoid the creation of hydrofluoric acid and damage to the equipment. Both commenters recommended 120 days. For the reasons provided by the commenters EPA agrees that 60 days is too limited for destruction. EPA is finalizing a requirement that the material be destroyed within 120 days of being imported.

EPA is requiring that the petitioner submit records indicating that the substance has been transformed or destroyed with the company's next quarterly reporting after its transformation or destruction. EPA is adding supporting prohibitions in § 84.5 for provisions that will be similar to 40 CFR 82.4(j)(2) and 82.15(b)(3) to prohibit the import of HFCs for processes that result in their transformation or destruction, or disposal by destruction, without having received a non-objection notice consistent with this petition process.

By providing an importer with documentation that the import is authorized, this will both expedite Customs clearance and result in a more secure border. It will prevent an importer from falsely claiming that their shipment does not require allowances or authorization from EPA because it is exempted. It also will track the movement of the import after entering the United States by attaching reporting obligations of the transformer or destruction facility.

[97] EPA is using the term ''date of importation'' consistent with CBP's definition at 19 CFR 101.1. ''Date of importation'' means ''in the case of merchandise imported otherwise than by vessel, the date on which the merchandise arrives within the Customs territory of the United States. In the case of merchandise imported by vessel, ''date of importation'' means the date on which the vessel arrives within the limits of a port in the United States with intent then and there to unlade such merchandise.'' This term is not identical to the term ''import'' as defined in 40 CFR 84.3, but is similar. Using CBP terminology will allow for the individual submitting information in ACE to better understand the meaning for this specific reporting element.

F. What other limitations are there on imports of HFCs?

1. Ban on Importing Feedstock HFCs in Cylinders

EPA proposed to prohibit the import of HFCs in cylinders designed to hold 100 pounds or less of a regulated substance intended for use in a process resulting in their transformation or destruction. As discussed in Section IX.E of this preamble, feedstock HFCs may be imported without expending consumption allowances. This minimum size restriction is intended to prevent the submission of false information that a particular shipment of HFCs in cylinders does not require allowances because they are for transformation or destruction processes. EPA does not anticipate this proposal would affect current business practices as these HFCs are typically imported and used in large volumes at specific facilities. Commenters, including companies that import feedstock HFCs, were supportive of this proposal. One commenter requested an exemption for HFCs used for research and development purposes as these are typically needed in smaller quantities. EPA responds that the Agency does not have sufficient information to say that these research and development applications qualify as transformation or that these small quantities could not be sourced domestically.

2. Imports of Heels

As proposed, any import of bulk regulated substance in any quantity requires consumption allowances. As with production, this requirement is intended to ensure that all the regulated substances listed in the AIM Act are appropriately phased down according to the schedule specified by Congress. EPA is concerned that allowing for imports of HFCs that are classified as ''U.S. goods returned'' or that are a ''heel'' within an otherwise empty container could provide avenues for illegal imports. For example, foreign produced ODS had sometimes been declared as a U.S. good returned to circumvent the allowance system. EPA proposed that allowances would be necessary for such imports.

One commenter supported an exemption of heels in cylinders, railcars, tank trucks, and ISO tanks, similar to how EPA opted to regulate ODS heels. The commenter stated that this would allow for easier import and export of regulated substances. Another commenter supported EPA's proposal to require allowances for the import of such. A third commenter noted that importing heels is a necessary part of the global supply chain. The commenter recommended that heels be treated as U.S. goods returned and that allowances be expended. The commenter also suggested that any returning ISO tank include evidence that it is directly connected to a full ISO tank shipment that originated in the United States.

EPA sees no statutory basis to exempt imports of heels from the requirement to expend allowances. As explained elsewhere, consumption allowances are required to be expended for imports of bulk chemicals, and there is no basis in the statute to change this requirement if a cylinder, railcar, tank truck, or ISO tank is only 5–8 percent full (the amount of a typical heel). Further, requiring imports of heels to involve allowance expenditure will prevent unlawful trade, since an importer could fraudulently mark something as a heel—and therefore exempt from needing allowances—when a container or tank was much fuller than a heel. In finalizing this requirement, EPA expects minimal disruption to normal activities since a cylinder, railcar, tank trunk, or ISO tank can be weighed to determine its mass, and therefore how many allowances will need to be expended to import any heel contained therein. Based on a review of Customs records, it also appears companies report this information to CBP already.

3. Transhipments

As proposed, companies that tranship HFCs do not need to expend allowances for that transhipment. Transhipped materials are intended to be imported into, and then exported out of, the country in identical quantities. To meet the definition of transhipped material, the HFCs cannot enter U.S. commerce. An entity does not have to expend consumption allowances for transhipped materials if the regulated substances are exported within six months of import. If a company does not export HFCs within six months of importation, the company would have to expend allowances. As explained in the reporting section, companies must notify the Agency when a transhipment is imported into and exported from the United States. EPA proposed that the reporting would be due within 30 working days of export, but is finalizing a shorter timeframe of 10 working days given CBP's regulations require a carrier to update the in-bond record within 2 business days of exportation (see 19 CFR 18.1(h)). The intent of these provisions is to minimize the risk of illegal imports through the guise of transhipments. The United States experienced this method of illegal importation during the phaseouts of CFCs and HCFCs.

EPA requested comment on the length of time a transhipment could reasonably be expected to be in the United States. One commenter recommended two months and another said one year is needed. Neither comment provided justification for their suggested timeframes. Therefore EPA is finalizing the six-month period as proposed.

G. How is EPA tracking the movement of HFCs?

The Agency proposed to establish a certification program that would use tracking or identification technology such as QR codes [98] or another tracking identifier to track the import, sale and distribution of HFCs starting January 1, 2024. EPA is largely finalizing this system as proposed, but, for reasons explained later in this section, is extending the compliance date for using this system. As of January 1, 2025, EPA will require QR codes on all containers imported, sold or distributed, or offered for sale or distribution, by producers and importers. As of January 1, 2026, EPA will require QR codes on all containers filled, sold or distributed, or offered for sale or distribution, by all other repackagers and cylinder fillers in the United States, including reclaimers and fire suppressant recyclers. As of January 1, 2027, EPA will require a QR code on every container of HFCs sold or distributed, offered for sale or distribution, purchased or received, or attempted to be purchased or received. This system is intended to ensure that HFCs imported into and distributed or sold in the United States for consumptive uses are covered by an allowance or were reclaimed or recycled for fire suppression use. Distribution and sale of HFCs that did not enter the market legally would lack a tracking identifier and thus could be easily spotted. This program supports compliance and, where needed, enforcement action. Buyers would also be able to know that they are purchasing legal HFCs. EPA took comment on the proposals related to this electronic tracking system, including ways to make it simple to use, while maintaining the

[98] A QR code is a type of matrix barcode that contains data for a locator, identifier, or tracker that points to a website or application using standardized encoding modes to store data. It is recognizable as black squares arranged in a square grid on a white background, which can be read by an imaging device such as a camera. In this rule we use the phrase ''QR code'' or ''tracking identifier'' as a stand-in for ''physical media that facilitate digital inventory tracking.'' EPA may or may not require QR codes specifically (bar codes or RFID chips are other possibilities, for example).

same functionality including the ability to report electronically.

EPA will assign certification IDs to producers and importers based on the quantity of production, consumption, and application-specific allowances they have. As allowances are expended, the certification IDs associated with those allowances will be assigned to the corresponding containers of HFCs prior to importation or being readied for transport from a production facility. For imports, the appropriate QR code needs to be affixed prior to importation. This will require coordination by the importer and the foreign producer to ensure the labels are affixed before arrival in the United States or before importation. While the foreign producer may be affixing the labels, it is the entity in the United States that is expending allowances who would be liable if the QR codes are not properly affixed. To allow for EPA to have a better understanding and oversight of the foreign company that will be filling the containers abroad, EPA is requiring reporting for imports on the name, address, contact person, email address, and phone number of the responsible party at the facility where the container of regulated substance(s) was filled. The certification ID system will be linked with EPA's allowance allocation tracking system to ensure that allowances were obtained for each MTEVe produced or imported. The certification will be tracked using a physical label with a QR code affixed to the container in which the material was sold after being produced in the United States or imported. When the QR code is scanned it will point to a website with a database that will indicate if the regulated substance in the container is legal, the quantity and common name of the HFC or HFC blend, the name it is currently being marketed under (*e.g.,* trade name or brand), and the date the container was filled.

Each time the material is bought/sold, or partitioned into another container, the tracking information must be updated. If HFCs are blended, the database entry for the identifier for that container must be updated by the blender to reflect that new information. EPA will establish protocols that ensure that once the tracking information is entered it may not be altered retroactively, thereby preserving the integrity of the information.

The container and its associated certification IDs must be tracked until it is sold to the final customer. The final customer will differ depending on the use of the HFCs. For example, EPA would consider an aerosol filler to be the final customer given the HFCs are being incorporated into a finished product. Similarly, a factory charging HFC refrigerant into a hermetically sealed appliance would be the final customer. HFCs used in field-charged or field-serviced applications, such as unitary split air conditioners, chillers, or refrigeration in supermarkets, would continue to have the certification accompany them until they are sold to a contractor or technician. HFCs used in fire suppression would continue to have the certification accompany them until they are sold to a company manufacturing products containing HFCs, such as fire extinguishers, or until they are sold to an entity installing fire suppression system cylinders in a total flooding application.

EPA's general understanding of the supply chain is that HFCs (from production or import) are shipped in large ISO tanks, railcars, individual cylinders or drums, and small cans. The material is then sold to entities in the distribution chain. The material may change hands one or more times before it is purchased by the final entity in the distribution chain and subsequently sold to the final customer. Anyone selling bulk HFCs would need to be registered in the system to allow for legal HFCs to be tracked from the point of import, sale, distribution, or offer for sale or distribution to the point of sale to the final customer (*i.e.,* the person that will use the HFCs) so that any illegal HFCs offered for sale at any point in the distribution chain could be identified. Sellers need to scan the containers as they are sold, and buyers who intend to sell the HFCs, other than the final customer, need to do the same.

Anyone who is filling a container or cylinder, whether for the first time or when transferring HFC from one container to one or more smaller or larger containers, is required to enter information in the system and generate a QR code for the new containers and add information on: the brand it would be sold under, the quantity and composition of HFCs in the container, the date it was filled, the certification IDs associated with the HFCs (if being repackaged), and the quantity of each HFC in the container.

EPA recognizes that not all HFCs would enter the market through the expenditure of an allowance. Most significantly, HFCs recovered from equipment (*e.g.,* refrigerants and fire suppressants) are sent for reclamation or recycling and can be resold into the market after they meet relevant standards. EPA received comment that companies that recycle HFCs used for fire suppression were not explicitly included in the proposed certification ID tracking system. As discussed below, EPA is modifying its proposed approach to add in coverage for fire suppressant recyclers.

Under the CAA section 608 regulations, reclaimers must be certified by EPA and report the amounts and names of the HFCs reclaimed on an annual basis. Recyclers of HFCs for fire suppression have not previously had to report to EPA but will be required to report information prospectively. EPA will generate certification IDs for reclaimers and fire suppressant recyclers in an amount equal to the quantity reclaimed or recycled in the previous year plus an amount based on the average annual growth in total United States HFC reclamation and recycling in the prior three years or 10 percent, whichever is higher. EPA anticipates reclamation and fire suppressant recycling will increase over time. Reclaimers and fire suppressant recyclers can request additional certification IDs from EPA if the initial distribution was insufficient and the reclaimer or recycler provides information to the Agency that can allow the Agency to confirm that additional reclamation or recycling is occurring. This could include reclamation totals for the same quarter in the prior year, a signed statement from a responsible official at the company stating the amount of reclamation they project for the remainder of the year based on current demand and available supply of recovered HFCs, or other documentation that shows how much additional reclamation is expected. The data behind the certification IDs and the QR code will be similar to that for HFCs produced or imported with allowances but will indicate that it is reclaimed or recycled and provide the name of the reclaimer or fire suppressant recycler.

To ensure regulated HFCs sold by reclaimers and fire suppressant recyclers are legal and eligible for sale, reclaimers and recyclers would need to log into the certification ID tracking system and, for each container of HFCs prior to selling regulated substances, provide information such as when the HFC was reclaimed or recycled and by whom; what regulated substance(s) (and/or the blend containing regulated substances) is in the container; how many kilograms were put in the container and on what date the container was filled; and for reclaimers certification that the purity of the batch was confirmed to meet the specifications in Appendix A to 40 CFR part 82, subpart F. If a container is filled with reclaimed and virgin HFC(s), the reclaimer and fire suppressant recycler

would also have to provide information on how much virgin HFC was used and have sufficient certification IDs to account for that newly produced or imported material to associate with the newly filled container.

EPA is also aware that under CAA sections 608 and 609, recovered HFC refrigerant can be resold if it was used only in a motor vehicle air conditioning (MVAC) equipment or MVAC-like appliance and is to be used only in MVAC equipment or MVAC-like appliance and recycled in accordance with 40 CFR part 82, subpart B (see 40 CFR 82.154(d)). This practice will be allowed to continue without requiring registration in the certification ID system. If someone is selling bulk HFCs, other than for use by that company for servicing MVAC equipment, for example to another auto shop, they need to be registered in the certification ID tracking system.

EPA recognizes that a large quantity of HFCs will already be in the United States market prior to the finalization of this rule. Therefore, the Agency initially proposed a compliance date of January 1, 2024, for these provisions and included a requirement that anyone in possession of containers of HFCs register their existing inventory of containers. As explained later in this section, after reviewing public comments EPA is extending this compliance date and is not finalizing the requirement to register inventory of containers that do not have certification IDs. After January 1, 2027, when the program is fully phased in, it will be unlawful for anyone to import, sell or distribute, or offer for sale or distribution, HFCs in a container that does not bear a legible QR code. The import, sale, distribution, offer for sale or distribution, purchase, receipt, and attempted purchase or receipt of uncertified bulk HFCs (or bulk HFCs in a container without a legible QR code) will be illegal and subject to civil and criminal enforcement to prevent smuggling and/or bypassing of the system.

EPA is also finalizing its proposal to require that any person who sells, distributes, or offers for sale or distribution, regulated substances must register with EPA in the certification ID system. To support this provision, EPA is prohibiting any person from purchasing or receiving, or attempting to purchase or receive regulated substances from someone that is not registered with EPA.

To ensure EPA is able to provide appropriate training and familiarize entities who will use the certification ID system, the agency is requiring that any person who produces, imports, reclaims, recycles for fire suppression uses, repackages or fills regulated substances, reclaimed regulated substances, or recycled regulated substances for fire suppression uses must register with EPA in the certification ID system at least six months before the date they are subject to the requirements (*e.g.,* producers would need to register no later than July 1, 2024). Likewise, any person who sells, distributes, or offers for sale or distribution, a container of bulk regulated substances must register with EPA in the certification ID system at least six months before the date they are subject to the requirements (*e.g.,* a distributor not already subject to the requirements would need to register no later than July 1, 2026).

Response to Comments

Some commenters expressed concerns about the cost and workability of the proposed QR code tracking system; many wanted more details about the design of the system and more time to comply. In particular, commenters expressed doubts about the ease of tracking individual cylinders of HFCs through commerce. EPA responds that the tracking system is an important part of the Agency's suite of compliance tools and is being finalized to support implementation of subsection (e)(2)(B) of the AIM Act (as discussed). EPA appreciates that it will require logistical adaptation and technological investment to set up and implement such a system effectively. For this reason, the Agency is finalizing an extended, phased-in roll out of the tracking system. Under this phased-in approach, the Agency will have more time to consult industry and develop an appropriate tracking system. Similarly, industry will have more time to adapt existing systems and/or procure any technology needed to support the tracking system and train staff. The new phase-in schedule starts January 1, 2025, for all containers imported and sold or distributed by producers and importers. On January 1, 2026, EPA will require QR codes on all containers filled and sold or distributed by all other repackagers and cylinder fillers in the United States, including reclaimers and fire suppressant recyclers. Finally, as of January 1, 2027, EPA will require a QR code on every container of HFCs sold or distributed.

These later dates allow for additional time to develop and pilot test the system in consultation with stakeholders (*e.g.,* including identifying ways to integrate EPA's system with a company's existing inventory management software and packaging equipment) and conduct training for users of the system. Phasing in the use of QR codes also negates the need for requiring registration of existing inventory. While this should provide sufficient time for anyone selling HFCs in containers without a valid QR code to sell all their inventory, EPA will monitor the market to see if registering inventory is needed.

A few commenters questioned EPA's authority for requiring reporting on individual containers of HFCs using a certification ID tracking system. Under the AIM Act, some companies will face burdens and costs associated with the Congressionally mandated phasedown; those increased burdens and costs unfortunately create economic incentives to avoid compliance. That reality increases EPA's statutory and policy imperative to identify and apply tools that counter those incentives to increase the rate of compliance. Given the risk of noncompliance, as described throughout Section IX, there is an imperative to use every reasonable tool at our disposal to ensure compliance and thus the objectives of the AIM Act. Identifying containers of HFCs that were illegally imported and produced is directly related to and supports EPA's ability to meet the statutory obligation in subsection (e)(2)(B) of the AIM Act. The tracking requirement is especially important for identifying illegal production—as that material will not have a check at the port like imports, and illegal imports that are able to evade authorities at the point of importation. The provision also reinforces the prohibition on disposable cylinders and ensures the universe of legal sales is understood through the required registration for anyone selling HFCs, and the requirements to scan QR codes and verify HFCs being purchased and sold are legal. Given the serious concerns about potential noncompliance and the undermining of Congress's directive to ensure reductions in production and consumption occur consistent with the statutory schedule, certification ID tracking will support EPA's ability to effectively implement the statute.

Comments noted that this proposal did not include fire suppressant recyclers. EPA has modified the regulatory text and approach to include fire suppressant recyclers. These companies will have to report to EPA and generate certification IDs on the same timeline as reclaimers. Some companies in the fire suppression industry expressed doubts about the ease of tracking individual cylinders of HFCs through commerce. EPA appreciates that fire suppression

companies deal in both bulk HFCs and products containing HFCs and engage in HFC recycling. EPA appreciates that this diversity of processes poses challenges to the implementation of bulk HFC tracking in fire suppression. However, these complexities are surmountable challenges to the creation of an effective HFC tracking system in this industry, and EPA intends to work with many stakeholders, including those in the fire suppression industry, in developing a workable system over the extended timeline being finalized here. EPA is committed to engaging in a thoughtful, iterative, and collaborative process to develop a tracking system that identifies illegal activity.

Some commenters wanted to be able to integrate the EPA tracking system into their existing inventory tracking systems. EPA appreciates that some companies have already made significant investments in digital inventory tracking systems. The Agency will use the extended timeline being finalized in this rule to work with these companies to identify opportunities to integrate existing systems with the new system for generating and tracking certification IDs.

Some comments expressed concerns about the reporting burden, in particular for reclaimers. To help ensure the quantity of regulated substances produced or consumed in the United States does not exceed the Congressionally mandated cap, EPA has determined that a comprehensive container tracking system is needed. This system will allow EPA to more readily identify HFCs that have been illegally produced or imported without allowances. While reclaimed and recycled material can be sold without allowances, EPA understands it is typically blended with virgin HFCs when sold, so inclusion in this certification ID tracking system is needed to track the movement of HFCs produced or imported with allowances. Additionally, reclaimers are putting additional HFCs onto the market each year for the same types of use that newly produced or imported material is used for. Including such material in the certification ID system allows for parity for anyone selling HFCs into the United States market and removes a potential loophole for a company that seeks to sell or distribute illegal material in the United States while claiming it is reclaimed or recycled. For these reasons, EPA is retaining its proposed inclusion of reclaimers and is adding in fire suppressant recyclers.

EPA has made changes to streamline the reporting that is required for the certification ID tracking system. For example, EPA has removed the requirement to include the date the batch was tested for purity and who certified the reclaimed regulated substance meets the purity requirement, and replaced it with a certification that the reclaimed material in a container was batch tested and meets the required purity standard in 40 CFR part 82, subpart F. EPA has also delayed the compliance dates and removed the requirement to register all inventory of cylinders held by companies prior to the compliance date.

Comments indicated the limit placed on how many certification IDs a reclaimer could generate in a year (5 percent or the average annual growth rate over the past three years for all reclaimers) was unnecessarily restrictive. EPA reviewed past reclamation data and determined that reclamation values regularly fluctuate by more than 5 percent. EPA has determined that 10 percent is a more appropriate value, in addition to relying on the average annual growth over the past three years for all reclamation. These same conditions would also apply to fire suppressant recyclers. Reclaimers and fire suppressant recyclers could still request additional certification IDs using the process described earlier in this section.

Some commenters were concerned about the level of detail that EPA might include in publicly available data. EPA intends to release several data elements associated with each container of HFCs to potential buyers of HFC material, to support this system. To allow buyers of HFCs to determine whether the HFC they are purchasing is legal to buy, EPA will release the following information: (1) Whether the HFC being sold is legal to purchase based on information available to EPA; (2) when the container was filled; (3) the specific HFCs in the container; and (4) and the brand name the HFCs are being sold under. EPA will also release a list of registered suppliers so purchasers know where they can legally buy HFCs. For further discussion on EPA's intentions to release data and what information will be maintained as confidential, readers are directed to Section X.C.

Most buyers desire to purchase only legal HFCs. However, in the absence of a way to distinguish between legal and illegal HFCs, buyers could unwittingly buy illegal HFCs and may be unintentionally supporting the demand for and trade in illegal HFCs. For example, in an enforcement case that concluded in 2018,[99] there was evidence that cylinders likely imported without allowances were bought and sold by multiple suppliers before they were finally determined to be counterfeit and likely illegally imported. There was no evidence that anyone in the supply chain knew the material was likely illegally imported other than the importer until the final purchaser noticed the refrigerant was off-spec and in a cylinder that did not match the typical packaging for that brand of product. For this reason, it is important to involve each buyer and seller in the accountability process and provide each buyer with accurate information on the origin of the HFCs they intend to purchase.

H. What reporting is required to support real-time review of imports?

In the proposed rule, EPA stated it intended to work with CBP to develop an automated electronic mechanism to check in real time whether there are sufficient allowances available to allow for an import of HFCs. EPA is finalizing requirements under AIM Act authority to provide information to EPA that generally aligns with existing CBP import filing requirements under current Customs laws. These requirements will allow for EPA to verify if allowances are available or the HFCs have prior approval for import in the case of HFCs imported for destruction or transformation under 40 CFR 84.25, or imported for transhipment under 40 CFR 84.31(c)(3), and confirm whether a shipment should be allowed to clear Customs or not. EPA is requiring that the following information be electronically filed through ACE no later than 14 days prior to importation consistent with CBP definitions at 19 CFR 101.1: Quantity of containers and weight; importer information; consignee information; the correct HTS code; a description of the cargo, including the chemical name(s) of the HFCs (*e.g.,* HFC-134a) and/or name(s) of the HFC blend(s) (*e.g.,* R-404A); the country of origin; and contact information associated with the shipment. Most of these elements are already required to be filed consistent with 19 CFR chapter I. Specific data elements that align with existing import filing submitted to CBP through ACE include: (1) Cargo description; (2) quantity; (3) quantity unit of measure code; (4) quantity unit of measure; (5) weight; (6) weight unit of measure; (7) port of entry; (8) scheduled entry date; (9) HTS code; (10) HTS description; (11)

[99] ''O.C. Man Pleads Guilty to Illegal Sales of Ozone-Depleting Refrigerant.'' *The Orange County Register,* Nov. 2018. Available at *www.ocregister.com/2018/03/08/o-c-man-pleads-guilty-to-illegal-sales-of-ozone-depleting-refrigerant.*

origin country; (12) importer name and importer of record identification; and (13) consignee name.

The data elements EPA is requiring import filing on, with the exception of one element (CAS Numbers), must already be filed with CBP through ACE or reported to EPA. Therefore, the Agency is assuming no additional reporting burden from this requirement. Given there is not currently a complete and exclusive list of HFC- and HFC blend-specific HTS codes, EPA is also requiring that anyone importing HFCs must report through ACE the CAS Number(s) of the HFC(s) included and, for HFCs that are in a mixture with other HFCs or other substances, either the ASHRAE numerical designation of the refrigerant or percentage of the mixture containing each regulated substance. EPA is also requiring that non-objection notices issued consistent with section 84.25 and proof that the importer has reported a transhipment to EPA consistent with 84.31(c)(3) be provided to CBP electronically by loading an image of the document to the Document Image System, or successor platform.

To ensure EPA has sufficient data to check in real-time if an importer has sufficient allowances or authorization for a particular shipment of HFCs, EPA is requiring that importers of HFCs report these data elements prior to importation. This reporting will be required under the AIM Act, and pursuant to EPA regulations codified in this rule, but for ease of implementation and to avoid duplicative electronic reporting, information required to be reported under EPA's part 84 regulations will be submitted as import filings and collected through a CBP electronic system (*e.g.,* ACE and its successor platforms). CBP will make these import filing data elements available to EPA for review. EPA is requiring that these data elements be filed no later than 14 days before importation. Further, although EPA acknowledges that CBP allows an importer to correct reported data elements for a certain period of time after the goods clear Customs, data elements reported pursuant to these part 84 regulations must be reported no later than 14 days prior to importation. EPA will make its determination on whether an importer has sufficient allowances for the import at the time of review based on the information provided. If the importer makes a valid Post Summary Correction or files a Protest that CBP approves consistent with 19 CFR chapter I that would change the number of allowances expended, EPA will adjust the importer's allowance balance. If after correction the amount imported exceeds an importer's available allowances, the importer would be in violation of 40 CFR part 84, subpart A and would be subject to administrative consequences and enforcement action.

As discussed elsewhere in this section, EPA and CBP require timely access to this information to ensure that EPA can meet the statutory requirement in subsection (e)(2)(B) that production and consumption do not exceed Congressionally directed levels. Under the AIM Act, some companies will face burdens and costs associated with the Congressionally mandated phasedown; those increased burdens and costs unfortunately create economic incentives to avoid compliance. That reality increases EPA's statutory and policy imperative to identify and apply tools that counter those incentives to increase the rate of compliance. Given the risk of noncompliance, as described throughout Section IX, there is an imperative to use every reasonable tool at our disposal to ensure compliance and thus the objectives of the AIM Act. Requiring companies to provide data to EPA through ACE so that EPA can conduct a real-time review of allowances while imported material is at the port is directly related to and supports EPA's ability to meet the statutory obligation in subsection (e)(2)(B) of the AIM Act. Given the serious concerns about potential noncompliance and the undermining of Congress's directive to ensure reductions in production and consumption occur consistent with the statutory schedule, real-time review of import data will support EPA's ability to effectively implement the statute.

The concept of providing information to EPA prior to importation is consistent with comments EPA received on the proposed rule. One commenter suggested EPA establish a system similar to the Notice of Arrival procedure for imports of pesticides.[100] The commenter noted that ''[a]n importer or its broker must already submit certain detailed information to Customs prior to arrival of the ship containing the HFCs. The initial information submitted includes, but is not limited to, the importer name and address, importer number, harmonized tariff code and country of origin.'' The commenter went on to state that EPA and CBP could use this information to make a determination to release the goods or examine them further. Another commenter noted that one problem in the EU was that they did not have a system where customs officials can cross-check whether imports are within a company's allowance quota and encouraged EPA to provide contemporaneous information to Customs officials. Another commenter noted similarly that the real-time check at the border is the most important tool to prevent illegal imports. Other commenters recommended prior notification to EPA before shipments arrive at a port of entry. The requirements finalized in this section are responsive to commenters' suggestions and help address concerns raised by the commenters.

Use of Harmonized Tariff System Codes

Consistent with EPA's proposal and the discussion in Section IX.A regarding administrative consequences, EPA is requiring that importers use the correct HTS code for bulk HFC imports and exports through this final rule. EPA notes that this is also required by current CBP regulations, so this provision would allow both agencies to bring enforcement action for use of inaccurate HTS codes. Use of the correct HTS code is important to ensuring EPA and by extension CBP have the information needed to conduct a real-time check on imports and ensure EPA meets the directive in subsection (e)(2)(B) of the AIM Act.

The United States International Trade Commission (USITC) maintains and publishes the HTS for the United States.[101] The United States HTS codes for bulk HFCs are contained in chapter 29 (for ''neat'' or single component HFCs) and chapter 38 (for mixtures or blends containing HFCs).[102] The current HTS codes that cover single component bulk HFCs include 2903.39.20.20, 2903.39.30.35, and 2903.39.20.45. For bulk HFCs in mixtures, 3824.78.00.20 and 3824.78.00.50, and to a lesser extent 3824.71.01.00, 3824.74.00.00, are generally the appropriate codes.

These codes are expected to be updated early in 2022 as part of the five- to six-year cycle for updating the global Harmonized Commodity Description and Coding System (often referred to as the Harmonized System).[103] USITC has

[100] See *https://www.epa.gov/compliance/importing-and-exporting-pesticides-and-devices#import.*

[101] For more information, see *https://www.usitc.gov/harmonized_tariff_information.*

[102] The current HTS is available at *https://hts.usitc.gov/current*

[103] For more information on the Harmonized System, see *http://www.wcoomd.org/en/topics/nomenclature/overview/what-is-the-harmonized-system.aspx.* The United Nations Environment Program's OzonAction developed a fact sheet explaining how the codes were updated globally, which EPA has placed in the docket.

proposed new codes that would disaggregate codes much further than the current codes under subheadings 2903.41.10 through 2903.49.00.[104] For bulk HFC mixtures/blends, the new codes would be under heading 3827, with most HFCs falling under subheadings 3827.51.00 through 3827.68.00.

X. What are the recordkeeping and reporting requirements?

Subsection (d)(1)(A) of the AIM Act specifies that on a periodic basis, but not less than annually, each company that, within the applicable reporting period, produces, imports, exports, destroys, transforms, uses as a process agent, or reclaims a regulated substance shall submit to EPA a report that describes, as applicable, the quantity of the regulated substance that the company: Produced, imported, and exported; reclaimed; destroyed by a technology approved by the Administrator; used and entirely consumed (except for trace quantities) in the manufacture of another chemical; or, used as a process agent.

This section presents an overview of the generally applicable requirements, provisions that received public comment, and provisions that EPA is finalizing differently than as proposed. The full reporting requirements can be found in § 84.31 of the regulatory text.

A. What are the generally applicable recordkeeping and reporting provisions?

Through this final rule, EPA is requiring recordkeeping and reporting for any company that produces, imports, exports, distributes, transforms, uses as a process agent, reclaims, or destroys regulated substances as well as any company that receives an application-specific allowance. Given that the AIM Act controls all production and consumption of HFCs in the United States, and data on import, export, destruction, reclaim, feedstock, and process agent use are relevant to determining national production and consumption figures, all companies are subject to the recordkeeping and reporting requirements and there is no minimum threshold for reporting. The AIM Act in subsection (d)(1)(A) provides EPA with clear authority to establish reporting requirements that apply to ''*each* person who, within the applicable reporting period, produces, imports, exports, destroys, transforms, uses as a process agent, or reclaims a regulated substance'' (emphasis added).

Unless otherwise specified, such as for application-specific allowance holders, EPA is requiring quarterly reporting. Quarterly reporting helps to ensure that annual production and consumption limits are not exceeded and is necessary for the Agency to review allowance transfer requests. Some stakeholders generally supported quarterly reporting, noting that it is consistent with the reporting for ODS. Other commenters preferred annual reporting as it is less burdensome. One such commenter stated that quarterly reporting is unnecessary given the real-time tracking information from the certification IDs. One commenter preferred biannual reporting and stated that the data provided would be more accurate than quarterly data. Another company requested that all reporting related to transformation be annual since there are no production and consumption allowances which are required to be tracked. EPA received additional comments on the timing for reclaimers and companies holding application-specific allowances as discussed separately below.

EPA is requiring quarterly reporting as proposed. EPA is aware of the reporting burden of this rule but disagrees that annual reporting will significantly reduce burden given that all the data elements must still be provided. Quarterly reporting is necessary to ensure that allocation limits are not exceeded and allow for trading of allowances. Providing data quarterly also has benefits to EPA by allowing more frequent review of allowances expended, which facilitates monitoring of compliance with the allocation limits and earlier identification of potential issues. EPA is also able to identify and correct inaccurate reporting when it arises. EPA disagrees that certification IDs are a substitute for quarterly reporting. The certification ID system will not be implemented for several years whereas the first year of allowances begins January 1, 2022, and reports will be due 45 days after the close of the first quarter. With regard to the comment that biannual data would be more accurate than quarterly data, EPA does not understand why that would be the case and the commenter did not provide an explanation. EPA expects companies to revise their data, regardless of reporting frequency, if they discover errors in previous submissions. With regard to the comment on reporting transformation activities, EPA responds that it is precisely because there are no production and consumption allowances that close monitoring through quarterly reporting is necessary. Without allowances, EPA must more carefully ensure that the regulated substances are transformed as required. EPA notes that data about process agents only needs to be reported annually.

Reports required by this section must be submitted within 45 days of the end of the applicable reporting period, unless otherwise specified. The reporting periods are January 1–March 31 (Quarter 1), April 1–June 30 (Quarter 2), July 1–September 30 (Quarter 3), and October 1–December 31 (Quarter 4). Quantities must be stated in terms of kilograms for each regulated substance unless otherwise specified. The report must be signed and attested by a responsible officer (*e.g.,* appropriate responsible officer under the CAA (42 U.S.C. 7401 *et seq.*)), and copies of records and reports must be retained for five years.

Section (d)(1)(C)(iii) of the AIM Act states that each periodic report shall include, as applicable, the information described for the baseline period of 2011 through 2013. EPA interprets this provision as allowing the Agency to collect information necessary to establish the United States' production and consumption baselines. EPA reads the phrase ''as applicable'' to mean that every quarterly report does not need to reiterate that baseline information, only an initial report.

Subsection (d)(1)(C) of the AIM Act specifies that reporting is no longer required if a company notifies EPA that they have permanently ceased production, import, export, destruction, transformation, use as a process agent, or reclamation of all regulated substances. Any activity that occurs earlier in that year before the cessation of activities must still be reported for that year. EPA is clarifying that the recordkeeping requirements still apply and thus the company that ceases reporting must maintain records for five years.

Subsection (d)(2) of the AIM Act states that EPA may allow an entity subject to the AIM Act's reporting requirements ''to combine and include the information required to be reported under [the AIM Act] with any other related information that the [company] is required to report.'' Many commenters urged EPA to minimize duplicative reporting between the AIM Act reporting requirements and the GHGRP. One commenter noted that the HFC timeline for the first quarter will be duplicative of annual GHGRP reports due March 31.

EPA is coordinating reporting for similar or identical data elements by

[104] See 85 FR 73294 and the associated investigation, number 1205–13, available at *https://www.usitc.gov/investigations/1205/1205-13.htm.*

using the same online portal for submitting both AIM and GHGRP data (e-GGRT) and intends to reduce duplicative reporting by populating the annual report submitted under GHGRP with data submitted under the AIM Act. Reports required by this rule must be submitted electronically using EPA's e-GGRT (or a future successor system). EPA is also requiring reports be at the facility level, and not at the corporate level, which will also add in synchronization between these two programs and better allow utilization of the e-GGRT system. Commenters supported facility-level reporting especially if it allows for use of the e-GGRT system. Reporting at the facility-level will also provide more detail to aid in EPA's review of compliance.

B. How is EPA responding to comments on the proposed recordkeeping and reporting provisions?

Holders of Application-Specific Allowances

Commenters requested that EPA limit the data collected from companies receiving application-specific allowances. They urged EPA to only collect information that is pertinent for implementing the phasedown of HFC usage in those end uses. One commenter provided input on specific data elements that EPA should remove or revise. Another urged EPA clarify that the information about regulated substances to be reported be limited to the application and not all regulated substances used by the company. A few commenters were also concerned about the sensitive nature of the data to be provided and urged EPA to put in place robust measures to protect data. A few commenters supported EPA's proposal for biannual reporting rather than quarterly reporting. One commenter recommended annual rather than biannual reporting as EPA will receive data on application-specific allowance expenditures through quarterly reports submitted by producers and importers. Several comments noted potential sensitivities around the supply chain for conferred application-specific allowances that would prevent the company using HFCs for application-specific purposes from knowing all the companies that may be conferred an application-specific allowance before it is used for production or import.

Any company issued application-specific allowances, or that receives application-specific allowances through a transfer or conferral, must certify to its producer, importer, and/or supplier when purchasing HFCs produced or imported using those allowances that the regulated substances are solely for the specified application in subsection (e)(4)(B)(iv) of the Act and will not be resold or used for other purposes. A copy of the certification must be maintained by the company that uses the HFCs produced or imported with those allowances. If allowances are conferred multiple times, the certification need not flow up the chain if companies seek to keep such information private. However, a certification must be held by all parties to each conferral.

Additionally, to facilitate the conferral of allowances, ensure the legitimacy of application-specific allowances that are conferred, and to ensure EPA has the requisite information to track application-specific allowances, the Agency is requiring anyone conferring an application-specific allowance to report that to EPA. The Agency would not need to pre-approve the conferral for it to proceed but would need to issue a confirmation notice that such allowances had changed hands. This accountability is necessary to ensure application-specific allowances are used for production and import in the same year they are issued, to ensure allowances conferred for one application are used in that application, to ensure a company conferring allowances has sufficient application-specific allowances for conferral, and to allow for complete tracking from the entity receiving allowances and the company using those allowances for production or import. As noted previously, there would be no limit on the number of conferrals and there would be no offset associated with conferrals so long as the company issued the application-specific allowances receives the HFCs produced or imported with such allowances.

In response to the comment requesting annual reporting, EPA responds that annual reporting would not provide EPA with the information needed to manage the program. Biannual reporting is necessary to gather the data for two objectives: (1) To provide end-of-year accounting that must be coordinated with other annual reporting processes, and (2) to provide information with sufficient time for EPA to determine by October 1 the quantity of application-specific allowances to allocate for the next year. EPA is finalizing its proposal that recipients of application-specific allowances report by July 31 and January 31 of each year.

Based on comments that the Agency limit the reporting requirements to information needed to implement the phasedown, EPA is not finalizing some of the proposed reporting requirements. The remaining data elements are necessary for EPA to either determine how many allowances to allocate or ensure the integrity of the application-specific allowance program. Given the dual nature of application-specific allowances, EPA needs reporting on whether the allowance was expended to produce or import the regulated substance. While EPA can gather some of this information from reports from producers and importers, such reports would not indicate the application and other details. EPA also needs to understand whether an application-specific allowance holder is expending the allowance themselves to directly import. In such instances, the allowance holder must also submit a report under Section 84.31(c) as an importer. To determine whether the Agency did not issue enough allowances, EPA is requiring reporting of the quantity of HFCs purchased from the open market. This will allow the Agency to confirm any request for additional allowances, assuming all allowances were also expended. For the opposite reason, EPA is requesting data on whether HFCs produced or imported through expending application-specific allowance are held in inventory. Combined with data on trades, this could indicate that the Agency allocated too many or too few allowances. For similar reasons, EPA is requiring information on quantities destroyed or recycled. EPA recognizes that this may not apply to all end uses. Lastly, EPA is retaining the requirement that the report include information about the companies to which application-specific allowances were conferred. Combined with the requirement to report to EPA when an allowance is conferred, this will allow the Agency to track the allowance conferral should it be used for purposes other than the application-specific end use for which it was allocated.

EPA is not finalizing the proposed reporting requirement for the quantity of each regulated substance contained in exported products. This is not information that the Agency needs to calculate consumption since it is not a bulk substance. Nor does the Agency need to know whether the application-specific allowances were expended to manufacture products for the domestic or export markets. Therefore, EPA is not finalizing those proposed data elements. However, EPA is finalizing a requirement that application-specific allowance holders that contract the manufacturing of defense sprays or metered dose inhalers, or the servicing of onboard aerospace fire suppression,

include contact information for the entity doing the manufacturing or servicing, and whether the responses in the quarterly report apply to the company that is allocated application-specific allowances or the company receiving the contract for manufacturing and/or servicing.

Based on the comments received, and consideration of the data the Agency already has received from application-specific allowance holders, EPA is streamlining the information included in the report due by July 31 of each year. The July 31 report must contain a description of plans to transition to regulated substances with a lower exchange value or alternatives to regulated substances. The added requirement to report information related to contracted out manufacturing and servicing is also only applicable to the July 31 report. Also, if a company is requesting additional allowances due to unique circumstances, the report must include a projection of the monthly quantity of additional regulated substances needed by month and a detailed explanation, including relevant supporting documentation to justify the additional need. Providing these data by month allows EPA to better assess how the facility will be scaling up its use and allow for a more thorough review of the company's projected need for HFCs. As noted previously, the unique circumstances that EPA will consider are: (1) New manufacturing capacity coming on line; (2) the acquisition of another domestic manufacturer or its manufacturing facility or facilities;[105] and (3) a global pandemic or other public health emergency that increases patients diagnosed with medical conditions treated by MDIs.

EPA is requiring the more comprehensive information envisioned in the proposal only from entities that are requesting application-specific allowances for the first time. Specifically, this report would include: (1) Total quantity of all regulated substances acquired for application-specific use in the previous three years, including a copy of the sales receipts, paid invoices, or other records documenting that quantity acquired; (2) the name of the entity or entities supplying regulated substances for application-specific use and contact information for those suppliers; (3) the quantities of regulated substances held in inventory for application-specific use as of June 30 of the prior year and June 30 in the current year; and (4) a description of plans to transition to regulated substances with a lower exchange value or alternatives to regulated substances.

Entities allocated application-specific allowances must maintain the following records: Records necessary to develop the biannual reports; a copy of certifications provided to producers and/or importers when conferring allowances; a copy of the annual submission requesting application-specific allowances; invoice and order records related to the purchase of regulated substances; records related to the transfer of application-specific allowances to other entities; and records documenting the use of regulated substances.

As discussed elsewhere in this final rule, EPA is establishing different, but functionally equivalent, requirements for DOD to report on mission-critical military end uses. DOD will need to submit a biannual report that will have different reporting elements to align with the unique information needed for administering the program. DOD will also need to manage and track conferral of allowances to the eventual producer(s) or importer(s) and keep appropriate records to support their reporting.

Reclaimers of HFCs

Reclaimers commented that the proposed rule, including the recordkeeping and reporting requirements, places a particularly high burden on reclaimers, which are predominantly small businesses. One stated that it is inappropriate for reclaimers to have the same level of recordkeeping and reporting as production and consumption allowance holders. This burden will increase the cost of reclaimed material and undermine future reclamation.

EPA is finalizing quarterly reporting for reclaimers. The data elements are generally the same as those under 40 CFR 82.164(d). While EPA proposed to require that reclaimers provide information on the quantities of used, reclaimed, and virgin HFCs held in inventory onsite at the end of each quarter, EPA is not finalizing this additional inventory report. As noted later in this section, EPA is requiring an annual report on inventory for reclaimers, consistent with that for producers, importers, and exporters.

Reclaimers must also provide a one-time report with information on inventory, the name of the laboratory that conducts the batch testing, a signed statement from that laboratory confirming there is an ongoing business relationship with the reclaimer, the number of batches tested for each regulated substance or blend containing a regulated substance in the prior year, and the number of batches that did not meet the specifications in Appendix A of 40 CFR part 82, subpart F in the prior year. Reclaimers must maintain records for five years, instead of the three years required under 40 CFR part 82, subpart F.

Under the existing regulations in subpart F codified at 40 CFR 82.164, reclaimers must also maintain records of the analyses conducted to verify that reclaimed refrigerant meets the necessary specifications prescribed in Appendix A to 40 CFR part 82, subpart F, based on AHRI Standard 700–2016, and maintain records on a transaction basis for three years of the names and addresses of persons sending them material for reclamation and the quantity of the material (the combined mass of refrigerant and contaminants) by refrigerant sent to them for reclamation.

Recyclers of HFCs Used as Fire Suppressants

Some commenters noted to the Agency that HFCs recovered from fire suppression applications are recycled but not reclaimed. To reclaim is a defined term pertaining to purifying refrigerants and verifying the purity based on an industry standard. Fire suppression agents are not refrigerants and are not subject to that industry standard. Consequently, companies other than EPA-certified reclaimers currently recycle such HFCs. EPA is requiring quarterly reports from companies that recycle HFCs used as fire suppressants that request similar information as reclaimer reports except for provisions related to that industry standard.

Specifically, recyclers must report the quantity of material (the combined mass of regulated substance and contaminants) by regulated substance sent to them for recycling, the total mass of each regulated substance, and the total mass of waste products. For the fourth quarter only, each recycler must provide the quantity of each regulated substance held in inventory onsite broken out by recovered, recycled, and virgin. Recyclers must also maintain records of the names and addresses of persons sending them material for recycling and the quantity of the material (the combined mass of regulated substance and contaminants) by regulated substance sent to them for recycling. Such records must be

[105] In addition to data and projections provided in the application, EPA would rely on previously reported data where appropriate to assess the need for the new owner.

maintained on a transactional basis for five years.

C. How will EPA treat HFC data collected under the AIM Act?

EPA proposed that several data elements that would be required to be reported pursuant to the AIM Act regulations would not be eligible for CBI treatment, and would be affirmatively released, including: (1) Company-level production and consumption data, (2) aggregated national data, (3) company-specific allowance data, (4) transfer data, (5) HFC-23 emissions data, and (6) information relevant to the Kigali Amendment and the Montreal Protocol. EPA alternatively proposed to not provide CBI treatment to any element reported to the Agency pursuant to the part 84 regulations and affirmatively release all data as reported to the Agency, though some of the identical data elements are required pursuant to the GHGRP and have been determined to be CBI under the GHGRP.

EPA is not finalizing its proposed determination that all data collected under the regulations established in this rulemaking are not entitled to CBI treatment. Accordingly, EPA is not finalizing the proposed alternative path to affirmatively release all data reported to the Agency in accordance with AIM Act reporting requirements. As further detailed in this section, EPA is finalizing that some data reported prospectively at chemical-specific and facility-specific levels, such as production and consumption data, will not be entitled to CBI treatment and will be affirmatively released by the Agency without further notice. EPA also will not provide confidential treatment to, and intends to make public without further notice, each company's allowance allocations and update remaining allowance balances periodically throughout the year. EPA is also making a final determination in this rule that some data elements are entitled to confidential treatment, including sales data, business relationships, pricing information, and many elements reported pursuant to the QR tracking system and by application-specific allowance holders. Remaining data elements reported to the Agency that are neither labeled as entitled to confidential treatment nor labeled as not entitled to confidential treatment in the memo to the docket can be claimed as CBI by reporting entities, and EPA will treat them as confidential pending possible future CBI determinations pursuant to EPA's CBI regulations at 40 CFR part 2. For all data elements that EPA is determining to be confidential or for which EPA will provide provisional confidential treatment if claimed by reporters as CBI, EPA will release aggregated data if there are three or more reporting entities. This section describes in more specificity what information the Agency is determining will not be provided confidential treatment, including those data elements for which the Agency is declining to follow prior CBI determinations made by the Greenhouse Gas Reporting Program, and what information will be treated as confidential business information.

1. Which specific data elements are not entitled to confidential treatment?

EPA is finalizing the proposal to not provide confidential treatment to, and hereby makes the determination to not provide confidential treatment to, and affirmatively release without further process, the following information: (1) Each company's EVe allowance allocation with allowance balances periodically updated throughout the year; (2) reported facility-level chemical-specific production data, including total production, and production for feedstock and destruction; (3) production data provided by chemical manufacturing facilities that produce HFC-23, specifically the amount and type of chemicals intentionally produced on a facility line that also produces HFC-23; (4) company-level, chemical-specific data on individual import and export shipments, including chemical type, quantity, source country, HTS code, port of entry, date, and the intended use if for destruction or transformation; (5) facility-level chemical-specific destruction data; (6) all data reported on transhipments; and (7) companies receiving transferred allowances and the quantity of allowances received.

As described in more detail in Section IX.G, EPA would release several data elements associated with each container of HFCs to potential buyers so they can verify the HFCs are legally produced, imported, recycled, or reclaimed, including: (1) Whether the HFC being sold is legal to purchase based on information available to EPA; (2) when the container was filled; (3) the specific HFC(s) in the container; (4) and the brand name the HFCs are being sold under. EPA will also release a list of registered suppliers so purchasers know where they can legally buy HFCs. EPA has provided in the docket a document that provides each individual data element required to be reported under the part 84 regulations and denotes EPA's final determination regarding whether each element will be entitled to confidential treatment or not. For data elements not explicitly listed in the document in the docket, if a company claims it as CBI, EPA will treat it that way pending a future determination, which would follow the CBI regulations.

Many entities that are required to report under EPA's newly established part 84 regulations were widely opposed to EPA's proposed approach of not providing confidential treatment for many elements reported to the Agency. Several commenters requested that EPA follow the approach to CBI treatment established under GHGRP. Some commenters stated that company-level production and consumption data are highly confidential. Some argued that increased data release divulges proprietary information to competitors and the Agency's overall transparency goals do not justify increased transparency through the release of information. One commenter opposed to the broader release of data said EPA could release the names of allowance holders and their allocation levels without revealing CBI. One commenter supported releasing EVe-weighted information as they consider the type of HFC(s) it uses or may use in the future to be CBI.

Commenters' arguments on this issue were generally broad, sweeping, and perfunctory. While commenters alleged that releasing reported information would be harmful to businesses or divulge proprietary information, commenters generally did not provide sufficient explanation in their comments to demonstrate their customary handling of the information proposed to be released, but instead simply relied on conclusory statements that most of the information should be kept confidential and EPA should rely on previous determinations made under different reporting regimes where they overlap with this rule. Accordingly, commenters did not provide sufficient information to demonstrate to EPA that any particular data element for which EPA is not providing confidential treatment should be treated as CBI.

Some commenters supported EPA's efforts to make more data reported under this program publicly available for reasons similar to those the Agency discussed in the proposed rule and reiterates here. Transparency will facilitate implementation of the allocation program and increase the public and current market participants' ability to provide complementary compliance scrutiny. It will allow the public and the industry to identify market participants and volumes in trade and thus enable them to alert EPA and other federal authorities when they suspect HFCs may have been produced,

imported, or sold without necessary allowances or any available exceptions in violation of the regulations at 40 CFR part 84, subpart A. Transparency in this program will also provide information on general trends and performance of the HFC phasedown program, which could inform public participation by means of petitions filed to the Agency under other provisions of the AIM Act and afford the public insight into the data upon which EPA relies for the Agency's decision making. Additional transparency will also allow neighboring communities to see how emissions from a particular facility compare to changes in HFC production levels.

Congress has required that the Administrator ''ensure that the annual quantity of all regulated substances produced or consumed in the United States does not exceed'' the annual caps described in subsection (e)(2)(B). Research shows that making data publicly available facilitates compliance. Qualitative studies have found that ''public disclosure is [an] underutilized tool; there is powerful evidence that publishing information about company performance drives better behavior, as pressure is applied by customers, neighbors, investors, and insurers.'' [106] A recent National Bureau of Economic Research working paper addressed the value of transparency.[107] The researchers examined the effects of data being reported to the GHGRP on emissions from electric power plants. They analyzed CO_2 emissions per megawatt from power plants in the United States pre- and post-establishment of GHGRP reporting (in 2010) and found that plants that were required to report post-2010 (emissions greater than 25,000 $MTCO_2e$ annually) showed decreasing emissions once reporting requirements entered into force, while plants that did not have to report showed increased emissions. The paper posits a causal relationship between the public availability of the emissions data and the decrease in emissions. The effect was stronger for publicly traded firms, and stronger yet if those firms were large (*i.e.,* included in the S&P 500).

EPA has acknowledged the importance of data transparency in prior rulemakings. As the Agency explained in the preamble to a proposed rule (78 FR 46006, July 30, 2013) concerning the National Pollutant Discharge Elimination System:

> To promote transparency and accountability, EPA intends to make [a] more complete set of data available to the public, providing communities and citizens with easily accessible information on facility and government performance. Such data provides a powerful incentive to improve performance by giving government, permittees, and the public ready access to compliance information. This can serve to elevate the importance of compliance information and environmental performance within regulated entities, providing opportunity for them to quickly address any noncompliance.

The same principles apply in this situation to incentivize compliance and allow the public and competing companies to identify and report noncompliance to EPA.

EPA understands that some of the data elements it is announcing an intention to release have previously been determined to be CBI under the GHGRP. Many of the data elements reported to subpart OO of the GHGRP were determined to be, and are treated as, confidential by EPA (see, *e.g.,* 76 FR 30782, May 26, 2011; 76 FR 73886, November 29, 2011; 77 FR 48072, August 13, 2012, 78 FR 71904, November 29, 2013; and, 81 FR 89188, December 9, 2016).[108] EPA has determined through this rulemaking and is now putting all potential submitters on notice that prospectively, these data elements will not be provided confidential treatment when submitted in accordance with EPA's Part 84 regulations established through this rule. Individual instances of these determinations are noted in a document included in the rulemaking docket. To be clear, determinations made in this rule that certain data elements will not be entitled to confidential treatment only apply prospectively.

The GHGRP and the AIM Act are separate programs with distinct goals; it is reasonable for EPA to take a different approach than has been taken for the GHGRP and release more disaggregated data than was released under that program. Ensuring compliance with a regulatory phasedown program, where EPA is obligated to ensure that domestic production and consumption aligns with a statutorily defined schedule, is different from a reporting program where one company's noncompliance would mean less accurate accounting, but where achieving mandated reductions of an environmentally harmful class of chemicals is not at stake. Further, the goals of GHGRP can be achieved while giving a multitude of data elements confidential treatment. In contrast, the Agency sees increased transparency and public access to the data EPA will be releasing as contributing to compliance under the AIM Act, which is essential to achieving the goals of the AIM Act. It is reasonable for EPA to take all necessary steps for the Agency to ensure both compliance with the consumption and production caps of subsection (e)(2)(B) and a level playing field between and among all obligated parties, who in most cases are operating in the same or overlapping competitive markets. Under the AIM Act, some companies will face burdens and costs associated with the Congressionally mandated phasedown; those increased burdens and costs unfortunately create economic incentives to avoid compliance. That reality increases EPA's statutory and policy imperative to identify and apply tools that counter those incentives to increase the rate of compliance. Transparency is one of those compliance tools. As further discussed in Section IX which details the enforcement and compliance provisions, a multifaceted compliance approach is important to help ensure, as EPA is explicitly obligated to do, the phasedown targets and associated environmental benefits Congress required are realized.

One commenter argued that EPA's proposed approach to not provide confidential treatment to the identified data elements was impermissible because the AIM Act did not change Exemption 4 of the Freedom of Information Act (''FOIA'') and regulations pursuant to the AIM Act cannot alter FOIA. EPA agrees that the AIM Act did not amend FOIA. FOIA and the Agency's accompanying regulations apply to situations where information has been claimed as confidential, the Agency is treating that information confidentially, and the Agency receives a FOIA request for that information or later decides to release the information on its own. In such an instance, the confidential status of the information has not been previously determined by the Agency. That is separate and distinct from what the Agency is doing in this rulemaking. Here, the Agency is determining through rulemaking that some of the data elements as listed in the document provided in the docket will not be treated as confidential by the Agency upon submission and cannot be claimed

[106] David Hindin and Jon Silberman, ''Designing More Effective Rules and Permits,'' *George Washington Journal of Energy & Environmental Law,* Spring 2016 at 103, 117–120.

[107] Lavender Yang, Nicholas Z. Muller, and Pierre Jinghong Liang, ''The Real Effects of Mandatory CSR Disclosure on Emissions: Evidence from the Greenhouse Gas Reporting Program,'' *National Bureau of Economic Research,* July 2021 Working Paper 28984. Available at *http://www.nber.org/papers/w28984.*

[108] For a summary, see *https://www.epa.gov/sites/production/files/2020-09/documents/ghgrp_cbi_tables_for_suppliers_8-28-20_clean_v3_508c.pdf.*

as such. This is not amending FOIA Exemption 4, but faithfully applying it in accordance with governing case law. As noted in the proposed rule, information determined in the rule not to be entitled to confidential treatment may be released upon submission. As such, 40 CFR part 2.201 through 2.215 do not apply to information determined not to be entitled to confidential treatment in this rule and there will be no further notice to the submitters prior to release of such information. As discussed in Section X.C.1, putting submitters on notice of how FOIA Exemption 4 will be applied in the context of this Rule is consistent with applicable case law, which incorporates the reasonable expectations of submitters about whether information submitted in particular instances will be kept confidential. Pursuant to this rule, reporters do not have a reasonable expectation that the data elements listed in the document provided in the docket as ''Not CBI'' will be entitled to confidential treatment, and therefore the Agency is not required to treat that information as confidential when it is received and maintained in Agency records.

Following finalization of this rule, companies are on full notice that EPA has determined that the identified data elements outlined in detail in the document provided in the rulemaking docket are not entitled to confidential treatment and therefore intends to not provide confidential treatment of those elements upon submission. Therefore, companies do not have a reasonable expectation that the information will be treated as confidential. Under recent Supreme Court case law, Exemption 4 of the FOIA should not apply to information submitted with the expectation that the information would be made public. See *Food Mktg. Inst.* v. *Argus Leader Media,* 139 S. Ct. 2356, 2360 (2019). *See also WP Co. LLC* v. *U.S. Small Bus. Admin.,* 502 F. Supp. 3d 1, 11 (D.D.C. 2020). A few commenters disagreed that EPA could alter expectations concerning CBI treatment through this rulemaking under the *Food Marketing* standard. The Agency disagrees. As a starting point, stakeholders have no basis for claims based on ''expectations'' on the handling of information prospectively reported to the Agency under these newly established regulations under the newly enacted AIM Act. The Congressionally ordered phasedown of HFCs is only beginning with this rule; it is these regulations that are creating and defining expectations for the handling of and public access to data submitted to EPA. The Agency is hereby setting a clear expectation that the data elements as listed in the document provided in the docket will not actually be treated as confidential for any submitters and is only applying the rule prospectively to information submitted after this clear expectation is in place.

But even if there were such ''expectations,'' as noted above, companies have not yet submitted the information to the Agency and this notice makes clear that companies should have the expectation that the information will be disclosed. Moreover, the information must still meet the applicable standard for confidentiality. In *Food Marketing,* the Supreme Court explained that information might be considered ''confidential'' under two conditions: ''In one sense, information communicated to another remains confidential whenever it is customarily kept private, or at least closely held, by the person imparting it.'' *Food Mktg. Inst.,* 139 S. Ct. at 2366. ''In another sense, information might be considered confidential only if the party receiving it provides some assurance that it will remain secret.'' *Id.* The Court determined that the first condition—that the information customarily be kept private or closely held by the submitter—must be met because ''it is hard to see how information could be deemed confidential if its owner shares it freely.'' *Id.* At 2363. As to the second condition—whether information must be communicated to the government with some assurance that it will be kept private—the Court left open the question of whether this condition was required to demonstrate that information is ''confidential'' within the meaning of Exemption 4, as that condition was clearly satisfied in the case before it. *Id.* At 2363. Accordingly, the Court held that ''[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4.'' *Id.* At 2366. The Supreme Court's opinion did not determine to what extent the second condition would be required to maintain confidentiality. However, subsequent guidance from the Department of Justice has clarified that where an express assurance is provided by the government that information will *not* be kept confidential upon submission, such information will generally not be entitled to confidential treatment. See Exemption 4 after the Supreme Court's Ruling in *Food Marketing Institute* v. *Argus Leader Media,* October 4, 2019, *https://www.justice.gov/oip/exemption-4-after-supreme-courts-ruling-food-marketing-institute-v-argus-leader-media.* (See also recent case law from the Federal District Court for the District of Columbia, *e.g., WP Co. LLC* v. *U.S. Small Bus. Admin.,* 502 F. Supp. 3d 1, 16 (D.D.C. 2020)).

Therefore, EPA's decision to clearly assert in this rule that EPA intends to release the designated information aligns with the Supreme Court's decision and the subsequent guidance that the government's assurances that a submission will be treated as *not* confidential should dictate the expectations of submitters.

Moreover, this interpretation and approach are consistent with other applicable case law. While the court did not specify that an assurance from the government was required, it was a key assumption underlying the decision that the information was entitled to confidential treatment. *Id.* At 874. In *Food Marketing,* the Supreme Court also noted that several earlier Circuit Court decisions had addressed the relevance of whether assurances of confidentiality had been provided prior to submission:

> ''In *GSA* v. *Benson,* 415 F. 2d 878, 881 (1969), for example, the Ninth Circuit concluded that Exemption 4 would '' 'protect information that a private individual wishes to keep confidential for his own purposes, but reveals to the government *under the express or implied promise' '' of confidentiality.* [emphasis added] The D.C. Circuit similarly held that Exemption 4 covered sales documents '' 'which would customarily not be released to the public' '' and which the government ''agreed to treat . . . as confidential.'' *Sterling Drug Inc.* v. *FTC,* 450 F. 2d 698, 709 (1971); see also *Grumman Aircraft Eng. Corp.* v. *Renegotiation Bd.,* 425 F. 2d 578, 580, 582 (1970) (information a private party ''submitted 'in confidence' '' or ''would not reveal to the public [is] exempt from disclosure'').''

Food Mktg. Inst., 139 S. Ct. at 2363. Here, the Agency is providing affirmative notice that the Agency will not provide confidential treatment for data elements reported under the part 84 AIM Act regulations as outlined in detail in the document provided in the rulemaking docket.

One commenter stated that the Trade Secrets Act provides businesses with a cause of action for divulging trade secrets, including business information such as market share and customer lists. The Trade Secrets Act (TSA) is a criminal statute that prohibits officers and employees of federal agencies from publishing or disclosing trade secrets and other CBI ''to any extent not authorized by law.'' 18 U.S.C. 1905. In

this instance, as explained in the prior paragraphs, the Agency is authorized to release information that is not entitled to confidential treatment. There is nothing in the TSA legislative history to suggest that Congress intended the phrase ''authorized by law'' to have a special, limited meaning different from the traditional understanding. This rulemaking, which included a notice and comment process, makes any future data releases authorized disclosures.

In addition to EPA providing notice that it will not provide confidential treatment for the listed elements, and therefore companies do not have a reasonable expectation that such information submitted after this rule is finalized will be withheld, some data elements collected pursuant to the reporting regulations established in this rule are also releasable because they are appropriately considered emission data, including data used as inputs to emissions equations, which is releasable under subsection (k)(1)(C), pursuant to its incorporation of CAA section 114 for purposes of the Act and any regulations promulgated under it, as if the AIM Act were part of title VI of the CAA. CAA section 114(c) provides that emission data shall be available to the public. Regarding annual facility-level information on HFC-23 generated and destroyed, these data are inputs into emission equations that are used under GHGRP subparts L and O to calculate and report emissions of HFC-23. Inputs into emission equations may be considered ''emission data'' and section 114(c) of the CAA provides that ''emission data'' shall be available to the public. Because subsection (k)(1)(C) of the AIM Act states that section 114 of the CAA applies to the AIM Act and rules promulgated under it as if the AIM Act were included in title VI of the CAA, the requirements under section 114(c) of the CAA that apply to ''emission data'' also apply to data gathered under the AIM Act that are determined to be ''emission data.'' EPA has determined that these elements related to HFC-23 are emission data and thus are not entitled to confidential treatment.

EPA further notes that some of these data elements determined not to be entitled to confidential treatment, particularly portions of chemical-specific company-level import data, are publicly available through a range of datasets.[109] These databases charge a fee for access to information on imports at the transaction level based on Customs data from the United States and other countries, including bills of lading. There are also websites that provide selected import data at no cost.[110] A submission available in the docket from First Continental International (NJ) Inc., dated March 12, 2021, shows the types of information that can be ascertained from these databases. Data that are already publicly available cannot be considered confidential or proprietary and do not merit confidential treatment. EPA's Chemical Data Registry also provides some HFC production and import data (*https://chemview.epa.gov*). One commenter disagreed with EPA's assertion that import data found in public ''pay-for'' databases are accurate, while another commenter disagreed that data were available for imports to the extent EPA stated at proposal. EPA appreciates that not all datasets are complete and that sometimes there is disagreement with Customs data, data reported to EPA, and data available in free and pay-for databases. In some cases, a company name is not released for a shipment. In others, the quantities may not match completely in all instances or the HTS code used may not match with the data reported to EPA. However, the Agency is not convinced that this is a reason to discount the data available in these datasets. Further, a significant amount of data is available in these databases, and as such it is not actually treated as confidential and therefore it is not appropriate to withhold such information under FOIA Exemption 4.

As noted at the start of this subsection, EPA intends to publish on its website the names of every entity receiving production allowances, consumption allowances, or application-specific allowances and the amount of allowances allocated. EPA intends to revise those data at least quarterly as allowances are expended. Under the ODS phaseout program, EPA released similar company-specific allowance data, including quantities produced or imported by each company in the baseline year by chemical and annual allocation amounts thereafter for nearly 30 years. EPA's experience has been that the release of this information has been important to reduce illegal imports, facilitate transfers, and provide third parties confidence that they were buying from a company that had allowances. EPA anticipates greater benefits will result from providing similar and more comprehensive HFC data. Releasing allowance allocation amounts will also provide context for understanding the reported production and import volumes. Commenters supported the release of this information.

One commenter stated that data regarding transformation is CBI. In this final rule, EPA is clarifying that the Agency will not provide confidential treatment to reported facility-level, company-specific, and chemical-specific data on production or import for transformation for the above-mentioned reasons, but EPA will provide confidential treatment to data related to companies' acquiring those regulated substances for transformation and processes in which the regulated substances are transformed. Releasing data on production (and import and export) for transformation is important given this type of production and import does not require an allowance. Additional transparency helps ensure there is visibility on the quantities entering and exiting the United States.

In addition to all of the above-noted items, should the United States join the Kigali Amendment to the Montreal Protocol, it would release data to the United Nations Environment Programme's Ozone Secretariat regarding HFC production, consumption, and limited emission data. On January 27th, 2021, the President issued an Executive Order on Tackling the Climate Crisis at Home and Abroad (Executive Order 14008; 86 FR 7619; January 27, 2021). Under part (j), the Executive Order directs the Secretary of State to prepare within 60 days a transmittal package seeking the Senate's advice and consent to ratification of the Kigali Amendment to the *Montreal Protocol on Substances that Deplete the Ozone Layer.* The Kigali Amendment requires an international phasedown of the production and consumption of HFCs. Should the United States join the Kigali Amendment, EPA is putting stakeholders on notice that it will

[109] Examples include PIERS (*https://ihsmarkit.com/products/piers.html*), Panjiva (*https://panjiva.com*), Datamyne (*https://www.datamyne.com*), and ImportGenius (*https://www.importgenius.com*). Mention of or referral to commercial products or services, and/or links to non-EPA sites does not imply official EPA endorsement of or responsibility for the opinions, ideas, data, or products presented at those locations, or guarantee the validity of the information provided. Mention of commercial products/services on non-EPA websites is provided solely as a pointer to information on topics related to environmental protection that may be useful to the public as they review this proposed rulemaking.

[110] Enigma, a data science firm, makes available online what appears to be the full Automated Manifest System import data from 2018–2020, including the names of shipment consignees and cargo descriptions (*https://aws.amazon.com/marketplace/pp/US-Imports-Automated-Manifest-System-AMS-Shipments/prodview-stk4wn3mbhx24*). Similarly, *usimports.info* makes a limited number of import database queries free to users, allowing them to see data on individual bills of lading (*https://usimports.info*).

report[111] the following data to the Ozone Secretariat:

- Annual U.S. HFC production in MT aggregated by chemical for each of the HFCs listed in subsection (c) of the AIM Act, including total HFC production for all uses and HFC production for feedstock in the United States;
- Annual U.S. HFC import in MT aggregated by chemical and by country imported from for each of the HFCs listed in subsection (c) of the AIM Act, including the amounts that are new (virgin), recovered and reclaimed, or for feedstock use;
- Annual U.S. HFC export in MT aggregated by chemical and by country exported to for each of the HFCs listed in subsection (c) of the AIM Act, including the amounts that are new (virgin), recovered and reclaimed, or for feedstock use;
- Annual U.S. HFC destruction in MT aggregated by chemical for each of the HFCs listed in subsection (c) of the AIM Act; and
- Annual facility-level information on HFC-23 generated and destroyed, including annual amounts of HFC-23:
  - Generated, whether captured or not;
  - generated and captured for all uses;
  - generated and captured for feedstock use in the United States;
  - generated and captured for destruction;
  - used for feedstock without prior capture;
  - destroyed without prior capture; and
  - generated emissions.

The Ozone Secretariat would release aggregated GWP-weighted annual production and consumption on the Ozone Secretariat's website.[112] Additional data elements released include annual amounts destroyed, aggregated for all reported chemicals under the Montreal Protocol in MT, import of recovered/recycled/reclaimed substances by group (*e.g.,* HFCs) in MT, and export of recovered/recycled/reclaimed substances in MT by group. Should the United States join the Kigali Amendment, EPA would also submit chemical-specific production and consumption data for 2011, 2012, and 2013 to establish the United States' baseline for HFCs.

[111] The reporting forms and instructions that EPA would use to submit data are available in the docket and on the Ozone Secretariat's website at *https://ozone.unep.org/countries/data-reporting-tools.*

[112] The Ozone Secretariat's handling of similarly reported data from the United States on ODS is available at *https://ozone.unep.org/countries/profile/usa.*

The Parties to the Montreal Protocol adopted Decision I/11 [113] during the First Meeting of the Parties, which provides the Parties' view on how to treat the confidentiality of data submitted to the Ozone Secretariat. In accordance with the decision, if the United States is submitting data that it has determined to be entitled to confidential treatment pursuant to this Rule, the United States has the ability to mark the data accordingly such that it will be treated with secrecy and maintained confidential by the Secretariat. EPA intends to mark any data for which the Agency is providing confidential treatment pursuant to this Rule as appropriate for confidential treatment in its annual reporting, were the United States to join the Kigali Amendment. The decision requests the Ozone Secretariat to only release aggregated data such that any data a Party to the Protocol considers to be confidential will not be disclosed. However, Parties to the Protocol may exercise their right under Article 12, paragraph b of the Protocol to have access to confidential data from other parties, provided that they send an application in writing that guarantees such data will be treated with secrecy and not disclosed or published in any way.

2. Which data elements has EPA determined are entitled to confidential treatment?

EPA understands that a certain amount of confidentiality is necessary for firms to function within a competitive market. Many commenters stated that data regarding HFC uses has no particular relevance to the phasedown. Application-specific end users had particular concern about the release of their data. Some raised concerns about national security and foreign competition if application-specific data were made public. They argued it is inconsistent with Congressional intent to support these applications by requiring companies to divulge sensitive information in order to receive allowances. With regard to transfers, many companies opposed the release of pricing data. With regard to the certification ID tracking system, many commenters were opposed to releasing data on customers, suppliers, handlers, and other entities in the chain of custody of the material.

[113] ''The Montreal Protocol on Substances That Deplete the Ozone Layer.'' *Unep.org,* United Nations Environment Programme. Available at *https://ozone.unep.org/treaties/montreal-protocol/meetings/first-meeting-parties/decisions/decision-i11-report-and-confidentiality-data.*

EPA is determining in this rule that some data elements are entitled to confidential treatment, including sales data, business relationships, pricing information, and many elements reported pursuant to the QR tracking system and by application-specific allowance holders. EPA is determining in this rule that the following reported elements, among others, are entitled to confidential treatment: (1) Information provided to the Agency in one-time reports or petitions, such as those provided by entities that transform or destroy HFCs; (2) information provided to the Agency in their requests for application-specific allowances, except for annual consumption information discussed earlier in this section; (3) information relating to an exchange or interaction between vendors or customers, such as pricing data; (4) most data viewable through the certification ID tracking system in the same manner (with the exceptions described in Section IX.G; and (5) transfer pricing information. EPA has provided in the docket a document that lists each individual data element required to be reported under the part 84 regulations and denotes whether each element is entitled to confidential treatment or not.

EPA has determined that these data elements are customarily and actually considered to be confidential and closely held by companies. EPA finds that these data elements meet the requirements of FOIA Exemption 4 and are therefore appropriately treated as confidential. EPA also does not see the same benefits of transparency of releasing these data elements for improved enforceability and function of the HFC phasedown program. For these reasons, the Agency is determining the listed data elements are deserving of confidential treatment.

3. How will EPA aggregate data for release?

For data elements that EPA has determined to grant confidential treatment, or where EPA is not making a determination on whether data is CBI at this time, and therefore will not be released in an unaggregated format, EPA will release information in an aggregated form. Specifically, EPA retains the discretion to release aggregated data for any element on which there are three or more reporting entities. The Agency has determined that this level of aggregation ensures no entity can back calculate a single data element, and therefore confidentiality can still be ensured.

In addition to this general rule, there are various data sets that the Agency intends to provide in aggregate form.

Through this rule, the Agency is putting stakeholders on notice that the following information will be released in aggregate form if there are three or more reporting entities. First, EPA intends to release annual aggregate amounts for each HFC produced and imported (summed) for use as a process agent, and aggregate annual emissions from such use by HFC. EPA requested comment on current process agent use of HFCs including which HFCs are used as a process agent, how the HFC is used as a process agent, which facilities use HFCs as a process agent, and the annual quantity of HFCs used as a process agent. EPA did not receive any comments providing such information. EPA proposed to release aggregated HFC process agent data, if the use of HFCs was in sufficient quantities and frequencies to allow for aggregation. EPA did not receive comment on releasing this aggregate data and thus is finalizing this as proposed.

Second, EPA intends to release aggregated annual chemical-specific HFC consumption volumes for each application-specific end use. This is similar to how the Agency provided chemical-specific data in the market characterizations. EPA is finalizing this approach as proposed. Providing these data to the general public allows EPA to show the scale of application-specific allowance use, identify where EPA's annual determination on the quantity of HFCs needed for the end use may need adjustment, and inform future rulemakings. This information will be aggregated across all application-specific allowance holders within a specific application, so EPA expects there will be no risk of divulging information submitters customarily keep private or closely held.

Third, EPA will release aggregated data on the quantity (in kilograms) of each HFC held in inventory as of December 31 of each year collectively by producers, importers, exporters, and reclaimers of HFCs summed together. This is analogous to the approach under CAA section 608 of releasing HFC reclamation data on a chemical-by-chemical basis. EPA will only release HFC-specific inventory values if there are three or more companies that have inventory of that HFC. Releasing inventory data can inform decisions of all companies in the marketplace. For example, lack of reliable and widely distributed information on the scale of the existing inventory of HCFC-22 likely contributed to dramatic price swings associated with delays in the issuance of prior EPA allocation rulemakings. While additional information on inventory on its own may not prevent price fluctuations, it could provide more price predictability for the step-downs. Releasing inventory data could also help producers and importers make decisions about which HFCs are in short supply and/or could help support a smooth transition away from high-GWP HFCs.

Fourth, EPA also intends to publish aggregated data on pricing of transfers, so long as there are at least three companies involved in transferring allowances that year. Specifically, if there are at least three companies involved in transfers, EPA would release the average cost of the transfers reported. Release of these data would provide the public with helpful information on the average value and scale of transfers associated with the HFC phasedown.

Similarly, EPA will release aggregated reclamation and fire suppressant recycling data by HFC consistent with the approach taken under CAA section 608 and its implementing regulations at 40 CFR part 82, subpart F. An example of these data is available at *https://www.epa.gov/section608/summary-refrigerant-reclamation-trends.* Release of these data aids industry and consumer understanding of the availability of various HFCs.

XI. What are the costs and benefits of this action?

EPA conducted a RIA, which estimated the costs and benefits of implementing the phasedown of HFCs as a result of the passage of the AIM Act, as realized by promulgating this rule. This analysis is intended to provide the public with information on the relevant costs and benefits of this action and to comply with executive orders.

EPA estimates that in 2022 the annual net benefits are $1.7 billion, reflecting compliance savings of $300 million and social benefits of $1.4 billion. In 2036, when the final phasedown step is reached at 15 percent of the statutorily defined HFC baseline, the estimated annual net benefits are $16.4 billion. Table 6 presents a summary of the annual costs and net benefits of the rule for selected years in the time period 2022–2050, but with the climate benefits discounted at 3 percent.

TABLE 6—BENEFITS, COSTS, AND NET BENEFITS OF THE FINAL RULE FOR 2022–2050

[Billions of 2020$][a b c]

Year	Climate benefits (discounted at 3%)	Costs (annual)	Net benefits
2022	$1.4	−$0.3	$1.7
2024	5.2	−0.1	5.1
2029	7.5	−0.6	8.1
2034	12.4	− 0.9	13.3
2036	15.7	−0.7	16.4
2045	25.1	−0.9	26.0
2050	29.7	−1.1	30.8

[a] Benefits include only those related to climate. See Table 4–24 in the RIA for the full range of SC–HFCs estimates. The costs presented in this table are annual estimates.

[b] Rows may not appear to add correctly due to rounding.

[c] Climate benefits are based on changes (reductions) in HFC emissions and are calculated using four different estimates of the SC–HFCs (model average at 2.5 percent, 3 percent, and 5 percent discount rates; and 95th percentile at 3 percent discount rate). The IWG emphasized, and EPA agrees, on the importance and value of considering the benefits calculated using all four estimates. As discussed in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990 (IWG 2021), a consideration of climate benefits calculated using discount rates below 3 percent, including 2 percent and lower, are also warranted when discounting intergenerational impacts.

Climate benefits presented in Tables 6, 7, and 8 are based on changes (reductions) in HFC emissions and are calculated using four different estimates of the social cost of HFCs (SC–HFCs) model average at 2.5 percent, 3 percent, and 5 percent discount rates; and 95th percentile at 3 percent discount rate). For the presentational purposes of

Tables 6 and 8, we show the benefits associated with the average SC–HFCs at a 3 percent discount rate, but the Agency does not have a single central SC–HFCs point estimate.

The SC–HFC estimates used in this analysis were developed using methodologies consistent with the methodologies underlying the interim estimates of the social cost of carbon ($SC\text{-}CO_2$), social cost of methane ($SC\text{-}CH_4$), and social cost of nitrous oxide ($SC\text{-}N_2O$) (collectively referred to as social cost of greenhouse gases (SC–GHG)) published in February 2021 by the IWG. As a member of the IWG involved in the development of the February 2021 Technical Support Document (TSD): Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990 (IWG 2021), EPA agrees that the interim SC–GHG estimates represent the most appropriate estimate of the SC–GHG until revised estimates have been developed reflecting the latest, peer reviewed science. The interim SC–GHG estimates were developed over many years, using a transparent process, peer-reviewed methodologies, the best science available at the time of that process, and with input from the public. Therefore, EPA views the methods to be appropriate for estimating SC–HFCs for use in benefit-cost analysis.

As discussed in the February 2021 TSD, the IWG emphasized the importance and value of considering the benefits calculated using all four estimates (model average at 2.5, 3, and 5 percent discount rates, and 95th percentile at 3 percent discount rate). In addition, the TSD explained that a consideration of climate benefits calculated using discount rates below 3 percent, including 2 percent and lower, is also warranted when discounting intergenerational impacts. As a member of the IWG involved in the development of the February 2021 TSD, EPA agrees with this assessment for the purpose of estimating climate benefits from HFC reductions as well, and will continue to follow developments in the literature pertaining to this issue.

Table 7 presents the sum of climate benefits across all HFCs reduced for the final rule for 2022, 2024, 2029, 2034, 2036, 2045, and 2050.

TABLE 7—CLIMATE BENEFITS FOR THE FINAL RULE FOR 2022–2050

[Billions of 2020$]

Year	Climate benefits by discount rate and statistic			
	5% (average)	3% (average)	2.5% (average)	3% (95th percentile)
2022	0.5	1.4	1.9	3.7
2024	2.2	5.2	7.0	13.8
2029	3.2	7.5	10.0	20.0
2034	5.5	12.4	16.2	33.0
2036	7.2	15.7	20.4	42.0
2045	12.0	25.1	32.2	67.4
2050	14.6	29.7	37.7	79.5

EPA estimates that the present value of cumulative net benefits evaluated from 2022 through 2050 is $272.7 billion at a three percent discount rate, comprising $260.9 billion in cumulative benefits due to reducing HFC emissions and $11.8 billion in cumulative compliance savings. The present value of net benefits is calculated over the 29-year period from 2022–2050, to account for the years that emissions will be reduced following the consumption reductions from 2022–2036. Over the 15-year period of the phasedown of HFCs, the present value of cumulative compliance costs is negative $5.4 billion, or $5.4 billion in savings, and the present value of cumulative social benefits is $94.8 billion, both at a three percent discount rate. Over the same 15-year period of the phasedown, the present value of cumulative net benefits is $100.2 billion. At a 7 percent discount rate over the 15-year period of the phasedown of HFCs, the present value of cumulative compliance costs is negative $3.7 billion, or $3.7 billion in savings. Over the same 15-year period of the phasedown, the present value of cumulative net benefits is $98.5 billion at a 7 percent discount rate for costs (and 3 percent for climate benefits). The comparison of benefits and costs in present value (PV) and equivalent annualized value (EAV) terms for the rule can be found in Table 8. Estimates in the table are presented as rounded values.

TABLE 8—SUMMARY OF ANNUAL VALUES, PRESENT VALUES, AND EQUIVALENT ANNUALIZED VALUES FOR THE 2022–2050 TIMEFRAME FOR ESTIMATED ABATEMENT COSTS, BENEFITS, AND NET BENEFITS FOR THE FINAL RULE

[Billions of 2020$, discounted to 2022] [a] [b]

Year	Climate benefits	Costs [c]		Net benefits	
	(3%) [c] [d]	3%	7%	3%	7%
Present Value	$260.9	−$11.8	−$6.4	$272.7	$267.4
Equivalent Annualized Value	13.6	−0.6	−0.5	14.2	14.1

[a] Rows may not appear to add correctly due to rounding.

[b] The annualized present value of costs and benefits are calculated over a 29-year period from 2022 to 2050.

[c] The costs presented in this table are consistent with the costs presented in RIA Chapter 3, Table 3–6.

[d] Climate benefits are based on changes (reductions) in HFC emissions and are calculated using four different estimates of the SC–HFCs (model average at 2.5 percent, 3 percent, and 5 percent discount rates; and 95th percentile at 3 percent discount rate). The IWG emphasized, and EPA agrees, on the importance and value of considering the benefits calculated using all four estimates. As discussed in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990 (IWG 2021), a consideration of climate benefits calculated using discount rates below 3 percent, including 2 percent and lower, are also warranted when discounting intergenerational impacts.

The estimation of $260.9 billion in benefits due to reducing HFC emissions involved three steps. First, the difference between the consumption of HFCs allowed under the rule and the consumption that would have been expected in a business-as-usual scenario was calculated for each year of the phasedown in exchange value-weighted tons (*i.e.,* EVe). Second, using EPA's Vintaging Model, the changes in consumption were used to estimate changes in HFC emissions, which generally lag consumption by some time as HFCs incorporated into equipment and products are eventually released to the environment. Finally, the climate benefits were calculated by multiplying the HFC emission reductions for each year by the appropriate social cost of HFC to arrive at the monetary value of HFC emission reductions.

EPA estimates the climate benefits for this rule using a measure of the social cost of each HFC (collectively referred to as SC–HFCs) that is affected by the rule. The SC–HFCs is the monetary value of the net harm to society associated with a marginal increase in HFC emissions in a given year, or the benefit of avoiding that increase. In principle, SC–HFCs includes the value of all climate change impacts, including (but not limited to) changes in net agricultural productivity, human health effects, property damage from increased flood risk and natural disasters, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. As with the estimates of the social cost of other GHGs, the SC–HFC estimates are found to increase over time within the models—*i.e.,* the societal harm from one metric ton emitted in 2030 is higher than the harm caused by one metric ton emitted in 2025—because future emissions produce larger incremental damages as physical and economic systems become more stressed in response to greater climatic change, and because GDP is growing over time and many damage categories are modeled as proportional to GDP. The SC–HFCs, therefore, reflects the societal value of reducing emissions of the gas in question by one metric ton. The SC–HFCs is the theoretically appropriate value to use in conducting benefit-cost analyses of policies that affect HFC emissions.

The benefits of this rule derive mostly from preventing the emissions of HFCs with high GWPs, thus reducing the damage from climate change that would have been induced by those emissions. The reduction in emissions follows from a reduction in the production and consumption of HFCs, measured in MMTEVe. It is assumed that all HFCs produced or consumed would be emitted eventually, either in their initial use (*e.g.,* as propellants), during the lifetime of HFC-containing products (*e.g.,* off-gassing from closed-cell foams or leaks from refrigeration systems), or during servicing or disposal of HFC-containing products.

The reductions in units of MMTEVe are calculated for each year by summing the tons abated for the options utilized for that year. EPA estimates that for the years 2022–2036 this action will avoid cumulative consumption of 3,152 MMTEVe of HFCs in the United States. The annual consumption avoided is estimated at 42 MMTEVe in the year 2022 and 282 MMTEVe in 2036. In order to calculate the climate benefits associated with consumption abatement, the consumption changes were expressed in terms of emissions reductions. EPA estimates that for the years 2022–2050 this action will avoid cumulative emissions of 4,560 MMTEVe of HFCs in the United States. The annual avoided emissions are estimated at 22 MMTEVe in the year 2022 and 171 MMTEVe in 2036. Note that the emissions avoided in each year is less than the consumption avoided in the same year because of the delay between when an HFC is produced or imported and when it is emitted to the atmosphere.

EPA received comments on the RIA including on the estimated costs and benefits of the rule. While some commenters supported the use and application of the SC–HFCs to monetize the climate benefits associated with the rule, others noted that the estimates were not peer reviewed. The SC–HFCs estimates used by EPA in the RIA were developed in a manner consistent with the methodology underlying estimates of the social cost of other greenhouse gases (SC-CO_2, SC-CH_4, and SC-N_2O) as presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990 (IWG 2021), which were developed over many years, using a transparent process, peer-reviewed methodologies, the best science available at the time of that process, and with input from the public.

Additional commenters noted methodological concerns with the underlying climate models and inputs used to generate the SC–GHG estimates that the SC–HFCs estimates are derived from. EPA recognizes the shortcomings and limitations associated with the current interim IWG estimates and underlying methodology. Since the SC–HFC estimates are based on the same methodology underlying the SC–GHG estimates presented in the IWG February 2021 TSD, they share a number of limitations that are common to those SC–GHG estimates. The limitations were outlined in the February 2021 TSD and include that the current scientific and economic understanding of discounting approaches suggests discount rates appropriate for intergenerational analysis in the context of climate change are likely to be less than 3 percent, near 2 percent or lower. Additionally, the IAMs used to produce these estimates do not include all of the important physical, ecological, and economic impacts of climate change recognized in the climate change literature, and the science underlying their ''damage functions''—*i.e.,* the core parts of the IAMs that map global mean temperature changes and other physical impacts of climate change into economic (both market and nonmarket) damages—lags behind the most recent research.

The modeling limitations do not all work in the same direction in terms of their influence on the SC–HFC estimates. However, as discussed in the February 2021 TSD, the IWG has recommended that, taken together, the limitations suggest that the SC–GHG estimates likely underestimate the damages from GHG emissions. Therefore, as a member of the IWG involved in the development of the February 2021 TSD, EPA agrees that the interim SC–GHG estimates represent the most appropriate estimate of the SC–GHG until revised estimates have been developed reflecting the latest, peer reviewed science. The 2021 TSD previews some of the recent advances in the scientific and economic literature that the IWG is actively following and that could provide guidance on, or methodologies for, addressing some of the limitations with the interim SC–GHG estimates, which also apply to the SC–HFC.

XII. Statutory and Executive Order Review

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. A summary of the potential costs and benefits associated with this action is included in Table 1 in Section I.C and additional details are provided in Section XI of this

final rulemaking. EPA has prepared an analysis of the potential costs and benefits associated with this action, which is available in Docket Number EPA–HQ–OAR–2021–0044.

B. Paperwork Reduction Act (PRA)

The information collection activities in this rule will be submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document that EPA prepared at proposal was assigned EPA ICR number 2685.01, and the updated ICR for the final rulemaking has been assigned EPA ICR number 2685.02. You can find copies of these ICRs in the docket for this rule (Docket Number EPA–HQ–OAR–2021–0044), and EPA ICR 2685.02 is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

Subsection (d)(1)(A) of the AIM Act specifies that on a periodic basis, but not less than annually, each company that, within the applicable reporting period, produces, imports, exports, destroys, transforms, uses as a process agent, or reclaims a regulated substance shall submit to EPA a report that describes, as applicable, the quantity of the regulated substance that the company: Produced, imported, and exported; reclaimed; destroyed by a technology approved by the Administrator; used and entirely consumed (except for trace quantities) in the manufacture of another chemical; or, used as a process agent. EPA is collecting such data regularly to support implementation of the AIM Act's HFC phasedown provisions. EPA is requiring quarterly reporting to ensure that annual production and consumption limits are not exceeded. It is also needed for EPA to be able to review allowance transfer requests, of which remaining allowances is a major component of EPA's review. In addition, EPA is collecting information in order to calculate allowances, to track the movement of HFCs through commerce, and to require auditing. Collecting these data elements allow for EPA to ensure that the annual quantity of regulated substances produced or consumed in the United States does not exceed the cap established by the AIM Act, consistent with subsection (e)(2)(B) of the Act.

All information sent by the submitter electronically is transmitted securely to protect information submitters customarily keep private or closely held. The reporting tool guides the user through the process of submitting CBI. Documents containing information claimed as CBI must be submitted in an electronic format, in accordance with the recordkeeping requirements. EPA also allows respondents to report CBI by fax and through courier.

Respondents/affected entities: Respondents and affected entities are individuals or companies that produce, import, export, transform, distribute, destroy, reclaim, fill, or package certain HFCs that are defined as a regulated substance under the AIM Act. Respondents and affected entities are also individuals and companies that produce, import, or export products in six statutorily specified applications: A propellant in MDIs; defense sprays; structural composite preformed polyurethane foam for marine and trailer use; the etching of semiconductor material or wafers and the cleaning of chemical vapor deposition chambers within the semiconductor manufacturing sector; mission-critical military end uses; and, onboard aerospace fire suppression.

Respondent's obligation to respond: Mandatory (AIM Act).

Estimated number of respondents: 10,654.

Frequency of response: Quarterly, biannual, annual, and as needed depending on the nature of the report.

Total estimated burden: 83,598 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $12,102,515 per year, includes $2,737,392 annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

EPA used data collected under the ICR for the Greenhouse Gas Reporting Program (OMB Control No. 2060–0629), as well as the associated reporting tool, the electronic Greenhouse Gas Reporting Tool (e-GGRT), in developing this rulemaking. EPA also requested an emergency ICR for a one-time collection request pertaining to data necessary to establish the United States consumption and production baselines, as well as to determine potential producers, importers, and application-specific end users who were not subject to the GHGRP (OMB Control No. 2060–0732, EPA ICR No. 2684.01). The emergency ICR for the one-time collection request was approved on April 22, 2021, and more information can be found here: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202103-2060-005*.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are suppliers of HFCs including producers, importers, exporters, reclaimers, companies that destroy HFCs, and companies that sell and distribute HFCs.

To determine whether this final rule would likely have a SISNOSE, EPA identified producers, importers, exporters, and reclaimers of HFCs from 2017 through 2019 that reported to EPA's Greenhouse Gas Reporting Program and CBP's ACE. Available economic data about each identified entity (*i.e.,* number of employees, annual sales) were obtained from the Dun and Bradstreet databases, and the sizes compared with the U.S. Small Business Administration's (SBA's) table of small business size standards matched to NAICS codes. The small business threshold is defined by SBA as the number of employees in the company and varied between 100 and 1,500 employees. There were identified HFC importers and reclaimers that met the definition of small businesses, but no HFC producers were identified as small businesses. To determine the likely economic impact on these small businesses, it was assumed that a percentage of the HFCs they imported would be replaced by an alternative, and the difference in the price between the HFCs and their alternatives was applied to determine any change in sales revenue. The methods used and assumptions made to perform this analysis are described in detail in the technical support document, *Economic Impact Screening Analysis for the Allowance System for an HFC Production and Consumption Phasedown,* found in the docket of this rule (Docket Number EPA–HQ–OAR–2021–0044).

EPA estimates that approximately 19 of the 8,738 potentially affected small businesses could incur costs in excess of one percent of annual sales and that approximately 15 small businesses could incur costs in excess of three percent of annual sales. Because there is not a significant number of small businesses that may experience a significant impact, it can be presumed that this action will have no SISNOSE.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538 and does

not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It does not have substantial direct effects on tribes on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action. EPA periodically updates tribal officials on air regulations through the monthly meetings of the National Tribal Air Association. EPA shared information on this rulemaking through that meeting and other fora.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children. Accordingly, EPA has evaluated the environmental health and welfare effects of climate change on children.

GHGs, including HFCs, contribute to climate change. The GHG emissions reductions resulting from the implementation of this rule will further improve children's health. The assessment literature cited in EPA's 2009 and 2016 Endangerment Findings concluded that certain populations and people at vulnerable stages of life, including children, the elderly, and people with low incomes, are most vulnerable to climate-related health effects. The assessment literature since 2016 strengthens these conclusions by providing more detailed findings regarding these groups' vulnerabilities and the projected impacts they may experience.

These assessments describe how children's unique physiological and developmental factors contribute to making them particularly vulnerable to climate change. Impacts to children are expected from heat waves, air pollution, infectious and waterborne illnesses, and mental health effects resulting from extreme weather events. In addition, children are among those especially susceptible to most allergic diseases, as well as health effects associated with heat waves, storms, and floods. Additional health concerns may arise in low-income households, especially those with children, if climate change reduces food availability and increases prices, leading to food insecurity within households. More detailed information on the impacts of climate change to human health and welfare is provided in Section III.B of this preamble.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action applies to certain regulated substances and certain applications containing regulated substances, none of which are used to supply or distribute energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

A summary of the Agency's approach for considering potential environmental justice concerns as a result of this rulemaking can be found in section IV of the preamble, and our environmental justice analysis can be found in the RIA, available in the docket for this rulemaking. As described in that analysis, this rule will reduce emissions of potent GHGs, which will reduce the effects of climate change, including the public health and welfare effects that disproportionately harm minority populations, low-income populations, and/or indigenous peoples.

At the same time, the Agency recognizes that phasing down the production of HFCs may cause significant changes in the location and quantity of production of both HFCs and their substitutes, and that these changes may in turn affect emissions of hazardous air pollutants at chemical production facilities. At proposal and in this final rule, EPA carefully evaluated available information on HFC production facilities and the characteristics of nearby communities to evaluate these impacts. EPA also solicited comment on whether these changes pose risks to communities with environmental justice concerns and what steps, if any, should be taken either under the AIM Act or under EPA's other statutory authorities to address any concerns that might exist. Based on this analysis and information gathered during the comment period, EPA finds evidence of environmental justice concerns near HFC production facilities from cumulative exposure to existing environmental hazards in these communities. However, given uncertainties about where and in what quantities HFC substitutes will be produced, EPA cannot determine the extent to which this rule will exacerbate or reduce existing disproportionate adverse effects on communities of color and low-income people as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). However, as noted in section IV, the Agency will continue to evaluate the impacts of this program on communities with environmental justice concerns and consider further action, as appropriate, to protect health in communities affected by HFC production.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 84

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Climate change, Emissions, Imports, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR chapter I as follows:

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.,* 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.,* 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.,* 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. In § 9.1 amend the table by:
■ a. Adding an undesignated center heading for ''Phasedown of Hydrofluorocarbons'' after the entry for ''82.184(e)''; and
■ b. Adding an entry for ''84.29'' in numerical order.

The additions read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
Phasedown of Hydrofluorocarbons	
84.29	2060–AV17
* * * * *	

■ 3. Effective October 5, 2021, add part 84 to read as follows:

PART 84—PHASEDOWN OF HYDROFLUOROCARBONS

Subpart A—Production and Consumption Controls

Subpart B—[Reserved]

Authority: Pub. L. 116–260, Division S, Sec. 103.

Subpart A—Production and Consumption Controls

§ 84.1 [Reserved]

§ 84.3 Definitions.

As used in this subpart, the term:

Administrator means the Administrator of the United States Environmental Protection Agency or his or her authorized representative.

Allowance means a limited authorization for the production or consumption of a regulated substance established under subsection (e) of section 103 in Division S, Innovation for the Environment, of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) (the AIM Act). An allowance allocated under subsection (e) of section 103 in Division S of the AIM Act does not constitute a property right.

Application-specific allowance means a limited authorization granted in accordance with subsection (e)(4)(B)(iv) of the AIM Act for the production or import of a regulated substance for use in the specifically identified applications that are listed in that subsection and in accordance with the restrictions to be determined. An application-specific allowance does not constitute a property right.

Bulk means a regulated substance of any amount that is in a container for the transportation or storage of that substance such as cylinders, drums, ISO tanks, and small cans. A regulated substance that must first be transferred from a container to another container, vessel, or piece of equipment in order to realize its intended use is a bulk substance. A regulated substance contained in a manufactured product such as an appliance, an aerosol can, or a foam is not a bulk substance.

Chemical vapor deposition chamber cleaning means, in the context of semiconductor manufacturing, a process type in which chambers used for depositing thin films are cleaned periodically using plasma-generated fluorine atoms and other reactive fluorine-containing fragments.

Confer means to shift unexpended application-specific allowances obtained in accordance with subsection (e)(4)(B)(iv) of the AIM Act from the end user allocated such allowances to one or more entities in the supply chain for the production or import of a regulated substance for use by the end user.

Consumption, with respect to a regulated substance, means production plus imports minus exports.

Consumption allowances means a limited authorization to produce and import regulated substances; however, consumption allowances may be used to produce regulated substances only in conjunction with production allowances. A person's consumption allowances are the total of the allowances obtained under § 84.11 or § 84.15 (with permitted modification to be determined).

Defense spray means an aerosol-based spray used for self-defense, including pepper spray and animal sprays, and containing the irritant capsaicin and related capsaicinoids (derived from oleoresin capsicum), an emulsifier, and an aerosol propellant.

Destruction means the expiration of a regulated substance to the destruction and removal efficiency actually achieved. Such destruction might result in a commercially useful end product, but such usefulness would be secondary to the act of destruction.

Etching means, in the context of semiconductor manufacturing, a process type that uses plasma-generated fluorine atoms and other reactive fluorine-containing fragments that chemically react with exposed thin films (*e.g.,* dielectric, metals) or substrate (*e.g.,* silicon) to selectively remove portions of material. This includes semiconductor production processes using fluorinated GHG reagents to clean wafers.

Exchange value means the value assigned to a regulated substance in accordance with AIM Act subsections (c) and (e), as applicable.

Exchange value equivalent (EVe) means the exchange value-weighted amount of a regulated substance obtained by multiplying the mass of a regulated substance by the exchange value of that substance.

Export means the transport from inside the United States or its territories to persons outside the United States or its territories, excluding United States military bases and ships for onboard use.

Exporter means the person who contracts to sell regulated substances for export or transfers regulated substances to his affiliate in another country.

Facility means one or more production lines at the same location owned by or under common control of the same person.

Final customer means the last person to purchase a bulk regulated substance before its intended use. Final customer includes, but is not limited to, air conditioning contractors in the residential air conditioning market, foam systems houses, aerosol fillers, semiconductor manufacturers, air conditioning and refrigeration equipment manufacturers that ship equipment pre-charged, and fire extinguisher manufacturers.

Foreign country means an entity that is recognized as a sovereign nation or country other than the United States of America.

Heel means the amount of a regulated substance that remains in a container after the container is discharged or

offloaded (that is no more than 10 percent of the volume of the container).

Import means to land on, bring into, or introduce into, or attempt to land on, bring into, or introduce into, any place subject to the jurisdiction of the United States, regardless of whether that landing, bringing, or introduction constitutes an importation within the meaning of the customs laws of the United States. Offloading used regulated substances recovered from equipment aboard a marine vessel, aircraft, or other aerospace vehicle during servicing is not considered an import.

Importer means any person who imports a regulated substance into the United States. ''Importer'' includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes:

(1) The consignee;

(2) The importer of record;

(3) The actual owner; or

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred.

Individual shipment means the kilograms of a regulated substance for which a person may make one (1) U.S. Customs entry, as identified in the non-objection notice obtained from the relevant Agency official.

Metered dose inhaler (MDI) means a handheld pressurized inhalation system that delivers small, precisely measured therapeutic doses of medication directly to the airways of a patient. MDIs treat health conditions such as asthma and chronic obstructive pulmonary disease and are approved for such use by the U.S. Food and Drug Administration (FDA).

Mission-critical military end uses means those uses of regulated substances by an agency of the Federal Government responsible for national defense that have a direct impact on mission capability, as determined by the U.S. Department of Defense, including, but not limited to uses necessary for development, testing, production, training, operation, and maintenance of Armed Forces vessels, aircraft, space systems, ground vehicles, amphibious vehicles, deployable/expeditionary support equipment, munitions, and command and control systems.

Non-objection notice means the limited authorization granted by the relevant Agency official to import a specific individual shipment of a regulated substance.

On board aerospace fire suppression means use of a regulated substance in fire suppression equipment used on board commercial and general aviation aircraft, including commercial-derivative aircraft for military use; rotorcraft; and space vehicles. On board commercial aviation fire suppression systems are installed throughout mainline and regional passenger and freighter aircraft, including engine nacelles, auxiliary power units (APUs), lavatory trash receptacles, baggage/crew compartments, and handheld extinguishers.

Person means any individual or legal entity, including an individual, corporation, partnership, association, state, municipality, political subdivision of a state, Indian tribe; any agency, department, or instrumentality of the United States; and any officer, agent, or employee thereof.

Process agent means the use of a regulated substance to form the environment for a chemical reaction or inhibiting an unintended chemical reaction (*e.g.,* use as a solvent, catalyst, or stabilizer) where the regulated substance is not consumed in the reaction, but is removed or recycled back into the process and where no more than trace quantities remain in the final product. A feedstock, in contrast, is consumed during the reaction.

Production/Produce means the manufacture of a regulated substance from a raw material or feedstock chemical (but not including the destruction of a regulated substance by a technology approved by the Administrator). The term production does not include:

(1) The manufacture of a regulated substance that is used and entirely consumed (except for trace quantities) in the manufacture of another chemical;

(2) The reclamation, reuse, or recycling of a regulated substance; or

(3) Insignificant quantities of a regulated substance inadvertently or coincidentally generated from any of the following, independent circumstances: during a chemical manufacturing process, resulting from unreacted feedstock, from the listed substance's use as a process agent present as a trace quantity in the chemical substance being manufactured, as an unintended byproduct of research and development applications, or during semiconductor manufacturing processes.

Production allowances means the limited authorization to produce regulated substances; however, production allowances may be used to produce regulated substances only in conjunction with consumption allowances. A person's production allowances are the total of the allowances obtained under § 84.9 or § 84.15 (with permitted modifications to be determined).

Production line means any process equipment (*e.g.,* reactor, distillation column) used to convert raw materials or feedstock chemicals into regulated substances or consume regulated substances in the production of other chemicals.

Reclaim means the reprocessing of regulated substances to all of the specifications in appendix A to 40 CFR part 82, subpart F (based on AHRI Standard 700–2016) that are applicable to that regulated substance and to verify that the regulated substance meets these specifications using the analytical methodology prescribed in section 5 of appendix A to 40 CFR part 82, subpart F.

Regulated substance means a hydrofluorocarbon listed in the table contained in subsection (c)(1) of the AIM Act and a substance included as a regulated substance by the Administrator under the authority granted in subsection (c)(3).

Space vehicle means a man-made device, either manned or unmanned, designed for operation beyond Earth's atmosphere. This definition includes integral equipment such as models, mock-ups, prototypes, molds, jigs, tooling, hardware jackets, and test coupons. Also included is auxiliary equipment associated with tests, transport, and storage, which through contamination can compromise the space vehicle performance.

Structural composite preformed polyurethane foam means a foam blown from polyurethane that is reinforced with fibers and with polymer resin during the blowing process, and is preformed into the required shape (*e.g.,* specific boat or trailer design) to increase structural strength while reducing the weight of such structures.

Transform means to use and entirely consume (except for trace quantities) a controlled substance in the manufacture of other chemicals. A regulated substance that is used and entirely consumed (except for trace quantities) in the manufacture of another chemical is called a feedstock.

Transhipment means the continuous shipment of a regulated substance, from a foreign country of origin through the United States or its territories, to a second foreign country of final destination, as long as the shipment does not enter U.S. commerce. A transhipment, as it moves through the United States or its territories, cannot be repackaged, sorted, or otherwise changed in condition.

Used regulated substances means regulated substances that have been recovered from their intended use systems (including regulated substances

that have been, or may be subsequently, recycled or reclaimed).

§ 84.5 [Reserved]

§ 84.7 Phasedown schedule.

(a) *Phasedown from baseline.* Total production and consumption of regulated substances in the United States in each year cannot exceed the amounts (shown as a percentage of baseline) in the following table:

Date	Percentage of production baseline (percent)	Percentage of consumption baseline (percent)
(1) 2022–2023	90	90
(2) 2024–2028	60	60
(3) 2029–2033	30	30
(4) 2034–2035	20	20
(5) 2036 and thereafter	15	15

(b) *Annual production and consumption limits.* (1) The production baseline for regulated substances is 382,554,619 metric tons of exchange value equivalent.

(2) The consumption baseline for regulated substances is 303,887,017 metric tons of exchange value equivalent.

(3) Total production and consumption in metric tons of exchange value equivalent for regulated substances in the United States in each year is derived by multiplying the production baseline or consumption baseline by the percentage in paragraph (a) of this section. Total production and consumption allowances issued under this subpart may not exceed the quantities shown in the following table:

Year	Total production (MTEVe)	Total consumption (MTEVe)
(i) 2022–2023	344,299,157	273,498,315
(ii) 2024–2028	229,532,771	182,332,210
(iii) 2029–2033	114,766,386	91,166,105
(iv) 2034–2035	76,510,924	60,777,403
(v) 2036 and thereafter	57,383,193	45,583,053

§ 84.9 Allocation of calendar-year production allowances.

(a) The relevant agency official will issue, through a separate notification, calendar year production allowances to entities that produced a regulated substance in 2020. The number of production allowances allocated to each eligible entity for 2022–2023 is calculated as follows:

(1) Take the average of the three highest annual exchange value-weighted production amounts that each eligible entity reported to the agency for calendar years 2011 through 2019;

(2) Sum the ''average high year'' values determined in step 1 of all eligible entities and determine each entity's percentage of that total;

(3) Determine the amount of general pool production allowances by subtracting the quantity of application-specific allowances for that year as determined in accordance with § 84.13 and the set-aside in § 84.15 from the production cap in § 84.7(b)(3);

(4) Determine individual entities' production allowance quantities by multiplying each entity's percentage determined in step 2 by the amount of general pool allowances determined in step 3.

(b)(1) EPA will allocate calendar year production allowances to individual entities by October 1 of the calendar year prior to the year in which the allowances may be used based on the exchange value-weighted quantities calculated in paragraph (a)(4) of this section.

(2) EPA will provide public notice of the list of companies receiving production allowances as well as the quantities they will be allocated by that date.

(3) In addition to the procedure in paragraph (a) of this section, the relevant agency official will allocate calendar year production allowances to entities that qualified for allowances under § 84.15.

(4) If there are remaining production allowances after distribution from the set-aside under § 84.15, the relevant agency official will distribute such allowances on a pro rata basis to the entities in paragraph (a) of this section by March 31 of the calendar year in which the allowances may be used.

§ 84.11 Allocation of calendar-year consumption allowances.

(a) The relevant agency official will issue, through a separate notification, calendar year consumption allowances to entities that imported or produced a bulk regulated substance in 2020, unless an individual accommodation is permitted by a relevant Agency official. If multiple importers are related through shared corporate or common ownership or control, the relevant agency official will calculate and issue allowances to a single corporate or common owner. The number of consumption allowances allocated to each eligible entity for 2022–2023 is calculated as follows:

(1) Take the average of the three highest annual exchange value-weighted consumption amounts chosen at the corporate or common ownership level for eligible entities reporting to the agency for each calendar year 2011 through 2019;

(2) Sum the ''average high year'' values determined in step 1 of all eligible entities and determine each entity's percentage of that total;

(3) Determine the amount of general pool consumption allowances by subtracting the quantity of application-specific allowances for that year as determined in accordance with § 84.13 and the set-aside in § 84.15 from the consumption cap § 84.7(b)(3);

(4) Determine individual entity consumption allowance quantities by multiplying each entity's percentage determined in step 2 by the amount of general pool allowances determined in step 3.

(b)(1) EPA will allocate calendar year consumption allowances to individual entities by October 1 of the calendar year prior to the year in which the allowances may be used based on the exchange value-weighted quantities calculated in paragraph (a)(4) of this section.

(2) EPA will provide public notice of the list of companies receiving consumption allowances as well as how they will be allocated by that date.

(c)(1) In addition to the procedure in paragraph (a) of this section, the relevant agency official will allocate calendar year consumption allowances to entities that qualified for allowances under § 84.15.

(2) If there are remaining consumption allowances after distribution from the set-aside under § 84.15, the relevant agency official will distribute such allowances on a pro rata basis to the entities in paragraph (a) of this section by March 31 of the calendar year.

§ 84.13 Allocation of application-specific allowances.

(a) Application-specific allowances are available to entities for calendar years 2022, 2023, 2024, and 2025 that use a regulated substance in the following applications:

(1) As a propellant in metered dose inhalers;

(2) In the manufacture of defense sprays;

(3) In the manufacture of structural composite preformed polyurethane foam for marine use and trailer use;

(4) In the etching of semiconductor material or wafers and the cleaning of chemical vapor deposition chambers within the semiconductor manufacturing sector;

(5) For mission-critical military end uses; and

(6) For on board aerospace fire suppression.

(b) Entities identified in paragraph (a) of this section must request application-specific allowances by July 31 of the calendar year prior to the year in which the allowances may be used starting with the calendar year 2023 allocation. The application must include the information required in § 84.31(h)(2) except for applications for mission-critical military end uses, which must include the information required in § 84.31(h)(3).

(1) Entities must provide additional information if requesting that EPA consider unique circumstances that are not reflected by the rates of growth calculated in paragraph (c)(1) of this section. The relevant agency official will consider the following situations as unique circumstances:

(i) Demonstrated manufacturing capacity coming on line;

(ii) The acquisition of another domestic manufacturer or its manufacturing facility or facilities; or

(iii) A global pandemic or other public health emergency that increases patients diagnosed with medical conditions treated by metered dose inhalers.

(2) [Reserved]

(c) The relevant agency official will determine the quantity of application-specific allowances to issue to each company by:

(1) Taking the higher of the use of regulated substances by the company in the specific application in the prior year multiplied by:

(i) The average growth rate of use for the company over the past three years; or

(ii) The average growth rate of use by all companies requesting allowances for that specific application over the past three years; and

(2) Accounting for any additional information provided regarding unique circumstances described in paragraph (b)(1) of this section; and

(3) Subtracting out any general pool allowances allocated to the company for that calendar year.

(d)(1) EPA will allocate application-specific allowances by October 1 of the calendar year prior to the year in which the allowances may be used. The relevant agency official will issue, through a separate notification, application-specific allowances to eligible entities consistent with paragraphs (a) through (c) of this section.

(2) EPA will provide public notice by that date of the list of entities receiving application-specific allowances, the quantity of allowances for each entity, and the specific application(s) for which the allowances may be used.

(e) Entities that use regulated substances in one of the six applications listed in paragraph (a) of this section and were not issued allowances as of October 1, 2021, may request allowances under the procedure in § 84.15. Such entities must meet the criteria for eligibility in this section and are subject to the requirements of this section and § 84.31(h).

(f) EPA will publish a list of entities allocated application-specific allowances, the application for which they may use regulated substances, and the quantity of allowances allocated.

(g) Application-specific allowances may be expended for either the import or production of a regulated substance.

(h) Entities allocated application-specific allowances may confer application-specific allowances to a producer, importer, or other supplier without being subject to the offset required of transfers of allowances to be determined. The recipient of a conferred application-specific allowance may continue to confer the allowance until it is expended for production or import. When conferring application-specific allowances, the conferring party must provide a statement certifying that the regulated substances produced or imported with the conferred allowances will only be used for the application-specific use associated with the allowance(s). The producer(s), importer(s), and/or supplier(s) receiving application-specific allowances must certify to the conferring party that they will not sell regulated substances produced or imported with application-specific allowances for any application or use other than the application-specific use associated with the allowance(s).

§ 84.15 Set-aside of application-specific allowances, production allowances, and consumption allowances.

(a) Total allowances available under this section to be allocated for calendar years 2022 and 2023 are:

(1) Up to 7.5 million metric tons of exchange value equivalent consumption allowances annually for calendar years 2022 and 2023.

(2) Up to 2.5 million metric tons of exchange value equivalent production allowances for calendar years 2022 and 2023.

(b)(1) Consumption and production allowances in paragraph (a) of this section are available in the form of application-specific allowances to entities that qualify for application-specific allowances under § 84.13 that were not issued allowances as of October 1, 2021.

(2) Entities must provide the relevant Agency official with the information contained in § 84.13 by November 30, 2021 to be eligible for consideration.

(c) Consumption allowances in paragraph (a) of this section are available to either:

(1) Persons who imported regulated substances in 2020 that were not required to report under 40 CFR part 98 and were not issued allowances as of October 1, 2021; or

(2) Persons who are newly importing regulated substances, do not share corporate or common ownership, corporate affiliation in the past five years, or familial relations with entities receiving allowances through this rule.

(d)(1) Persons who meet the criteria listed in paragraph (c)(1) of this section must provide the relevant Agency

official with the following information by November 30, 2021, to be eligible for consideration:

(i) Name and address of the company, the complete ownership of the company (with percentages of ownership), and contact information for a designated representative at the company;

(ii) The following information on an annual basis for all years between 2011 and 2020 where the person imported regulated substances:

(A) The total quantity (in kilograms) imported of each regulated substance each year, including each shipment, dates of and port of entry for each import, and country from which the imported regulated substances were imported;

(B) The Harmonized Tariff Schedule codes and CAS numbers for the regulated substances or blends imported;

(C) The quantity (in kilograms) of regulated substances imported for use in processes resulting in their transformation or destruction; and

(D) The quantity (in kilograms) of regulated substances sold or transferred during that year to each person for use in processes resulting in their transformation or destruction.

(iii) The following information on an annual basis for all years between 2011 and 2020 where the person exported regulated substances:

(A) The names and addresses of the exporter and the recipient of the exports;

(B) The exporter's Employer Identification Number;

(C) The quantity of each specific regulated substance exported, including the quantity of regulated substance that is used, reclaimed, or recycled;

(D) The date on which, and the port from which, the regulated substances were exported from the United States or its territories;

(E) The country to which the regulated substances were exported; and

(F) The Harmonized Tariff Schedule codes and CAS numbers for the regulated substances shipped.

(2) Persons who meet the criteria listed in paragraph (c)(2) of this section must provide the relevant Agency official with the following information by November 30, 2021, to be eligible for consideration:

(i) Name and address of the company, the complete ownership of the company (with percentages of ownership), and contact information for a designated representative at the company;

(ii) Whether the company is a woman- or minority-owned business;

(iii) Contact information for the owner of the company;

(iv) The date of incorporation and State in which the company is incorporated;

(v) State license identifier;

(vi) A plan for importing regulated substances;

(vii) A prospective foreign exporter that the applicant anticipates working with;

(viii) A certification that the business owner understands the regulatory requirements of this part and will make best efforts to comply with the regulatory requirements; and

(ix) A certification that the information submitted is complete, accurate, and truthful.

(e) The relevant Agency official will allocate calendar-year 2022 and 2023 allowances in paragraph (a) of this section no later than March 31, 2022, in the following manner:

(1) First, persons who meet the criteria listed in paragraph (b) of this section are allocated application-specific allowances (subtracted from both the production and consumption portions of the set-aside pool) for 2022 equal to the estimated need, based on projected, current, and historical trends, and subject to the same conditions for such allowances in § 84.13;

(2) Second, persons who meet the criteria listed in paragraph (c)(1) of this section are allocated allowances for 2022 by calculating their ''average high year'' based on the formula in § 84.11(a)(1) and then applying the same reduction percentage between the values calculated in § 84.11(a)(1) and (4) for all general pool allowance holders.

(3) Third, persons who meet the criteria listed in paragraph (c)(2) of this section are allocated up to 0.2 million metric tons exchange value equivalent in allowances for 2022 and 2023.

(4) If the eligible requests received total an amount of allowances that exceeds the remaining quantity of allowances in the set-aside pool, after subtracting allowances issued under paragraphs (b)(1) and (c)(1) of this section, the amount provided to each person who meets the criteria listed in paragraph (c)(2) of this section that has applied to the set-aside pool will be allocated an amount of allowances that is reduced on a pro rata basis. If any allowances remain after the steps outlined in paragraphs (b)(1) and (c)(1) and (2) of this section, those allowances will be distributed to the persons who meet the criteria listed in §§ 84.9 and 84.11 on a pro rata basis.

(f) EPA is placing restrictions on allowances allocated under this section.

(1) Allowances allocated to persons under paragraph (e)(3) of this section, due to their eligibility of meeting the criteria in paragraph (c)(2) of this section, may not be transferred to another entity.

(2) Allowances issued under this section are not available to companies that are a subsidiary of, have any common ownership stake with, had corporate affiliation in the past five years with, or have a familial relationship with another allowance holder.

(g) EPA will provide public notice by March 31, 2022, of the list of entities receiving allowances under this paragraph, the quantity of allowances for each entity, and the specific application(s) for which the allowances may be used, where applicable.

§§ 84.17–84.29 [Reserved]

§ 84.31 Recordkeeping and reporting.

(a) through (g) [Reserved]

(h) *Holders of application-specific allowances.* (1) [Reserved]

(2) *New Requests.* Persons requesting application-specific allowances for the first time must submit to EPA the following information:

(i) A description of the use of regulated substances and a detailed explanation of how the use is an application-specific use listed in § 84.13(a);

(ii) Total quantity (in kilograms) of all regulated substances acquired for application-specific use in the previous three years, including a copy of the sales records, invoices, or other records documenting that quantity;

(iii) The name of the entity or entities supplying regulated substances for application-specific use and contact information for those suppliers;

(iv) The quantities (in kilograms) of regulated substances held in inventory for application-specific use as of June 30 of the prior year and June 30 in the current year;

(v) A description of plans to transition to regulated substances with a lower exchange value or alternatives to regulated substances;

(vi) If a company is requesting additional allowances due to one or more of the circumstances listed in § 84.13(b)(1), the report must include a projection of the monthly quantity of additional regulated substances needed by month in the next calendar year and a detailed explanation, including relevant supporting documentation to justify the additional need; and

(vii) If a company is contracting out the manufacturing of defense sprays or metered dose inhalers, or contracting out the servicing of onboard aerospace fire suppression, the name, address, and email address for a representative of the

person doing the manufacturing or servicing, and clarification on whether the responses in paragraph (h)(2) of this section apply to the company that is requesting application-specific allowances or the company receiving the contract for manufacturing and/or servicing using application-specific allowances.

(3) *Report for Application-specific Allowances for Mission-critical Military End Use.* The Department of Defense must provide a report to EPA biannually by July 31 (covering prior activity from January 1 through June 30) and January 31 (covering prior activity from July 1 through December 31) of each year contains the following information:

(i) The quantity (in kilograms) of each regulated substance acquired for application-specific use by conferring application-specific allowances;

(ii) The quantity of inventory on June 30 of each regulated substance for application-specific use held by the Department of Defense or held under contract by another company for use by the Department of Defense;

(iii) The quantity of each regulated substance requested for mission-critical military end uses in the next calendar year;

(iv) The broad sectors of use covered by current mission-critical military end uses in the next calendar year; and

(v) A description of plans to transition application-specific use(s) to regulated substances with a lower exchange value or alternatives to regulated substances, including not-in-kind substitutes.

§§ 84.33–84.35 [Reserved]

Subpart B—[Reserved]

Appendix A to Part 84—[Reserved]

■ 4. Add § 84.1 to read as follows:

§ 84.1 Purpose and scope.

(a) The purpose of the regulations in this subpart is to implement certain provisions of the American Innovation and Manufacturing Act of 2020 (AIM Act), enacted as part of Public Law 116–260. In particular, the AIM Act imposes limits on the production and consumption of certain regulated substances, according to a specified schedule, which are addressed by this subpart. (b) This subpart applies to any person that produces, transforms, destroys, imports, exports, sells or distributes, offers for sale or distribution, recycles for fire suppression, or reclaims a regulated substance and to end users in the six applications listed in subsection (e)(4)(B)(iv) of the AIM Act.

■ 5. Amend § 84.3 by:

■ a. Revising and republishing the definitions of ''Application-specific allowance'', ''Consumption allowances'', ''Exchange value'', ''Individual shipment'', and ''Non-objection notice'';

■ b. Revising the first sentence of the introductory text to the definition of ''Production/Produce''; and

■ c. Revising and republishing the definitions of ''Production allowances'' and ''Regulated substance''.

The revisions and republications read as follows:

§ 84.3 Definitions.

* * * * *

Application-specific allowance means a limited authorization granted in accordance with subsection (e)(4)(B)(iv) of the AIM Act for the production or import of a regulated substance for use in the specifically identified applications that are listed in that subsection and in accordance with the restrictions contained at § 84.5(c). An application-specific allowance does not constitute a property right.

* * * * *

Consumption allowances means a limited authorization to produce and import regulated substances; however, consumption allowances may be used to produce regulated substances only in conjunction with production allowances. A person's consumption allowances are the total of the allowances obtained under § 84.11 or § 84.15 as may be modified under §§ 84.17 (availability of additional consumption allowances), 84.19 (transfer of allowances), and 84.35 (administrative consequences).

* * * * *

Exchange value means the value assigned to a regulated substance in accordance with AIM Act subsections (c) and (e), as applicable, and as provided in appendix A to this part.

* * * * *

Individual shipment means the kilograms of a regulated substance for which a person may make one (1) U.S. Customs entry, as identified in the non-objection notice obtained from the relevant Agency official in accordance with § 84.25.

* * * * *

Non-objection notice means the limited authorization granted by the relevant Agency official to import a specific individual shipment of a regulated substance in accordance with § 84.25.

* * * * *

Production/Produce means the manufacture of a regulated substance from a raw material or feedstock chemical (but not including the destruction of a regulated substance by a technology approved by the Administrator as provided in § 84.29).

* * *

* * * * *

Production allowances means the limited authorization to produce regulated substances; however, production allowances may be used to produce regulated substances only in conjunction with consumption allowances. A person's production allowances are the total of the allowances obtained under § 84.9 or § 84.15 as may be modified under §§ 84.19 (transfer of allowances) and 84.35 (administrative consequences).

* * * * *

Regulated substance means a hydrofluorocarbon listed in the table contained in subsection (c)(1) of the AIM Act and a substance included as a regulated substance by the Administrator under the authority granted in subsection (c)(3). A current list of regulated substances can be found in appendix A to this part.

* * * * *

■ 6. Add § 84.5 to read as follows:

§ 84.5 Prohibitions relating to regulated substances.

(a) *Production.* (1) As of January 1, 2022, no person may produce regulated substances, intentionally or unintentionally, in excess of the quantity of unexpended production allowances and consumption allowances or unexpended application-specific allowances held by that person under the authority of this subpart at that time in that control period. Every kilogram of production in excess of allowances expended constitutes a separate violation of this subpart. The required amount of allowances that must be expended will be calculated to the tenth with a minimum expenditure of 0.1 allowances for any production of regulated substances.

(2) As of January 1, 2022, no person may expend production allowances to produce a quantity of regulated substances unless that person expends an equal quantity of consumption allowances at the same time.

(3) A person is not required to expend production, consumption, or application-specific allowances to produce regulated substances if the regulated substances are destroyed using a technology approved by the Administrator for destruction under § 84.29 within 30 days of generating the regulated substance if the destruction technology is located at the facility where production occurred or 120 days

of generating the regulated substance if the destruction technology is not located at the facility where production occurred.

(4) No person may expend production or consumption allowances for generation of HFC-23 that is emitted at the same facility as where it is produced. Consistent with this prohibition, prior to the emissions standard compliance date established in § 84.27, neither production nor consumption allowances are required for HFC-23 emitted at the same facility as where it is produced.

(b) *Import.* This paragraph applies starting January 1, 2022.

(1) No person may import bulk regulated substances, except:

(i) By expending, at the time of the import, consumption or application-specific allowances in a quantity equal to the exchange-value weighted equivalent of the regulated substances imported, with the required amount of allowances calculated to the tenth, but a minimum expenditure of 0.1 allowances is required for any import of regulated substances;

(ii) After receipt of a non-objection notice for substances for use in a process resulting in their transformation or their destruction in accordance with § 84.25(a);

(iii) After receipt of a non-objection notice for used regulated substances imported for destruction in accordance with § 84.25(b); or

(iv) As a transhipment in accordance with § 84.31(c)(3) if all transhipped regulated substance is exported from the United States within six months of its import.

(2) Each person meeting the definition of importer for a particular regulated substance import transaction is jointly and severally liable for a violation of paragraph (b)(1) of this section, unless they can demonstrate that another party who meets the definition of an importer met one of the exceptions set forth in paragraph (b)(1).

(3) Imports authorized under paragraph (b)(1)(ii) of this section may not be in containers designed to hold 100 pounds or less of a regulated substance.

(4) A person issued a non-objection notice for the import of an individual shipment of regulated substances under paragraph (b)(1)(ii) or (iii) of this section may not transfer or confer the right to import.

(5) No person may introduce into U.S. commerce any regulated substance claimed as a transhipment.

(6) Every kilogram of bulk regulated substances imported contrary to this paragraph (b) constitutes a separate violation of this subpart. Import of less than one kilogram of bulk regulated substance contrary to this paragraph (b) constitutes a separate violation of this subpart.

(c) *Application-specific uses.* (1) As of January 1, 2022, no person may confer application-specific allowances for the production or import of a regulated substance in excess of the amount of unexpended application-specific allowances held by that person under the authority of this subpart at that time in that control period. No person may expend an application-specific allowance for regulated substances to be used in any application other than the one identified by the application-specific allowance expended. Every kilogram of production or import in excess of the application-specific allowances expended by the producer or importer constitutes a separate violation of this subpart. Production or import of less than one kilogram of regulated substance in excess of the application-specific allowances expended by the producer or importer constitutes a separate violation of this subpart.

(2) No person may use a regulated substance produced or imported by expending application-specific allowances for any purpose other than those for which the application-specific allowance was allocated, and as set forth in this paragraph (c). Application-specific allowances are apportioned to a person under §§ 84.13 and 84.15 for the production or import of regulated substances solely for the individual application listed on the allowance, which may include:

(i) A propellant in metered dose inhalers;

(ii) Defense sprays;

(iii) Structural composite preformed polyurethane foam for marine use and trailer use;

(iv) The etching of semiconductor material or wafers and the cleaning of chemical vapor deposition chambers within the semiconductor manufacturing sector;

(v) Mission-critical military end uses, such as armored vehicle engine and shipboard fire suppression systems and systems used in deployable and expeditionary applications; and

(vi) On board aerospace fire suppression.

(3) This provision applies starting January 1, 2022.

(i) No person may acquire application-specific allowances unless for use in the same application as associated with the application-specific allowance. No person may transfer or confer application-specific allowances unless for use in the same application as associated with the application-specific allowance.

(ii) No person may acquire or sell regulated substances produced or imported using application-specific allowances for use in anything other than the application for which it was originally allocated. Every kilogram of a regulated substance imported or exported in contravention of this paragraph constitutes a separate violation of this subpart. Import or export of less than one kilogram of regulated substance in contravention of this paragraph constitutes a separate violation of this subpart.

(d) *Calendar-year allowances.* All production, consumption, and application-specific allowances are valid only for the calendar year for which they are allocated (*i.e.,* January 1 through December 31). No person may expend, transfer, or confer a production, consumption, or application-specific allowance after December 31 of the year for which it was issued.

(e) *International transfers.* This paragraph applies starting January 1, 2022. (1) No person subject to the requirements of this subpart may transfer a production allowance to a person in a foreign country unless that country has established the same or similar requirements or otherwise undertaken commitments regarding the production and consumption of regulated substances as are contained in the AIM Act, as determined by the relevant agency official.

(2) No person may transfer production allowances to or from a person in a foreign country without satisfying the requirements in § 84.19. Every production allowance transferred in contravention of this paragraph constitutes a separate violation of this subpart.

(f) *Sale and distribution.* No person may sell or distribute, or offer for sale or distribution, any regulated substance that was produced or imported in violation of paragraphs (a) through (d) of this section, except for such actions needed to re-export the regulated substance. Every kilogram of a regulated substance sold or distributed, or offered for sale or distribution, in contravention of this paragraph constitutes a separate violation of this subpart. Sale or distribution, or offer for sale or distribution, of less than one kilogram of regulated substance in contravention of this paragraph constitutes a separate violation of this subpart.

(g) *False information.* No person may provide false, inaccurate, or misleading information to the EPA when petitioning, reporting, or for any

communication required under this subpart.

(h) *Disposable cylinders.* (1) As of July 1, 2025, no person may import or domestically fill a regulated substance in a non-refillable cylinder.

(2) As of January 1, 2027, no person may sell or distribute, or offer for sale or distribution regulated substances contained in a non-refillable cylinder.

(3) Small cans containing less than two pounds of regulated substances that have a self-sealing valve that meets the requirements in 40 CFR 82.154(c)(2) are not subject to this restriction.

(i) *Labeling.* (1) As of January 1, 2022, no person may sell or distribute, offer for sale or distribution, or import containers containing a regulated substance that lacks a label or other permanent markings stating the common name(s), chemical name(s), or ASHRAE designation of the regulated substance(s) or blend contained within, and the percentages of the regulated substances if a blend.

(2) No person other than the importer may repackage regulated substances that were initially unlabeled or mislabeled. In order to repackage the regulated substances, the importer must either:

(i) Expend consumption allowances equal to the amount of allowances that would be required if each cylinder were full of HFC-23; or

(ii) Verify the contents with independent laboratory testing results and affix a correct label on the container that matches the lab-verified test results before the date of importation (consistent with the definition at 19 CFR 101.1) of the container.

(3)(i) No person producing, importing, reclaiming, recycling for fire suppression, or repackaging regulated substances may sell or distribute, or offer for sale or distribution, regulated substances without first testing a representative sample of the regulated substances that they are producing, importing, reclaiming, recycling for fire suppression, or repackaging to verify that the composition of the regulated substance(s) matches the container labeling. For regulated substances sold or distributed or offered for sale and distribution as refrigerants, sampling must be done consistent with appendix A to 40 CFR part 82, subpart F—Specifications for Refrigerants.

(ii) No person may sell or distribute, or offer for sale or distribution, regulated substances as a refrigerant that do not meet the specifications in appendix A to 40 CFR part 82, subpart F—Specifications for Refrigerants.

(j) *Relationship to other laws.* Section (k) of the AIM Act states that sections 113, 114, 304, and 307 of the Clean Air Act (42 U.S.C. 7413, 7414, 7604, 7607) shall apply to this section and any rule, rulemaking, or regulation promulgated by the Administrator pursuant to this section as though this section were expressly included in title VI of that Act (42 U.S.C. 7671 *et seq.*). Violation of this part is subject to Federal enforcement and the penalties laid out in section 113 of the Clean Air Act.

§ 84.13 [Amended]

■ 7. In § 84.13, in the first sentence in paragraph (h), remove the text ''to be determined'' and add in its place the text ''in § 84.19''.

■ 8. Add §§ 84.17, 84.19, 84.21, 84.23, 84.25, 84.27, and 84.29 to read as follows:

* * * * *

Sec.

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§ 84.17 Availability of additional consumption allowances.

A person may obtain at any time during the year, in accordance with the provisions of this section, consumption allowances equivalent to the quantity of regulated substances that the person exported from the United States and its territories to a foreign country in accordance with this section.

(a) The exporter must submit to the relevant Agency official a request for consumption allowances setting forth the following:

(1) The identities and addresses of the exporter and the recipient of the exports;

(2) The exporter's Employer Identification Number;

(3) The names, telephone numbers, and email addresses of contact persons for the exporter and the recipient;

(4) The quantity (in kilograms) and name of the regulated substances exported;

(5) The source of the regulated substances and the date purchased;

(6) The date on which, and the port from which, the regulated substances were exported from the United States or its territories;

(7) The country to which the regulated substances were exported;

(8) A copy of the bill of lading and the invoice indicating the net quantity (in kilograms) of regulated substances shipped and documenting the sale of the regulated substances to the purchaser; and

(9) The Harmonized Tariff Schedule codes of the regulated substances exported.

(b) The relevant Agency official will review the information and documentation submitted under paragraph (a) of this section and will issue a notice to the requestor within 15 working days.

(1) The relevant Agency official will determine the quantity of regulated substances that the documentation verifies was exported and issue consumption allowances equivalent to the quantity of regulated substances that were exported.

(i) The grant of the consumption allowances will be effective on the date the notice is issued.

(ii) The consumption allowances will be granted to the person the exporter indicates, whether it is the producer, the importer, or the exporter.

(iii) The consumption allowances will be valid until December 31 of the same calendar year in which the regulated substances were exported.

(2) The relevant Agency official will issue a notice that the consumption allowances are not granted if the official determines that the information and documentation do not satisfactorily substantiate the exporter's claims.

§ 84.19 Transfers of allowances.

(a) *Inter-company transfers.* As of January 1, 2022, a person (''transferor'') may transfer to any other person (''transferee'') any quantity of the transferor's production allowances, consumption allowances, or application-specific allowances for use by the same type of application, as long as the following conditions are met:

(1) An offset equal to five percent of the amount of allowances transferred will be deducted from the transferor's production allowance balance if a transfer is made of production allowances, or deducted from the transferor's consumption allowance balance if a transfer is made of consumption allowances. In the case of transferring application-specific allowances, one percent of the amount of allowances transferred will be deducted from the transferor's application-specific allowance balance.

(2) The transferor must submit to the relevant Agency official a transfer claim setting forth the following:

(i) The identities and addresses of the transferor and the transferee;

(ii) The names, telephone numbers, and email addresses of contact persons for the transferor and the transferee;

(iii) The type of allowances being transferred, including the specific application (if applicable), for which allowances are to be transferred;

(iv) The quantity (in MTEVe) of allowances being transferred;

(v) The total cost of the allowances transferred;

(vi) The amount of unexpended allowances of the type and for the year being transferred that the transferor holds under authority of this subpart as of the date the claim is submitted to EPA;

(vii) The quantity of the offset to be deducted from the transferor's allowance balance; and

(viii) For transfers of application-specific allowances, a signed document from the transferee certifying that the transferee will use the application-specific allowances only for the same application for which the application-specific allowance was allocated.

(3) The relevant Agency official will determine whether the records maintained by EPA indicate that the transferor possesses unexpended allowances sufficient to cover the transfer claim as of the date the transfer claim is processed. The transfer claim is the quantity in EVe to be transferred plus the quantity of the offset. The relevant Agency official will take into account any previous transfers, any production, and allowable imports and exports of regulated substances reported by the transferor. Within three working days of receiving a complete transfer claim, the relevant Agency official will take action to notify the transferor and transferee as follows:

(i) The relevant Agency official will issue a non-objection notice to both the transferor and transferee indicating if EPA's records show that the transferor has sufficient unexpended allowances to cover the transfer claim. In the case of transfers of production allowances or consumption allowances, the relevant agency official will reduce the transferor's balance of unexpended allowances by the quantity to be transferred plus five percent of that quantity. In the case of transfers of application-specific allowances the relevant agency official will reduce the transferor's balance of unexpended allowances by the quantity to be transferred plus one percent of that quantity. The transferor and the transferee may proceed with the transfer when the relevant agency official issues a non-objection notice. However, if EPA ultimately finds that the transferor did not have sufficient unexpended allowances to cover the claim, the transferor and transferee will be liable for any violations of the regulations of this subpart that occur as a result of, or in conjunction with, the improper transfer.

(ii) The relevant Agency official will issue an objection notice disallowing the transfer if EPA's records show that the transferor has insufficient unexpended allowances to cover the transfer claim, that the transferor has failed to respond to one or more Agency requests to supply information needed to make a determination, or that the transferor or transferee has been notified of an impending administrative consequence and therefore is disallowed from transferring allowances in accordance with § 84.35. Either transferor or transferee may file a notice of appeal, with supporting reasons, with the relevant Agency official within 10 working days after receipt of the objection notice. The official may affirm or vacate the disallowance. If no appeal is filed electronically by the tenth working day after notification, the disallowance shall be final on that day.

(4) The transferer and transferee must maintain a copy of the transfer claim and a copy of EPA's non-objection or objection notice for five years.

(b) *International transfers of production allowances*—(1) *Requests.* A person may request to increase or decrease their production allowances for a specified control period through transfers of such allowances with a person in a foreign country if the applicable conditions in this paragraph are met. Once transferred, all allowances transferred consistent with this paragraph will function as a production allowance, as defined in § 84.3.

(i) *Timing of requests.* Any request for an increase or decrease in production allowances based on an international transfer under this paragraph must be submitted by October 1 of the year prior to the calendar year in which the transferred allowances would be usable.

(ii) *Timing of the transfer.* International transfers under this paragraph will be deemed to occur, and the transferred allowances will be usable, as of January 1 of the calendar year to which the transfer applies.

(2) *Transfer from a person in a foreign country—information requirements.* (i) A person requesting to change their production allowances based on a transfer from a person in a foreign country must submit to the relevant Agency official at the time the international transfer is requested a signed document from an official representative in that country's embassy in the United States stating that the appropriate authority within that country has revised the domestic production limits for that country equal to the lowest of the following three production quantities and identifying which of the following three production quantities was lowest:

(A) The maximum production level permitted in § 84.7(b) in the year of the international transfer minus the quantity of production allowances (in exchange value-weighted kilograms) to be transferred;

(B) The maximum production level for the applicable regulated substances that are allowed under applicable law (including the foreign country's applicable domestic law) minus the quantity of production allowances (in exchange value-weighted kilograms) to be transferred; or

(C) The average of the foreign country's actual national production level of the applicable regulated substances for the three calendar years prior to the year of the transfer minus the quantity of production allowances (in exchange value-weighted kilograms) to be transferred.

(ii) A person requesting a revision based on a transfer from a foreign country (''transferee'') must also submit to the relevant Agency official a true copy of the document that sets forth the following:

(A) The identity and address of the transferee;

(B) The foreign country authorizing the transfer;

(C) The names, telephone numbers, and email addresses of contact persons for the transferee and for the person in the foreign country;

(D) The name of the chemical and quantity (in kilograms) of production being transferred;

(E) Documentation that the foreign country possesses the necessary quantity of unexpended production rights;

(F) The calendar year to which the transfer applies; and

(G) A signed statement from a responsible official describing whether the increased production is intended for export or the market in the United States.

(3) *Transfer to a person in a foreign country—Information requirements.* A person requesting a transfer to a person in a foreign country must submit a request to the relevant Agency official that sets forth the following information:

(i) The identity and address of the person seeking to transfer the allowances (''transferor'');

(ii) The foreign country authorizing the transfer;

(iii) The names, telephone numbers, and email addresses of contact persons for the transferor and for the person in the foreign country;

(iv) The name of the chemical and quantity (in kilograms) of allowable production being transferred; and

(v) The calendar year to which the transfer applies;

(vi) A signed statement from a responsible official requesting that the relevant Agency official revise the number of production allowances the transferor holds such that the aggregate national production in the United States is equal to the lowest of the following three production quantities and identifying which of the following three production quantities was lowest:

(A) The maximum production level permitted in § 84.7(b) in the year of the international transfer minus the quantity of production allowances (in exchange value-weighted kilograms) to be transferred;

(B) The maximum production for the applicable regulated substances that are allowed under applicable law minus the quantity of production allowances (in exchange value-weighted kilograms) to be transferred; or

(C) The average of the United States' actual national production level of the applicable regulated substances for the three calendar years prior to the year of the transfer minus the quantity of production allowances (in exchange value-weighted kilograms) to be transferred.

(4) *Review of international transfer request to a foreign country.* After receiving a transfer request that meets the requirements of paragraph (b)(3) of this section, the relevant Agency official may, at his/her discretion, consider the following factors in deciding whether to approve such a transfer:

(i) Possible economic hardships created by a transfer;

(ii) Potential effects on trade;

(iii) Potential environmental implications; and

(iv) The total quantity of unexpended production allowances held by entities in the United States.

(5) *Notice of transfer.* The relevant Agency official will review the submitted requests to determine whether the foreign country in which the person is located has enacted or otherwise established the same or similar requirements or otherwise undertaken commitments regarding the production and consumption of regulated substances as are contained in the AIM Act, within a reasonable time frame of the date of its enactment. If it is determined that these conditions are not met, the relevant Agency official will notify the requestor in writing that no transfers to or from the country can occur. If these conditions are satisfied such that transfers to or from the country can occur, the relevant Agency official will consider if the request meets the applicable requirements of paragraph (b) of this section. If the request meets the requirements of paragraph (b)(2) of this section for transfers from foreign countries and paragraph (b)(3) of this section for transfers to foreign countries, and if the relevant Agency official has not decided to disapprove the request based on consideration of factors listed in paragraph (b)(4) of this section if applicable, the relevant Agency official will notify the person in writing that the appropriate production allowances were either granted or deducted and specify the control period to which the transfer applies. Notifications of production allowances granted or deducted will be provided before January 1 of the calendar year to which the transfer applies.

(i) For transfers from a foreign country, such notification will reflect a revision of the balance of allowances held by the recipient of the transfer to equal the unexpended production allowances held by the recipient of the transfer plus the quantity of allowable production transferred from the foreign country minus an offset of five percent of the quantity transferred. The relevant Agency official will not adjust available allowances until the foreign country's representative has confirmed the appropriate number of allowances were deducted in the foreign country.

(ii) For transfers to a foreign country, such notification will reflect a revision of the balance of production allowances for the transferor such that the aggregate national production of the regulated substance to be transferred is equal to the value the relevant Agency official determines to be the lowest of:

(A) The maximum production level permitted in § 84.7(b) in the year of the international transfer minus the quantity of production allowances transferred and minus an offset of five percent of the quantity transferred; or

(B) The maximum production level for the applicable regulated substances that is allowed under applicable law (in exchange-value weighted kilograms) minus the quantity of production allowances transferred and minus an offset of five percent of the quantity transferred; or

(C) The average of the actual annual U.S. production of the applicable regulated substances for the three years prior to the date of the transfer (in exchange-value weighted kilograms minus the quantity of production allowances transferred and minus an offset of five percent of the quantity transferred).

(6) *Revised production limit for previous transferors.* If the average actual U.S. production during the three most recent calendar years before the date of the transfer is less than the total allowable U.S. production for the applicable regulated substances permitted in § 84.7(b) for a calendar year for which international transfers are approved to occur, the aggregate allowed national U.S. production of those substances will be reduced by an additional amount beyond a simple deduction of the number of allowances reflected in the notifications under paragraph (b)(5)(ii)(B) of this section. In these circumstances, the relevant Agency official will revise the production limit for each transferor who obtained approval of a transfer of the applicable regulated substances to a foreign country in the same calendar year and notify each transferor of the revision in writing. The amount of the revision will equal the result of the following set of calculations:

(i) The total U.S. allowable production of the applicable regulated substances minus the average of the actual annual U.S. production of those substances during the three most recent calendar years prior to the calendar year of the transfer.

(ii) The quantity of production allowances for the applicable regulated substances transferred by the transferor in that calendar year divided by the total quantity of production allowances for those substances approved for transfer to a person in a foreign country by all the persons approved to make such transfers in that calendar year.

(iii) The result of paragraph (b)(6)(i) of this section multiplied by the result of paragraph (b)(6)(ii) of this section.

(iv) The unexpended production allowances held by the person minus the result of paragraph (b)(6)(iii) of this section.

(7) *Effective date of revised production limits.* If a revision is issued under paragraph (b)(6) of this section, the change in production allowances will be effective on the date that the notification is issued.

§ 84.21 Sale or conveyance of regulated substances produced or imported with application-specific allowances.

(a) *Sale or conveyance of regulated substances produced or imported using application-specific allowances.* (1) As of January 1, 2022, any person receiving an application-specific allowance (application-specific seller) may sell or

convey regulated substances produced or imported by expending that allowance to another person within the same application (application-specific purchaser) provided that the relevant Agency official approves the sale or conveyance.

(2) The application-specific seller must submit a claim to the relevant Agency official for approval before the sale or conveyance can take place. The claim must set forth the following:

(i) The identities and addresses of the application-specific seller and the application-specific purchaser;

(ii) The name, telephone numbers, and email addresses of contact persons for the application-specific seller and the application-specific purchaser;

(iii) The amount of each regulated substance being sold or conveyed;

(iv) The cost of the regulated substance being sold or conveyed;

(v) The application for which allowances were allocated and the specific products that the application-specific purchaser plans to produce with the regulated substances; and

(vi) Certification that the regulated substances will be used only for the same application for which the application-specific allowance under which the substances were produced or imported was allocated.

(3) The application-specific purchaser must submit a letter to the relevant Agency official stating that it concurs with the terms of the sale or conveyance as requested by the application-specific seller.

(4) Once the claim is complete, and if EPA does not object to the sale or conveyance, the relevant agency official will issue letters to the application-specific seller and the application-specific purchaser within 10 business days indicating that the transaction may proceed. EPA reserves the right to disallow a transaction if the claim is incomplete, or if it has reason to believe that the application-specific purchaser plans use the regulated substance in anything other than the stated application. If EPA objects to the transaction, the relevant agency official will issue letters to the application-specific seller and the application-specific purchaser stating the basis for disallowing the transaction.

(5) The burden of proof is placed on the application-specific purchaser to retain sufficient records to prove that the sold or conveyed regulated substances are used only for the stated application.

(b) [Reserved].

§ 84.23 Certification identification generation and tracking.

(a) *Scope and applicability.* Certification identifications may only be generated by a person that produces, imports, reclaims, recycles for fire suppression use, repackages, or blends regulated substance for distribution or sale in bulk and reports to EPA consistent with paragraph (d) of this section. All containers of bulk regulated substance, with the limited exceptions described in paragraph (b)(4) of this section, must be associated with certification identifications on the following schedule:

(1) As of January 1, 2025, all containers of bulk regulated substances imported and all containers sold or distributed by producers and importers must have a QR code.

(2) As of January 1, 2026, all containers of bulk regulated substances filled and all containers sold or distributed by all other repackagers and cylinder fillers in the United States not included in paragraph (a)(1) of this section, including reclaimers and fire suppressant recyclers must have a QR code.

(3) As of January 1, 2027, every container of bulk regulated substances sold or distributed, offered for sale or distribution, purchased or received, or attempted to be purchased or received must have a QR code.

(b) *Prohibitions.* Every kilogram of bulk regulated substances imported, sold or distributed, offered for sale or distribution, purchased or received, or attempted to be purchased or received in violation of this section is a separate violation of this subpart. Import, sale or distribution, offer for sale or distribution, purchase or receipt, or attempt to purchase or receive less than one kilogram of regulated substances in violation of this section is a separate violation of this subpart.

(1) No person may import, sell or distribute, or offer for sale or distribution, and no person may purchase or receive, or attempt to purchase or receive, a bulk regulated substance unless the container has a valid certification identification.

(2) No person may import, sell or distribute, or offer for sale or distribution, bulk regulated substances unless that person is registered with EPA consistent with paragraph (d) of this section.

(3) No person may purchase or receive, or attempt to purchase or receive, bulk regulated substances from a person that is not registered with EPA consistent with paragraph (d) of this section;

(4) The following situations are exempt from the prohibitions in paragraphs (b)(1) through (3) of this section:

(i) The regulated substances are part of a transhipment and the person transhipping the regulated substance has reported to EPA consistent with § 84.31(c)(3);

(ii) The regulated substances were previously used, have been recovered from a piece of equipment, and are intended for reclamation or fire suppressant recycling and:

(A) The person selling or distributing the regulated substances certifies in writing to the person purchasing or receiving the regulated substances that they were recovered from a piece of equipment and provides the date of recovery; and

(B) The person purchasing or receiving the regulated substances is an EPA-certified reclaimer, a registered fire suppressant recycler consistent with paragraph (d) of this section, or a registered supplier of regulated substances consistent with paragraph (d).

(iii) The regulated substances were imported consistent with the petition process described in § 84.25;

(iv) The regulated substances were collected for destruction and sent to a destruction facility directly or through an aggregator that is reporting to EPA consistent with § 84.31(c)(5); or

(v) The regulated substances were recovered from a motor vehicle air conditioner (MVAC) or MVAC-like appliance in accordance with 40 CFR part 82, subpart B and are sold or distributed or offered for sale or distribution by the same person who recovered the regulated substances for use only in MVAC equipment or MVAC-like appliances.

(5) No producer or importer may request certification identifications that would exceed their currently available allowances.

(6) A person who reclaims regulated substances or recycles regulated substances for fire suppression uses may request certification identifications at a level equal to their reported reclamation or recycling for the prior year plus an amount based on the average annual growth in total U.S. reclamation of regulated substances in the prior three years or 10 percent, whichever is higher. If further certification identifications are needed, the reclaimer or recycler must notify EPA 45 days in advance of exceeding their allowed level and request approval to generate additional certification identifications. The request must estimate the additional certification identifications needed for

the next six months and provide an explanation for the increased level of reclamation or recycling. The relevant agency official will review the request and adjust the amount of certification identifications for the person as appropriate within 21 days. Additional requests can be submitted throughout the year as needed.

(7) No regulated substance repackager or blender may request certificate identifications unless they have allowances. They may generate QR codes based on the certification identifications associated with the containers they acquire.

(c) *Required Practices.* The following practices are required, unless the person purchasing or receiving the bulk regulated substance is listed in paragraph (b)(4) of this section:

(1) Any person producing, importing, reclaiming, recycling for fire suppression uses, repackaging, selling or distributing, or offering to sell or distribute bulk regulated substances must register with EPA consistent with paragraph (d) of this section.

(2) Any person who imports, sells or distributes, or offers for sale or distribution a container of regulated substance, reclaimed regulated substance, or recycled regulated substances for fire suppression uses must permanently affix a QR code to the container that documents a valid certification identification using the standards defined by EPA prior to the import, sale or distribution, or offer for sale or distribution of the container. For the purposes of this subpart, examples of when a container of regulated substance or reclaimed regulated substance is imported, sold or distributed, or offered for sale or distribution include the date of importation (consistent with 19 CFR 101.1) and departure from a production, reclamation, fire suppressant recycling, repackaging or filling facility.

(3) At the time of sale or distribution or offer for sale or distribution, a person selling or distributing or offering for sale or distribution a container of regulated substance must ensure there is a valid and legible certification identification on each container of regulated substance, scan the certification identification system to identify a transaction, identify the person receiving the regulated substance, and indicate whether the person receiving the regulated substance is a supplier or final customer.

(4) At the time of sale or distribution, a person taking ownership of a container of regulated substance that is a registered supplier must ensure there is a valid and legible certification identification on each container of regulated substance and scan the certification identification in the certification identification system to identify a transaction.

(d) *Recordkeeping and Reporting*—(1) *Importers.* Any person importing a container of bulk regulated substance must enter the following information in the certification identification system to generate a QR code and associated certification identification for each container of regulated substance imported: the name or brand the regulated substance is being sold and/or marketed under, the date it was imported, the unique serial number associated with the container, the amount and name of the regulated substance(s) in the container, the name, address, contact person, email address, and phone number of the responsible party at the facility where the container of regulated substance(s) was filled, and certification that the contents of the cylinder match the substance(s) identified on the label.

(2) *Reclaimers.* Any person filling a container with a reclaimed regulated substance must enter the following information in the certification identification system to generate a QR code and associated certification identification for each container of regulated substance sold or distributed or offered for sale or distribution: the name or brand the regulated substance is being sold and/or marketed under, when the regulated substance was reclaimed and by whom, the date the reclaimed regulated substance was put into a container, the unique serial number associated with the container, the amount and name of the regulated substance(s) in the container, and certification that the purity of the batch was confirmed to meet the specifications in appendix A to 40 CFR part 82, subpart F. If a container is filled with reclaimed and virgin regulated substance(s), the reclaimer must provide the amount of virgin regulated substance included in the container and the certification identification(s) associated with that regulated substance.

(3) *Fire suppressant recyclers.* Any person filling a container with a recycled regulated substance for fire suppression purposes must enter the following information in the certification identification system to generate a QR code and associated certification identification for each container of regulated substance sold or distributed or offered for sale or distribution: the name or brand the regulated substance is being sold and/or marketed under, the date the container was filled and by whom, the unique serial number associated with the container, and the amount and name of the regulated substance(s) in the container. If a container is filled with recycled and virgin regulated substance(s), the recycler must provide the amount of virgin regulated substance included in the container and the certification identification(s) associated with that regulated substance.

(4) *Producers and repackagers.* Anyone who is filling a container, whether for the first time after production or when transferring regulated substances from one container to one or more smaller or larger containers, must enter information in the certification identification system and generate a QR code for the container(s) of packaged regulated substances sold or distributed or offered for sale or distribution: the name or brand the regulated substance is being sold and/or marketed under, the date the container was filled and by whom, the certification identification(s) associated with the regulated substance being packaged, the unique serial number associated with the container, the amount and name of the regulated substance(s) in the container, the quantity of containers it was packaged in, the size of the containers, and the name, address, contact person, email address, and phone number of the responsible party at the facility where the container(s) were filled.

(5) *Receiving recovered regulated substances.* Any person receiving recovered regulated substances for purposes of reclamation or fire suppressant recycling must keep a copy of the written certification required under paragraph (b)(4)(ii) of this section for five years.

(6) *Certification identification generators registration.* Any person who produces, imports, reclaims, recycles for fire suppression uses, repackages or fills a container of regulated substances, reclaimed regulated substances, or recycled regulated substances for fire suppression uses must register with EPA in the certification identification system at least six months before the date they are subject to the requirement in paragraph (a) of this section. The report must contain the name and address of the company, contact information for the owner of the company, the date(s) of and State(s) in which the company is incorporated and State license identifier(s), the address of each facility that sells or distributes or offers for sale or distribution regulated substances, how the company introduces bulk regulated substances

into U.S. commerce, and the categories of final customers the entity sells or distributes regulated substances to. If any of the registration information changes, these reports must be updated and resubmitted within 60 days of the change.

(7) *Supplier registration.* Any person who sells, distributes, or offers for sale or distribution, bulk regulated substances must register with EPA in the certification identification system at least six months before the date they are subject to the requirement in paragraph (a) of this section. The report must contain the name and address of the company, contact information for the owner of the company, the date(s) of and State(s) in which the company is incorporated and State license identifier(s), the address of each facility that sells or distributes regulated substances, and the categories of final customers the supplier sells or distributes regulated substances to. If any of the registration information changes, these reports must be updated and resubmitted within 60 days of the change.

§ 84.25 Required processes to import regulated substances as feedstocks or for destruction.

(a)(1) *Petition to import regulated substances for use in a process resulting in transformation or destruction.* A person must petition the relevant Agency official for the import of each individual shipment of a regulated substance imported for use in a process resulting in transformation or destruction in order to not expend allowances. A petition is required at least 30 days before the shipment is to arrive at a U.S. port, and must contain the following information:

(i) Name, Harmonized Tariff Schedule code, and quantity in kilograms of each regulated substance to be imported;

(ii) Name and address of the importer, the importer ID number, and the contact person's name, email address, and phone number;

(iii) Name and address of the consignee and the contact person's name, email address, and phone number;

(iv) Source country;

(v) The U.S. port of entry for the import, the expected date of import, and the vessel transporting the material. If at the time of submitting the petition the importer does not know this information, and the importer receives a non-objection notice for the individual shipment in the petition, the importer is required to notify the relevant Agency official of this information prior to the date of importation of the individual shipment into the United States;

(vi) Name and address of any intermediary, including a contact person's name, email address and phone number, who will hold the material before the regulated substances are transformed or destroyed;

(vii) Name, address, contact person, email address, and phone number of the responsible party at the facility where the regulated substance will be used in a process resulting in the substance's transformation or destruction;

(viii) An English translation, if needed, of the export license, application for an export license, or official communication acknowledging the export from the appropriate government agency in the country of export;

(ix) The capacity of the container; and

(x) The unique identification number of the container used to transport the regulated substances as part of the petition.

(2) *Review of petition to import for use in a process resulting in transformation or destruction.* (i) The relevant Agency official will initiate a review of the information submitted under paragraph (a)(1) of this section and take action within 21 days to issue either an objection notice or a non-objection notice for the individual shipment to the person who submitted the petition.

(ii) The relevant Agency official may issue an objection notice to a petition for the following reasons:

(A) If the relevant Agency official determines that the information is insufficient; that is, if the petition lacks or appears to lack any of the information required under paragraph (a)(1) of this section or other information that may be requested during the review of the petition necessary to verify that the regulated substance is for use in a process resulting in transformation or destruction;

(B) If the relevant Agency official determines that any portion of the petition contains false, inaccurate, or misleading information, or the official has information from other U.S. or foreign government agencies indicating that the petition contains false, inaccurate, or misleading information.

(iii) Within 10 working days after receipt of an objection notice with the basis being ''insufficient information,'' the importer may re-petition the relevant Agency official. If no re-petition is taken by the tenth working day after the date on the objection notice, the objection shall become final. Only one re-petition will be accepted for any petition received by EPA.

(iv) Any information contained in the re-petition which is inconsistent with the original petition must be identified and a description of the reason for the inconsistency must accompany the re-petition.

(v) In cases where the relevant Agency official does not object to the petition, the official will issue a non-objection notice.

(vi) If, following EPA's issuance of a non-objection notice, new information is brought to EPA's attention which shows that the non-objection notice was issued based on false, inaccurate, or misleading information, then EPA has the right to:

(A) Revoke and void the non-objection notice from the approval date;

(B) Pursue all means to ensure that the regulated substance is not imported into the United States; and

(C) Take appropriate enforcement and apply administrative consequences.

(3) *Timing.* (i) An individual shipment authorized through a non-objection notice must be used in the process resulting in its transformation within one year of import.

(ii) An individual shipment authorized through a non-objection notice must be used in the process resulting in its destruction within 120 days of import.

(4) *Quantity.* An individual shipment authorized through a non-objection notice may not exceed the quantity (in MTEVe) of the regulated substance stated in the non-objection notice.

(b)(1) *Petition to import used regulated substances for disposal by destruction.* A person must petition the relevant Agency official for the import of each individual shipment of a used regulated substance imported for purposes of destruction in order to not expend allowances. A petition is required at least 30 working days before the shipment is to leave the foreign port of export, and contain the following information:

(i) Name, Harmonized Tariff Schedule code, and quantity in kilograms of each regulated substance to be imported;

(ii) Name and address of the importer, the importer ID number, and the contact person's name, email address, and phone number;

(iii) Name and address of the consignee and the contact person's name, email address, and phone number;

(iv) Name and address of any intermediary who will hold regulated substances imported for destruction, and the contact person's name, email address, and phone number;

(v) Source country;

(vi) An English translation, if needed, of the export license (or application for an export license) from the appropriate government agency in the country of export;

(vii) The U.S. port of entry for the import, the expected date of import, and the vessel transporting the material. If at the time of submitting the petition the importer does not know this information, and the importer receives a non-objection notice for the individual shipment in the petition, the importer is required to notify the relevant Agency official of this information prior to the entry of the individual shipment into the United States; and

(viii) Name, address, contact person, email address, and phone number of the responsible party at the destruction facility.

(2) *Review of petition to import for destruction.* (i) The relevant Agency official will initiate a review of the information submitted under paragraph (b)(1) of this section and take action within 30 working days to issue either an objection notice or a non-objection notice for the individual shipment to the person who submitted the petition.

(ii) The relevant Agency official may issue an objection notice to a petition for the following reasons:

(A) If the relevant Agency official determines that the information is insufficient; that is, if the petition lacks or appears to lack any of the information required under paragraph (b)(1) of this section or other information that may be requested during the review of the petition necessary to verify that the regulated substance is used;

(B) If the relevant Agency official determines that any portion of the petition contains false, inaccurate, or misleading information, or the relevant Agency official has information from other U.S. or foreign government agencies indicating that the petition contains false, inaccurate, or misleading information;

(C) If allowing the import of the used regulated substance would run counter to government restrictions from either the country of recovery or export regarding regulated substances;

(D) If destruction capacity is installed or is being installed for that specific regulated substance in the country of recovery or country of export and the capacity is funded in full or in part through the Multilateral Fund to the Montreal Protocol.

(iii) Within 10 working days after receipt of an objection notice with the basis being ''insufficient information,'' the importer may re-petition the relevant Agency official. If no re-petition is taken by the tenth working day after the date on the objection notice, the objection shall become final. Only one re-petition will be accepted for any petition received by EPA.

(iv) Any information contained in the re-petition that is inconsistent with the original petition must be identified and a description of the reason for the inconsistency must accompany the re-petition.

(v) In cases where the relevant Agency official does not object to the petition, the official will issue a non-objection notice.

(vi) If, following EPA's issuance of a non-objection notice, new information is brought to EPA's attention which shows that the non-objection notice was issued based on false, inaccurate, or misleading information, then EPA and the relevant Agency official has the right to:

(A) Revoke and void the non-objection notice from the approval date;

(B) Pursue all means to ensure that the regulated substance is not imported into the United States; and

(C) Take appropriate enforcement and apply administrative consequences.

(3) *Timing.* An individual shipment authorized through a non-objection notice must be destroyed within 120 days of import.

(4) *Quantity.* An individual shipment authorized through a non-objection notice may not exceed the quantity (in MTEVe) of the regulated substance stated in the non-objection notice.

(5) *Proof of destruction.* For each individual shipment of a used regulated substance imported with the intent to destroy that substance for which EPA issues a non-objection notice, an importer must submit to the Administrator records indicating that the substance has been destroyed with their quarterly reports in § 84.31(c)(1).

(6) *Recordkeeping.* The person receiving the non-objection notice from the relevant Agency official for a petition to import used regulated substances must maintain the following records for five years:

(i) A copy of the petition;

(ii) The EPA non-objection notice;

(iii) The bill of lading for the import;

(iv) The U.S. Customs entry number; and

(v) Records demonstrating that the substance has been destroyed in accordance with approved technologies in § 84.29.

§ 84.27 Controlling emissions of HFC-23.

(a) No later than October 1, 2022, as compared to the amount of chemical intentionally produced on a facility line, no more than 0.1 percent of HFC-23 created on the line may be emitted.

(1) *Requests for extension.* The producer may submit a request to the relevant Agency official to request a six-month extension, with a possibility of one additional six-month extension, to meet the 0.1 percent HCFC-23 limit. No entity may have a compliance date later than October 1, 2023.

(2) *Timing of request.* The extension request must be submitted to EPA no later than August 1, 2022, for a first-time extension or February 1, 2023, for a second extension.

(3) *Content of request.* The extension request must contain the following information:

(i) Name of the facility submitting the request, contact information for a person at the facility, and the address of the facility.

(ii) A description of the specific actions the facility has taken to improve their HFC-23 control, capture, and destruction; the facility's plans to meet the 0.1 percent HFC-23 limit including the expected date by which the equipment will be installed and operating; and verification that the facility has met all applicable reporting requirements.

(4) *Review of request.* Starting on the first working day following receipt by the relevant Agency official of a complete request for extension, the relevant Agency official will initiate review of the information submitted under paragraph (a)(3) of this section and take action within 30 working days. Any grant of a compliance deferral by the relevant Agency official will be made public.

(b) Captured HFC-23 is permitted to be destroyed at a different facility than where it is produced. In such instances, HFC-23 emissions during the transportation to and destruction at the different facility will be incorporated into calculations of whether the producer meets the 0.1 percent standard outlined in paragraph (a) of this section.

§ 84.29 Destruction of regulated substances.

(a) The following technologies are approved by the Administrator for destruction of all regulated substances except for HFC-23:

(1) Cement kiln;

(2) Gaseous/fume oxidation;

(3) Liquid injection incineration;

(4) Porous thermal reactor;

(5) Reactor cracking;

(6) Rotary kiln incineration;

(7) Argon plasma arc;

(8) Nitrogen plasma arc;

(9) Portable plasma arc;

(10) Chemical reaction with hydrogen and carbon dioxide;

(11) Gas phase catalytic de-halogenation; and

(12) Superheated steam reactor.

(b) The following technologies are approved by the Administrator for destruction of HFC-23:

(1) Gaseous/fume oxidation;

(2) Liquid injection incineration;

(3) Reactor cracking;

(4) Rotary kiln incineration;

(5) Argon plasma arc;

(6) Nitrogen plasma arc;

(7) Chemical reaction with hydrogen and carbon dioxide; and

(8) Superheated steam reactor.

■ 9. Amend § 84.31 by adding paragraphs (a) through (g), (h)(1) and (4) through (7), and (i) through (k) to read as follows:

§ 84.31 Recordkeeping and reporting.

(a) *Recordkeeping and reporting.* Any person who produces, imports, exports, transforms, uses as a process agent, destroys, reclaims, or repackages regulated substances or is receiving application-specific allowances in the six applications listed in subsection (e)(4)(B)(iv) of the AIM Act must comply with the following recordkeeping and reporting requirements:

(1) Reports required by this section must be submitted within 45 days of the end of the applicable reporting period, unless otherwise specified.

(2) Reports, petitions, and any related supporting documents must be submitted electronically in a format specified by EPA.

(3) Records and copies of reports required by this section must be retained for five years.

(4) Quantities of regulated substances must be stated in terms of kilograms unless otherwise specified.

(5) Reports are no longer required if an entity notifies the Administrator that they have permanently ceased production, import, export, destruction, transformation, use as a process agent, reclamation, or packaging of regulated substances, but the entity must continue to comply with all applicable recordkeeping requirements.

(b) *Producers.* Persons (''producers'') who produce regulated substances must comply with the following recordkeeping and reporting requirements:

(1) *One-time report.* Within 120 days of January 1, 2022, or within 120 days of the date that a producer first produces a regulated substance, whichever is later, every producer must submit to the Administrator a report describing:

(i) The method by which the producer in practice measures daily quantities of regulated substances produced;

(ii) Conversion factors by which the daily records as currently maintained can be converted into kilograms of regulated substances produced, including any constants or assumptions used in making those calculations (*e.g.,* tank specifications, ambient temperature or pressure, density of the regulated substance);

(iii) Internal accounting procedures for determining plant-wide production;

(iv) The quantity of any fugitive losses accounted for in the production figures;

(v) A list of any coproducts, byproducts, or emissions from the production line that are other regulated substances; ozone-depleting substances listed in 40 CFR part 82, subpart A; or hazardous air pollutants initially identified in section 112 of the Clean Air Act, and as revised through rulemaking and codified in 40 CFR part 63;

(vi) The estimated percent efficiency of the production process for the regulated substance; and

(vii) A description of any processes that use a regulated substance as a process agent. Within 60 days of any change in the measurement procedures or the information specified in the above report, the producer must submit a report specifying the changes to the relevant Agency official.

(2) *Reporting—producers.* Within 45 days after the end of each quarter, each producer of a regulated substance must provide to the relevant Agency official a report containing the following information for each facility:

(i) The quantity (in kilograms) of production of each regulated substance used in processes resulting in their transformation by the producer and the quantity (in kilograms) intended for transformation by a second party;

(ii) The quantity (in kilograms) of production of each regulated substance used in processes resulting in their destruction by the producer and the quantity (in kilograms) intended for destruction by a second party;

(iii) The quantity (in kilograms) of production of each regulated substance used as a process agent by the producer and the quantity (in kilograms) intended for use as a process agent by a second party;

(iv) The quantity (in exchange value equivalents) of allowances expended for each regulated substance and the quantity (in kilograms) of each regulated substance produced;

(v) The quantity (in kilograms) of regulated substances sold or transferred during the quarter to a person other than the producer for use in processes resulting in their transformation, destruction, or use as a process agent;

(vi) The quantity (in kilograms) of regulated substances produced by the producer that were exported by the producer or by other U.S. companies to a foreign country that will be transformed or destroyed and therefore were produced without expending production or consumption allowances;

(vii) For transformation in the United States or by a person in a foreign country, one copy of a transformation verification from the transformer for the specific regulated substance(s) and a list of additional quantities shipped to that same transformer for the quarter;

(viii) For destruction in the United States or by a person in a foreign country of a regulated substance that was produced without allowances, one copy of a destruction verification for each particular destroyer confirming it destroyed the same regulated substance, and a list of additional quantities shipped to that same destroyer for the quarter;

(ix) A list of the entities conferring application-specific allowances from whom orders were placed, and the quantity (in kilograms) of specific regulated substances produced for those listed applications; and

(x) For the fourth quarter report only, the quantity of each regulated substance held in inventory on December 31.

(3) *Recordkeeping—producers.* Every producer of a regulated substance must maintain the following records:

(i) Dated records of the quantity (in kilograms) of each regulated substance produced at each facility;

(ii) Dated records of the quantity (in kilograms) of regulated substances produced for use in processes that result in their transformation, destruction, or as a process agent;

(iii) Dated records of the quantity (in kilograms) of regulated substances sold for use in processes that result in their transformation, destruction, or as a process agent;

(iv) Dated records of the quantity (in kilograms) of regulated substances produced by expending conferred application-specific allowances and quantity sold for use in each listed application;

(v) Copies of invoices or receipts documenting sale of regulated substances for use in processes that result in their transformation, destruction, or as a process agent;

(vi) Dated records of the quantity (in kilograms) of each regulated substance used at each facility as feedstocks or destroyed in the manufacture of a regulated substance or in the manufacture of any other substance, and any regulated substance introduced into the production process of the same regulated substance at each facility;

(vii) Dated records of the quantity (in kilograms) of each regulated substance used at each facility as a process agent;

(viii) Dated records identifying the quantity (in kilograms) of each coproduct and byproduct chemical not a regulated substance produced within each facility also producing one or more regulated substances;

(ix) Dated records of the quantity (in kilograms) of raw materials and feedstock chemicals used at each facility for the production of regulated substances;

(x) Dated records of the shipments of each regulated substance produced at each plant;

(xi) Dated records of batch tests of regulated substances packaged for sale or distribution;

(xii) The quantity (in kilograms) of regulated substances, the date received, and names and addresses of the source of used materials containing regulated substances which are recycled or reclaimed at each plant;

(xiii) Records of the date, the regulated substance, and the estimated quantity of any spill or release of a regulated substance that equals or exceeds 100 pounds;

(xiv) The transformation verification in the case of transformation, or the destruction verification in the case of destruction, showing that the purchaser or recipient of a regulated substance, in the United States or in another foreign country, certifies the intent to either transform or destroy the regulated substance, or sell the regulated substance for transformation or destruction in cases when allowances were not expended; and

(xv) The certifications from application-specific allowance holders stating that the regulated substances were purchased solely for an application listed in § 84.5(c)(2) and will not be resold for use in a different application or used in any other manufacturing process.

(4) *Additional Requirements: producers of HFC-23.* (i) Each producer of HFC-23 must include the following additional information in their one-time report in paragraph (b)(1) of this section:

(A) Information on the capacity to produce the intended chemical on the line on which HFC-23 is produced;

(B) A description of actions taken at the facility to control the generation of HFC-23 and its emissions;

(C) Identification of approved destruction technology and its location intended for use for HFC-23 destruction;

(D) A copy of the destruction removal efficiency report associated with the destruction technology; and

(E) Within 60 days of any change in the information specified in the above report, the producer must submit a report specifying the changes to the relevant Agency official.

(ii) Each producer of HFC-23 must include the following additional information in their fourth quarter report:

(A) Annual facility-level data on HFC-23 (in metric tons) on amounts: Emitted; generated; generated and captured for any purpose; generated and captured for consumptive use; generated and captured for feedstock use in the United States; generated and captured for destruction; used for feedstock without prior capture; and destroyed without prior capture.

(B) [Reserved]

(iii) If captured HFC-23 is destroyed in a subsequent control period, producers must submit records to EPA indicating the HFC-23 has been destroyed in their next quarterly report.

(iv) In developing any required report, each producer of HFC-23 must abide by the following monitoring and quality assurance and control provisions:

(A) To calculate the quantities of HFC-23 generated and captured for any use, generated and captured for destruction, used for feedstock without prior capture, and destroyed without prior capture, facilities shall comply with the monitoring methods and quality assurance and control requirements set forth at 40 CFR 98.414 and the calculation methods set forth at 40 CFR 98.413, except 40 CFR 98.414(p) shall not apply.

(B) To calculate the quantity of HFC-23 emitted, facilities shall comply with the monitoring methods and quality assurance and control requirements set forth at 40 CFR 98.124 and the calculation methods set forth at 40 CFR 98.123.

(5) *Agency assumption*—For any person who fails to maintain the records required by this paragraph, or to submit the reports required by this paragraph, EPA may assume that the person has produced at full capacity during the period for which records were not kept.

(c) *Importers.* Persons (''importers'') who import regulated substances must comply with the following recordkeeping and reporting requirements:

(1) *Reporting—importers.* Within 45 days after the end of each quarter, an importer of a regulated substance must submit to the relevant Agency official a report containing the following information:

(i) Summaries of the records required in paragraph (c)(2) of this section for the previous quarter;

(ii) The total quantity (in kilograms) imported of each regulated substance for that quarter;

(iii) The Harmonized Tariff Schedule codes for the regulated substances or blends imported;

(iv) A list of the application-specific allowance holders from whom orders were placed, number of application-specific allowances conferred, and the quantity (in kilograms) of specific regulated substances imported for those listed applications;

(v) The quantity (in kilograms) of regulated substances imported for use in processes resulting in their transformation or destruction;

(vi) The quantity (in kilograms) of regulated substances sold or transferred during that quarter to each person for use in processes resulting in their transformation or destruction;

(vii) The transformation verifications showing that the purchaser or recipient of imported regulated substances intends to transform those substances or destruction verifications showing that the purchaser or recipient intends to destroy the regulated substances;

(viii) Records required under § 84.25(b)(5) documenting proof that material imported for destruction was destroyed; and

(ix) For the fourth quarter report only, the quantity of each regulated substance held in inventory on December 31.

(2) *Recordkeeping—importers.* An importer of a regulated substance must maintain the following records:

(i) The quantity (in kilograms) of each regulated substance imported, either alone or in mixtures, including the percentage of each mixture that consists of a regulated substance;

(ii) The quantity (in kilograms) of used regulated substances imported for destruction under the process described in § 84.25(b);

(iii) The quantity (in kilograms) of regulated substances imported for use in processes resulting in their transformation or destruction;

(iv) The quantity (in kilograms) of regulated substances imported and sold for use in processes that result in their transformation or destruction;

(v) The date on which the regulated substances were imported;

(vi) The port of entry through which the regulated substances passed;

(vii) The country from which the imported regulated substances were imported;

(viii) The company that produced the imported regulated substances;

(ix) The Harmonized Tariff Schedule code for the regulated substances imported;

(x) The importer number for the shipment;

(xi) A copy of the bill of lading for the import;

(xii) The invoice for the import;

(xiii) The U.S. Customs entry number;

(xiv) Dated records documenting the sale or transfer of regulated substances for use in processes resulting in their transformation or destruction;

(xv) Copies of transformation verifications or destruction verifications indicating that the regulated substances will be transformed or destroyed;

(xvi) Dated records of the quantity of regulated substances imported for an application listed at § 84.5(c)(2);

(xvii) The certifications from application-specific allowance holders stating that the regulated substances were purchased solely for an application listed in § 84.5(c)(2) and will not be resold for use in a different application or used in any other manufacturing process;

(xviii) Dated records of batch tests of regulated substances packaged for sale or distribution; and

(xix) For any entity subject to an order issued by the Department of Commerce that is receiving allowances for 2022 or 2023, documentation of cash deposit of and final payment of the antidumping and countervailing duty for regulated substances imported.

(3) *Transhipments.* (i) A person must notify the relevant Agency official of each shipment of a regulated substance that is to be transhipped through the United States. The notification is required at least 30 working days before the shipment is to leave the foreign port of export for importation into the United States as a transhipment, and must contain the following information:

(A) Name, Harmonized Tariff Schedule code, and quantity in kilograms of each regulated substance to be transhipped;

(B) Name and address of the importer, the importer ID number, and the contact person's name, email address, and phone number;

(C) Source country; and

(D) The U.S. port of entry, the expected date of importation, and the vessel transporting the material. If at the time of submitting the petition the importer does not know this information, the importer is required to notify the relevant Agency official of this information prior to the entry of each shipment into the United States.

(ii) The person in paragraph (c)(3)(i) of this section must notify the relevant Agency official of each shipment of a regulated substance that has been transhipped when it is exported from the United States. The notification is required at least 10 working days after the shipment is exported from the United States, and must contain the following information:

(A) Name, Harmonized Tariff Schedule code, and quantity in kilograms of each regulated substance to be transhipped;

(B) Name and address of the importer, the importer ID number, and the contact person's name, email address, and phone number; and

(C) Date of departure and name of vessel.

(iii) Any person who tranships a regulated substance must maintain records that indicate:

(A) That the regulated substance shipment originated in a foreign country;

(B) That the regulated substance shipment is destined for another foreign country; and

(C) That the regulated substance shipment will not enter U.S. commerce within the United States.

(4) *Additional recordkeeping requirements—importers of used regulated substances for destruction.* A person receiving a non-objection notice from the relevant Agency official to import used regulated substances for destruction must maintain the following records:

(i) A copy of the petition to import for destruction;

(ii) The EPA non-objection notice;

(iii) A copy of the export license, export license application, or official communication from the appropriate government agency in the country of export;

(iv) An English translation of the document in paragraph (c)(4)(iii) of this section;

(v) U.S. Customs entry documents for the import that must include the Harmonized Tariff Schedule codes;

(vi) The date, amount, and name of the regulated substances sent for destruction, per shipment;

(vii) An invoice from the destruction facility verifying the shipment was received; and

(viii) Records from the destruction facility indicating that the substance has been destroyed.

(5) *Recordkeeping requirements—aggregators.* A person aggregating a regulated substance prior to destruction, regardless of whether the person is an importer, must:

(i) Maintain transactional records that include the name and address of the entity from whom they received the regulated substance imported for destruction;

(ii) Maintain transactional records that include the name and address of the entity to whom they sent the regulated substance imported for destruction;

(iii) Maintain records that include the date and quantity of the imported regulated substance received for destruction;

(iv) Maintain records that include the date and quantity of the imported regulated substance sent for destruction; and

(v) If the person is the final aggregator of such a regulated substance before the material is destroyed, maintain a copy of records indicating that the substance has been destroyed.

(6) *Recordkeeping requirements—vessel owners/operators.* A person offloading regulated substances recovered from equipment aboard a marine vessel, aircraft, or other aerospace vehicle while in a U.S. port must maintain records of the company name, vessel name or identifier, location of the appliance, date of recovery, person doing the recovery, the amount of regulated substances recovered and type of refrigerant recovered for each servicing event, and the amount of each regulated substance or blend of regulated substances offloaded and the date it was offloaded.

(7) *Additional reporting for importers.* A person importing a regulated substance, or their agent, must include the following no later than 14 days before importation via a Customs and Border Protection-authorized electronic data interchange system, such as the Automated Broker Interface:

(i) Cargo Description;

(ii) Quantity;

(iii) Quantity Unit of Measure Code;

(iv) Quantity Unit of Measure;

(v) Weight;

(vi) Weight Unit of Measure;

(vii) Port of Entry;

(viii) Scheduled Entry Date;

(ix) Harmonized Tariff Schedule (HTS) code;

(x) Harmonized Tariff Schedule (HTS) Description;

(xi) Origin Country;

(xii) Importer Name and Importer Number;

(xiii) Consignee Entity Name;

(xiv) CAS Number(s) of the regulated substance(s) imported and, for regulated substances that are in a mixture, either the ASHRAE numerical designation of the refrigerant or the percentage of the mixture containing each regulated substance;

(xv) If importing regulated substances for transformation or destruction, a copy of the non-objection notice issued consistent with § 84.25; and

(xvi) If importing regulated substances as a transhipment, a copy of the confirmation documenting the importer reported the transhipment consistent with paragraph (c)(3)(i) of this section.

(8) *One-time report—payment of antidumping and countervailing duties.* By November 30, 2021, any entity importing regulated substances subject to an antidumping and countervailing duty order issued by the Department of Commerce that is receiving allowances for 2022 or 2023 must provide documentation of cash deposit of and final payment of such duties for the regulated substances imported from January 1, 2017, through May 19, 2021, or provide evidence that those imports were not subject to such duties for those years.

(d) *Exporters.* Persons (''exporters'') who export regulated substances must comply with the following reporting requirements:

(1) *Reporting requirements—exporters.* Within 45 days after the end of each quarter, each exporter of a regulated substance must submit to the relevant Agency official a report containing the following information if such information was not already reported under paragraph (b)(2) of this section:

(i) The names and addresses of the exporter and the recipient of the exports;

(ii) The exporter's Employer Identification Number;

(iii) The quantity of each specific regulated substance exported, including the quantity of regulated substance that is used, reclaimed, or recycled;

(iv) The date on which, and the port from which, the regulated substances were exported from the United States or its territories;

(v) The country to which the regulated substances were exported;

(vi) The Harmonized Tariff Schedule codes for the regulated substances shipped;

(vii) For persons exporting for transformation or destruction of the regulated substance, the invoice or sales agreement containing language similar to the transformation verifications that importers use, or destruction verifications showing that the purchaser or recipient intends to destroy the regulated substances; and

(viii) For the fourth quarter report only, the quantity of each regulated substance held in inventory on December 31.

(2) *Used regulated substances.* Any exporter of used regulated substances must indicate on the bill of lading or invoice that the regulated substance is used.

(e) *Second-party transformation and destruction.* Any person who transforms or destroys regulated substances produced or imported by another person must comply with the following recordkeeping and reporting requirements:

(1) *Reporting—second-party transformation and destruction.* Any person who transforms or destroys regulated substances produced or imported by another person must report the following for each facility:

(i) The names and quantities (in kilograms) of the regulated substances transformed for each calendar year within 45 days after the end of that year; and

(ii) The names and quantities (in kilograms) of the regulated substances destroyed for each calendar year within 45 days after the end of that year.

(2) *Recordkeeping—second-party transformation and destruction.* Any person who transforms or destroys regulated substances produced or imported by another person must maintain the following:

(i) Copies of the invoices or receipts documenting the sale or transfer of the regulated substances to the person;

(ii) Records identifying the producer or importer of the regulated substances received by the person;

(iii) Dated records of inventories of regulated substances at each plant on the first day of each quarter;

(iv) Dated records of the quantity (in kilograms) of each regulated substance transformed or destroyed;

(v) In the case where regulated substances were purchased or transferred for transformation purposes, a copy of the person's transformation verification;

(vi) Dated records of the names, commercial use, and quantities (in kilograms) of the resulting chemical(s) when the regulated substances are transformed;

(vii) Dated records of shipments to purchasers of the resulting chemical(s) when the regulated substances are transformed; and

(viii) In the case where regulated substances were purchased or transferred for destruction purposes, a copy of the person's destruction verification.

(3) *Transformation verifications.* Any person who purchases regulated substances for purposes of transformation must provide the producer or importer of the regulated substances with a transformation verification that the regulated substances are to be used in processes that result in their transformation. The verification can only be valid for one year. The transformation verification shall include the following:

(i) Identity and address of the person intending to transform the regulated substances;

(ii) The quantity (in kilograms) of regulated substances intended for transformation;

(iii) Identity of shipments by purchase order number(s), purchaser account number(s), location(s), or other means of identification;

(iv) Period of time over which the person intends to transform the regulated substances; and

(v) Signature and title of the verifying person.

(4) *Destruction verifications.* Any person who purchases or receives regulated substances in processes that result in their destruction shall provide the producer or importer of the regulated substances with a destruction verification that the regulated substances are to be used in processes that result in their destruction. The verification can only be valid for up to 120 days. The destruction verification shall include the following:

(i) Identity and address of the person intending to destroy regulated substances;

(ii) The quantity (in kilograms) of regulated substances intended for destruction;

(iii) Identity of shipments by purchase order number(s), purchaser account number(s), location(s), or other means of identification;

(iv) The destruction efficiency at which such substances will be destroyed;

(v) Period of time over which the person intends to destroy regulated substances; and

(vi) Signature and title of the verifying person.

(5) *Transformation reporting—one-time report.* Within 120 days of January 1, 2022, or within 120 days of the date that an entity first transforms a regulated substance, whichever is later, any person who transforms a regulated substance must provide EPA with a one-time report containing the following information:

(i) A description of the transformation use;

(ii) A description of all technologies and actions taken to minimize emissions of regulated substances;

(iii) The name of the product manufactured in the process;

(iv) A list of any coproducts, byproducts, or emissions from the line on which the regulated substance is to be transformed that are other regulated substances; ozone-depleting substances listed in 40 CFR part 82, subpart A; or hazardous air pollutants initially identified in section 112 of the Clean Air Act, and as revised through rulemaking and codified in 40 CFR part 63;

(v) The estimated annual fugitive emissions by chemical associated with the transformation process;

(vi) The anticipated ratio of regulated substance used for transformation to the amount of end product manufactured; and

(vii) A mass balance equation of the transformation reaction.

(f) *All destruction facilities*—(1) *Destruction—one-time report.* Within 120 days of January 1, 2022, or within 120 days of the date that an entity first destroys a regulated substance, whichever is later, every person who destroys regulated substances, whether in a process for destruction or for disposal of a used substance, shall provide EPA with a report containing the following information:

(i) The destruction unit's destruction efficiency;

(ii) The methods used to determine destruction efficiency;

(iii) The methods used to record the volume destroyed;

(iv) The name of other relevant federal or state regulations that may apply to the destruction process; and

(v) Any changes to the information in this paragraph must be reflected in a revision to be submitted to EPA within 60 days of the change(s).

(2) *Proof of destruction.* Any person who destroys used regulated substances for disposal of that substance, shall provide the importer or aggregator with a record indicating the substance was destroyed within 30 days of the date of destruction.

(g) *Process agents*—(1) *Reporting—one-time report.* Within 120 days of January 1, 2022, or within 120 days of the date that an entity first uses a regulated substance as a process agent, whichever is later, any person who uses a regulated substance as a process agent must provide EPA a one-time report containing the following information:

(i) A description of the process agent use that includes details of the percentages of process agent retained within the process, recovered after the process, and emitted or entrained in the final product;

(ii) A description of all technologies and actions taken to minimize emissions of regulated substances;

(iii) The name of the product and byproducts manufactured in the process; and

(iv) The anticipated ratio of process agent emissions to end product manufactured.

(2) *Annual report.* Any person who uses a regulated substance as a process agent must provide an annual report containing the following information:

(i) Contact information including email address and phone number for a primary and alternate contact person;

(ii) The amount of regulated substance used as a process agent;

(iii) The amount of product and the amount of byproducts manufactured (including amounts eventually destroyed or used as feedstock);

(iv) The stack point source emissions; and

(v) A description of any regulated substance emission reduction actions planned or currently under investigation.

(h) * * *

(1) *Reporting.* Any person allocated application-specific allowances, except for persons receiving application-specific allowances for mission-critical military end uses, must submit to the relevant Agency official a report by July 31 (covering prior activity from January 1 through June 30) and January 31 (covering prior activity from July 1 through December 31) of each year. The report shall contain the following information:

(i) The quantity (in kilograms) of regulated substances acquired through conferring allowances during the previous six months;

(ii) The quantity (in kilograms) of regulated substances acquired through expending allowances and directly imported during the previous six months;

(iii) The quantity (in kilograms) of regulated substances purchased for application-specific use without expending application-specific allowances during the previous six months (*i.e.,* from the open market);

(iv) The quantity (in kilograms) of inventory on the last day of the previous six-month period of each regulated substance for application-specific use held by the reporting company or held under contract by another company for the reporting company's use;

(v) The quantity (in kilograms) of each regulated substance for application-specific use that was destroyed or recycled during the previous six months;

(vi) The names and contact information of each company to which application-specific allowances were conferred, and the quantity of allowances conferred from each company, and the quantity of regulated substances received from each company;

(vii) In the July 31 report only, a description of plans to transition application-specific use of regulated substances to regulated substances with a lower exchange value or alternatives to regulated substances;

(viii) In the July 31 report only, if a company is requesting additional allowances due to one or more of the circumstances listed in § 84.13(b)(1), the report must include a projection of the monthly quantity of additional regulated substances needed for application-specific use(s) by month in the next calendar year and a detailed explanation, including relevant supporting documentation to justify the additional need; and

(ix) In the July 31 report only, if a company is contracting out the manufacturing of defense sprays or metered dose inhalers, or paying another person (whether it is in cash, credit, goods, or services) to perform the servicing of onboard aerospace fire suppression, the name, address, and email address for a representative of the person doing the manufacturing or servicing, and clarification on whether the responses in paragraph (h)(1) of this section apply to the company that is allocated application-specific allowances or the company receiving the contract for manufacturing and/or servicing using application-specific allowances.

* * * * *

(4) *Conferral of allowances.* Entities who confer application-specific allowances, except for the conferral of allowances for mission-critical military end uses, must submit the following information about each conferral to the relevant Agency official prior to conferring allowances:

(i) The identities and addresses of the conferrer and the conferee;

(ii) The names, telephone numbers, and email addresses of contact persons for the conferrer and the conferee;

(iii) The specific application for which application-specific allowances are to be conferred;

(iv) The quantity (in MTEVe) of application-specific allowances being conferred;

(v) The amount of unexpended application-specific allowances of the type and for the year being conferred that the conferrer holds under authority of this subpart as of the date the claim is submitted to EPA; and

(vi) A certification from the conferrer and the conferee stating that the regulated substances being acquired, produced, or imported are solely for an application listed in § 84.5(c)(2) and will not be resold for use in a different application or used in any other manufacturing process.

(5) *Confirmation of conferral.* If the conferrer has sufficient application-specific allowances for the conferral, the conferral will occur and the relevant

Agency official will issue a confirmation notice to both the conferrer and conferee documenting the conferral occurred. The relevant agency official will reduce the conferrer's balance of unexpended allowances by the quantity conferred. However, if EPA ultimately finds that the conferrer did not have sufficient unexpended allowances to cover the conferral or that the regulated substances produced or imported with conferred allowances are used for anything other than the specific application identified in the conferee's submittal and for the application those allowances were allocated for, the conferrer and conferee will be liable for any violations of the regulations of this subpart that occur as a result of, or in conjunction with, the improper conferral.

(6) *Recordkeeping.* Entities who receive via allocation, transfer, or conferral of application-specific allowances, except for mission-critical military end uses, must maintain the following records for five years:

(i) Records necessary to develop the biannual reports;

(ii) A copy of certifications provided to entities when conferring and transferring allowances for application-specific use;

(iii) A copy of confirmation notices when conferring allowances for application-specific use;

(iv) A copy of the annual submission requesting application-specific allowances;

(v) Invoices and order records related to the purchase of regulated substances;

(vi) Records related to the transfer and conferral of application-specific allowances to other entities; and

(vii) Records documenting how regulated substances acquired with application-specific allowances were used.

(7) *Recordkeeping—Mission-Critical Military End Uses.* The Department of Defense must maintain the following records:

(i) Records necessary to develop the annual report;

(ii) A copy of certifications provided to entities when conferring allowances for application-specific use;

(iii) Invoices and order records related to the purchase of regulated substances;

(iv) Records documenting the conferral(s) of application-specific allowances to other entities up to and including the producer and or importer of the chemical;

(v) Records documenting the transfer of regulated substances to an agent or unit of the Department of Defense where the regulated substance will be used for mission-critical applications; and

(vi) Copies of current and historical plans prescribed by the Office of the Secretary of Defense documenting internal Department of Defense monitoring and review procedures for accuracy.

(i) *Reclaimers.* Persons (''reclaimers'') who reclaim regulated substances must comply with the following recordkeeping and reporting requirements:

(1) *One-time report.* By February 14, 2022, any person who reclaims a regulated substance must provide a one-time report containing the following information:

(i) The quantity of each regulated substance held in inventory as of December 31, 2021, broken out by whether the regulated substance is recovered, reclaimed, and virgin;

(ii) The name of the laboratory that conducts batch testing and a signed statement from that laboratory confirming there is an ongoing business relationship with the reclaimer;

(iii) The number of batches tested for each regulated substance or blend containing a regulated substance in the prior year; and

(iv) The number of batches that did not meet the specifications in appendix A to 40 CFR part 82, subpart F in the prior year.

(2) *Quarterly Reporting.* Within 45 days after the end of each quarter, each reclaimer of a regulated substance must submit to the relevant Agency official a report containing the quantity of material (the combined mass of regulated substance and contaminants) by regulated substance sent to them for reclamation, the total mass of each regulated substance, and the total mass of waste products.

(3) *Annual Reporting.* Within 45 days after the end of the fourth quarter, each reclaimer of a regulated substance must submit to the relevant Agency official a report containing the quantity of each regulated substance held in inventory onsite as of December 31 broken out by whether the regulated substance is recovered, reclaimed, and virgin.

(4) *Recordkeeping.* (i) Reclaimers must maintain records, by batch, of the results of the analysis conducted to verify that reclaimed regulated substance meets the necessary specifications in appendix A to 40 CFR part 82, subpart F (based on AHRI Standard 700–2016). Such records must be maintained for five years.

(ii) Reclaimers must maintain records of the names and addresses of persons sending them material for reclamation and the quantity of the material (the combined mass of regulated substance and contaminants) by regulated substance sent to them for reclamation. Such records must be maintained on a transactional basis for five years.

(j) *Fire suppressant recycling.* Persons (''recycler'') who recycle regulated substances used as a fire suppressant must comply with the following recordkeeping and reporting requirements:

(1) *Quarterly Reporting.* Within 45 days after the end of each quarter, each recycler of a regulated substance used as a fire suppressant must submit to the relevant Agency official a report containing the quantity of material (the combined mass of regulated substance and contaminants) by regulated substance sent to them for recycling, the total mass of each regulated substance recycled, and the total mass of waste products.

(2) *Annual Reporting.* Within 45 days after the end of the fourth quarter, each recycler of a regulated substance used as a fire suppressant must submit to the relevant Agency official a report containing the quantity of each regulated substance held in inventory onsite broken out by recovered, recycled, and virgin.

(3) *Recordkeeping.* Recyclers must maintain records of the names and addresses of persons sending them material for recycling and the quantity of the material (the combined mass of regulated substance and contaminants) by regulated substance sent to them for recycling. Such records must be maintained on a transactional basis for five years.

(k) *Treatment of Data submitted under 40 CFR part 84.* (1) Except as otherwise provided in paragraph (i) of this section, 40 CFR 2.201 through 2.215 and 2.301 do not apply to data submitted under this part that EPA has determined through rulemaking to be either of the following:

(i) Emission data, as defined in 40 CFR 2.301(a)(2), determined in accordance with section 114(c) and 307(d) of the Clean Air Act; or

(ii) Data not otherwise entitled to confidential treatment.

(2) Except as otherwise provided in paragraph (k)(4) of this section, 40 CFR 2.201 through 2.208 and 2.301(c) and (d) do not apply to data submitted under this part that EPA has determined through rulemaking to be entitled to confidential treatment. EPA shall treat that information as confidential in accordance with the provisions of 40 CFR 2.211, subject to paragraph (h)(4) of this section and 40 CFR 2.209.

(3) Upon receiving a request under 5 U.S.C. 552 for data submitted under this part that EPA has determined through rulemaking to be entitled to confidential

treatment, the relevant Agency official shall furnish the requestor a notice that the information has been determined to be entitled to confidential treatment and that the request is therefore denied. The notice shall include or cite to the appropriate EPA determination.

(4) A determination made through rulemaking that information submitted under this part is entitled to confidential treatment shall continue in effect unless, subsequent to the confidentiality determination through rulemaking, EPA takes one of the following actions:

(i) EPA determines through a subsequent rulemaking that the information is emission data or data not otherwise entitled to confidential treatment; or

(ii) The Office of General Counsel issues a final determination, based on the requirements of 5 U.S.C. 552(b)(4), stating that the information is no longer entitled to confidential treatment because of change in the applicable law or newly discovered or changed facts. Prior to making such final determination, EPA shall afford the business an opportunity to submit comments on pertinent issues in the manner described by 40 CFR 2.204(e) and 2.205(b). If, after consideration of any timely comments submitted by the business, the Office of General Counsel makes a revised final determination that the information is not entitled to confidential treatment, the relevant agency official will notify the business in accordance with the procedures described in 40 CFR 2.205(f)(2).

■ 10. Add §§ 84.33 and 84.35 to read as follows:

§ 84.33 Auditing of recordkeeping and reporting.

(a) Any person producing, importing, exporting, reclaiming, or recycling for fire suppression a regulated substance, as well as any person receiving application-specific allowances, must arrange for annual third-party auditing of reports submitted to EPA except for persons receiving application-specific allowances for mission-critical military end uses.

(b) For producers, importers, and exporters, auditors must review the inputs the regulated entities used to develop quarterly and annual reports including:

(1) The amount of production and consumption allowances allocated;

(2) The amount, timing, and parties to allowance transfers, and the associated documentation and offset amount;

(3) Records documenting the amount of regulated substances imported, exported, produced, and destroyed, transformed, or sent to another entity for such purpose;

(4) Records documenting any application-specific allowances allocated or conferred from other companies, including the amounts of allowances conferred, regulated substances purchased and/or sold, the specific application for which the regulated substances were provided, and the names, telephone numbers, and email addresses for contact persons for the recipient companies;

(5) The date and the port from which regulated substances were imported or exported;

(6) A copy of the bill of lading and the invoice indicating the quantity of regulated substances imported or exported;

(7) Relevant Harmonized Tariff Schedule codes;

(8) The number and type of railcars, ISO tanks, individual cylinders, drums, small cans, or other containers used to store and transport regulated substances;

(9) The inventory of regulated substances as of the end of the prior calendar year;

(10) A random sample (5 percent or 10, whichever is higher) of batch testing results;

(11) A random sample (5 percent or 10, whichever is higher) of certification identifications requested and generated and where associated regulated substances are sold and distributed; and

(12) All other reports submitted to EPA under this subpart.

(c) For companies issued application-specific allowances by EPA, auditors must review the following:

(1) Records documenting the amount of application-specific allowances allocated;

(2) The amount, timing, and parties to allowance transfers, and the associated documentation and offset amount;

(3) Records documenting any application-specific allowances conferred to or from other companies, including the amounts of allowances conferred, regulated substances purchased, the specific application for which the regulated substances were provided, and the names, telephone numbers, and email addresses for contact persons for the recipient companies;

(4) Records documenting the total amount of regulated substances purchased for the application-specific end use, and the amount of regulated substances sold to another company for application-specific used;

(5) Inventory of regulated substances at the end of the calendar year; and

(6) All other reports submitted to EPA under this subpart.

(d) For reclaimers and fire suppressant recyclers, auditors must review the following:

(1) The quantity of regulated substances received for reclamation or recycling;

(2) A random sample (5 percent or 10, whichever is higher) of records documenting the names and addresses of persons sending them material and the quantity of the material, measured in the combined mass of refrigerant and contaminants, by regulated substance to them;

(3) Records documenting the quantity of regulated substances reclaimed;

(4) A random sample (5 percent or 10, whichever is higher) of certification identifications requested and generated and where the associated regulated substances are sold and distributed; and

(5) All other reports submitted to EPA under this subpart.

(e) An auditor must meet the following requirements:

(1) The auditor must be a certified public accountant, or firm of such accountants, that is independent of the regulated person. Such an auditor must comply with the requirements for professional conduct, including the independence requirements, and the quality control requirements in 40 CFR 1090.1800(b)(1)(ii), as well as applicable rules of state boards of public accountancy. Such an auditor must also meet the requirements to perform an attestation engagement in 40 CFR 1090.1800(b)(1)(ii).

(2) The auditor must meet the independence requirements in paragraph (f) of this section.

(3) Any auditor suspended or debarred under 2 CFR part 1532 or 48 CFR part 9, subpart 9.4, is not qualified to perform attestation engagements under this section.

(f) All reports required under this paragraph must be signed and certified as meeting all the applicable requirements of this subpart by the independent third-party auditor. The auditor must:

(1) Attest that the information in the audit report is accurate;

(2) Attest that the company submitted all required reports to the Agency or specify which reports are missing and provide an assessment on whether missing reports should have been submitted; and

(3) Obtain a signed statement from a responsible corporate officer that all reports submitted to the EPA for the prior calendar year are complete and accurate.

(g) The following provisions apply to each audit performed under this section:

(1) The auditor must prepare a report identifying the applicable procedures specified in this section along with the auditor's corresponding findings for each procedure. The auditor must submit the report electronically to EPA by May 31 of the year following the compliance period.

(2) The auditor must identify any instances where compared values do not agree or where specified values do not meet applicable requirements under this part.

(3) Laboratory analysis refers to the original test result for each analysis of a product's properties.

(4) For a reclaimer that relies on a third-party laboratory for batch testing, the laboratory analysis consists of the results provided by the third-party laboratory.

(h) The independent third party, their contractors, subcontractors, and their organizations must be independent of the regulated party. All the criteria listed in paragraph (a) of this section must be met by each person involved in the specified activities in this section that the independent third party is hired to perform for a regulated party.

(1) *Employment criteria.* No person employed by an independent third party, including contractor and subcontractor personnel, who is involved in a specified activity performed by the independent third party under the provisions of this section, may be employed, currently or previously, by the regulated party for any duration within the 12 months preceding the date when the regulated party hired the independent third party to provide services under this section.

(2) *Financial criteria.* (i) The third-party's personnel, the third-party's organization, or any organization or individual that may be contracted or subcontracted by the third party must meet all the following requirements:

(A) Have received no more than one-quarter of their revenue from the regulated party during the year prior to the date of hire of the third party by the regulated party for any purpose.

(B) Have no interest in the regulated party's business. Income received from the third party to perform specified activities under this section is excepted.

(C) Not receive compensation for any specified activity in this section that is dependent on the outcome of the specified activity.

(ii) The regulated party must be free from any interest in the third-party's business.

(iv) Department of Defense data and reports for application-specific allowances for mission-critical military end uses shall be subject to internal Department of Defense monitoring and review for accuracy as prescribed by the Office of the Secretary of Defense. The results of this review shall be reported electronically to EPA by May 31 of the year following the compliance period.

§ 84.35 Administrative consequences.

(a) The relevant agency official may retire, revoke, or withhold the allocation of allowances, or ban a company from receiving future allowance allocations, using the process outlined in paragraph (b) of this section. Applying an administrative consequence to retire, revoke, or withhold allocation of allowances does not, in any way, limit the ability of the United States to exercise any other authority to bring an enforcement action under any applicable law or regulation.

(b) The relevant agency official will provide a company notice if the Agency intends to retire, revoke, or withhold allocation of allowances, or ban the company from receiving future allowance allocations. The notice will specify the conduct leading to the administrative consequence and what the consequence will be. The relevant agency official will provide such notice no less than 30 days before the impending consequence.

(1) After the relevant agency official provides notice of an impending administrative consequence, the company for which such consequence is pending may not expend, transfer, or confer any allowances.

(2) Any company receiving such a notification may provide information or data to EPA on why the administrative consequence should not be taken within 14 days of the date of the EPA's notice.

(3) If EPA does not receive a response within 14 days of the date of the Agency notice of impending administrative consequence, the administrative consequences will be effective on the date specified in the notice.

■ 11. Add appendix A to part 84 to read as follows:

Appendix A to Part 84—Regulated Substances

HFCs Listed as Regulated Substances in the AIM Act [1]

HFC	Chemical formula	Exchange value
HFC-134	CHF_2CHF_2	1,100
HFC-134a	CH_2FCF_3	1,430
HFC-143	CH_2FCHF_2	353
HFC-245fa	$CHF_2CH_2CF_3$	1,030
HFC-365mfc	$CF_3CH_2CF_2CH_3$	794
HFC-227ea	CF_3CHFCF_3	3,220
HFC-236cb	$CH_2FCF_2CF_3$	1,340
HFC-236ea	CHF_2CHFCF_3	1,370
HFC-236fa	CF_3CH2CF_3	9,810
HFC-245ca	$CH_2FCF_2CHF_2$	693
HFC-43-10mee	$CF_3CHFCHFCF_2CF_3$	1,640
HFC-32	CH_2F_2	675
HFC-125	CHF_2CF_3	3,500
HFC-143a	CH_3CF_3	4,470
HFC-41	CH_3F	92
HFC-152	CH_2FCH_2F	53
HFC-152a	CH_3CHF_2	124
HFC-23	CHF_3	14,800

[1] This table includes all isomers of the substances above, regardless of whether the isomer is explicitly listed on its own.

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16, 1100, 1107, et al.
Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports, and Premarket Tobacco Product Applications and Recordkeeping Requirements; Final Rules
Applications for Premarket Review of New Tobacco Products; Draft Guidance for Industry; Withdrawal; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1107

[Docket No. FDA–2016–N–3818]

RIN 0910–AH89

Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this final rule to provide additional information on the content and format of reports intended to demonstrate the substantial equivalence of a tobacco product (SE Reports). The final rule also establishes the general procedures FDA intends to follow when evaluating SE Reports, including procedures that address communications with the applicant and the confidentiality of data in an SE Report. The final rule will provide applicants with more certainty and clarity related to preparing and submitting SE Reports.

DATES: This rule is effective November 4, 2021.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–5700.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson or Nathan Mease, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 877–287–1373, *AskCTP@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

This final rule provides further information on the content and format of SE Reports, including the information that SE Reports must contain. FDA is finalizing this rule after reviewing comments to the proposed rule (84 FR 12740, April 2, 2019), as well as the SE review experience the Agency has gained since enactment of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31). As explained in the proposed rule, the SE Reports that FDA has seen to date range widely in the level of detail included, with some reports including very little information on the comparison of the new tobacco product with a predicate tobacco product and some including much more. This final rule will provide applicants with a better understanding of the level of detail that an SE Report must contain. The final rule also addresses issues such as FDA communications with the applicant, the retention of records that support the SE Report, confidentiality of SE Reports, and electronic submission of the SE Report and amendments.

B. Summary of the Major Provisions of the Final Rule

Under the final rule, an SE Report must provide information comparing the new tobacco product to a predicate tobacco product, including information that will enable FDA to uniquely identify the new tobacco product and the predicate tobacco product, as well as comparison information. The requirements will help ensure that an SE Report provides information necessary for FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007 (as required by section 910(a)(2)(A) of the FD&C Act).

In addition, the rule explains how an applicant can amend or withdraw an SE Report, and explains how an applicant may transfer ownership of an SE Report to a new applicant. The rule also addresses FDA communications with applicants on SE Reports and explains FDA review cycles and FDA actions, including the issuance of orders and the rescission of orders. The rule also establishes the length of time records related to the SE Report must be maintained, describes FDA's disclosure provisions, and requires electronic submission of SE Reports, unless the applicant requests and is granted a waiver.

C. Legal Authority

This rule is being issued based upon FDA's authority to require premarket review of new tobacco products under sections 905(j) and 910(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387e(j) and 387j(a)), FDA's authority to require reports under section 909(a) of the FD&C Act (21 U.S.C. 387i(a)), FDA's authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387b and 387c), as well as FDA's rulemaking and inspection authorities under sections 701(a) and 704 of the FD&C Act (21 U.S.C. 371(a) and 374).

D. Costs and Benefits

This final rule would impose incremental compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, and fill out a form for SE Reports. We estimate that the present value of industry compliance costs ranges from $0.4 million to $3.4 million, with a primary estimate of $1.9 million at a 3 percent discount rate, and from $0.4 million to $2.9 million, with a primary estimate of $1.6 million at a 7 percent discount rate over 10 years. Annualized industry compliance costs over 10 years range from $0.05 million to $0.39 million, with a primary estimate of $0.22 million at a 3 percent discount rate and from $0.06 million to $0.42 million, with a primary estimate of $0.23 million at a 7 percent discount rate.

The incremental benefits of this final rule are potential time-savings to industry and cost-savings to government. The final rule clarifies when applicants may certify that certain

characteristics are identical in the new tobacco product and the predicate tobacco product. Certifying may save applicants time in preparing their SE Reports. We anticipate shorter review times for SE Reports as a result of this final rule. In addition, based on our experience with prior SE Reports, we believe this final rule will lead to higher quality SE Reports, saving us time in review and requiring fewer staff to review SE Reports, which will result in cost-savings. We estimate that the present value of government cost-savings ranges from $15.1 million to $150.6 million, with a primary estimate of $50.2 million at a 3 percent discount rate, and from $12.4 million to $124 million, with a primary estimate of $41.3 million at a 7 percent discount rate over 10 years. Annualized government cost-savings over 10 years range from $1.8 million to $17.7 million, with a primary estimate of $5.9 million at both 3 and 7 percent discount rates.

The qualitative benefits of this final rule include additional clarity to industry about the requirements for the content and format of SE Reports. The final rule would also establish the general procedures we will follow in reviewing and communicating with applicants. In addition, this final rule would make the SE pathway more predictable.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation	What it means
ANPRM	Advance Notice of Proposed Rulemaking
CCS	Container Closure System
CORESTA	Cooperation Centre for Scientific Research Relative to Tobacco
CTP	Center for Tobacco Products
DQPH	Different Questions of Public Health
ENDS	Electronic Nicotine Delivery System
EA	Environmental Assessment
E.O.	Executive Order
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FSC	Fire Standard Compliant
FOIA	Freedom of Information Act
GRAS	Generally Recognized as Safe
HPHC	Harmful and Potentially Harmful Constituents
HTP	Heated Tobacco Products
MDSS	Manufacturing Data Sheet Specification
NEPA	National Environmental Policy Act of 1969
NSE	Not Substantially Equivalent
PDU	Power Delivery Unit
PM	Particulate Matter
PMTA	Premarket Tobacco Application
PRA	Paperwork Reduction Act of 1995
QRA	Quantitative Risk Assessment
RIA	Regulatory Impact Analysis
RYO	Roll-Your-Own
SE	Substantial Equivalence
TPMF	Tobacco Product Master File
TSNA	Tobacco-Specific Nitrosamines
VOC	Volatile Organic Compound

III. Background

The FD&C Act, as amended by the Tobacco Control Act, generally requires that before a new tobacco product may be introduced into interstate commerce for commercial distribution in the United States, the new tobacco product must undergo premarket review by FDA. Section 910(a)(1) of the FD&C Act defines a ''new tobacco product'' as: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

The FD&C Act establishes three premarket review pathways for a new tobacco product:

- Submission of a premarket tobacco application under section 910(b);
- submission of a report intended to demonstrate that the new tobacco product is substantially equivalent to a predicate tobacco product under section 905(j)(1)(A) (''SE Report''); and
- submission of a request for an exemption under section 905(j)(3) (implemented at § 1107.1 (21 CFR 1107.1)).

Under section 910(a)(2)(B) of the FD&C Act, a manufacturer of a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, that submitted an SE Report [1] prior to March 23, 2011, may continue to market the tobacco product unless FDA issues an order that the tobacco product is not substantially equivalent (''provisional'' tobacco products). For any new tobacco product introduced or delivered for introduction into interstate commerce for commercial distribution on or after March 22, 2011, or for which a substantial equivalence report was not submitted prior to March 23, 2011, a manufacturer must first submit a premarket application for the new tobacco product to FDA, and FDA must issue an order authorizing the commercial distribution of the new tobacco product or find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act, before the product may be introduced into commercial distribution. If a new tobacco product is marketed without an order or a finding of exemption from substantial equivalence, it is adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act and subject to enforcement action.

Since the enactment of the Tobacco Control Act, FDA has received thousands of SE Reports, many of which lacked the information necessary for FDA to make a substantial equivalence determination. To assist applicants in better preparing an SE Report, on April 2, 2019, FDA issued a proposed rule to provide additional information regarding the content and format of reports intended to establish the substantial equivalence of a tobacco product. FDA received about 100 comments to the docket for the proposed rule, including comments from tobacco product manufacturers and trade organizations, retailers, representatives of tribes/tribal organizations, public health groups, individual consumers, and other submitters. We summarize and respond to these comments in section V of this rule. After considering these comments, FDA developed this final rule, which includes changes made in response to the comments.

IV. Legal Authority

As described in the following paragraphs, FDA is issuing this rule to address the content, form, and manner of reports intended to demonstrate the substantial equivalence of a new tobacco product to a predicate tobacco product. The rule also addresses record keeping, reports, and the information essential to FDA's implementation of the FD&C Act. In accordance with section 5 of the Tobacco Control Act, FDA intends that the requirements established by this rule are severable and that the invalidation of any provision of this rule would not affect the validity of any other part of this rule.

Section 910(a)(2) of the FD&C Act requires a new tobacco product to be the subject of a premarket tobacco product application (PMTA) marketing order unless FDA has issued an SE order authorizing its commercial distribution or the tobacco product is exempt from substantial equivalence. To satisfy the requirement of premarket review, a manufacturer may submit a report intended to demonstrate the substantial

[1] In this rule, FDA refers to ''SE applications'' as ''SE Reports,'' but the terms both refer to a premarket submissions under section 905(j)(1)(A) of the FD&C Act.

equivalence of a new tobacco product to a predicate tobacco product under section 905(j) of the FD&C Act. Section 905(j) provides that FDA may prescribe the form and manner of the substantial equivalence report, and section 910(a)(4) of the FD&C Act requires that as part of the 905(j) report, the manufacturer provide an adequate summary of any health information related to the new tobacco product or state that such information will be made available upon request.

Based on the information provided by the applicant, section 910(a)(3)(A) of the FD&C Act authorizes FDA to issue an order finding substantial equivalence when FDA finds that the new tobacco product is in compliance with the requirements of the FD&C Act and either: (1) Has the same characteristics as the predicate tobacco product or (2) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to regulate the product under the PMTA provisions because the product does not raise different questions of public health.

Section 909(a) of the FD&C Act authorizes FDA to issue regulations requiring tobacco product manufacturers or importers to maintain such records, make such reports, and provide such information as may be reasonably required to assure that their tobacco products are not adulterated or misbranded and to otherwise protect public health.

Under section 902(6)(A) of the FD&C Act, a tobacco product is adulterated if it is required to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i) of the FD&C Act. Under section 903(a)(6) of the FD&C Act, a tobacco product is misbranded if a notice or other information respecting it was not provided as required by section 905(j) of the FD&C Act. In addition, a tobacco product is misbranded if there is a failure or refusal to furnish any material or information required under section 909 (section 903(a)(10)(B) of the FD&C Act).

Section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act, and section 704 of the FD&C Act provides FDA with general inspection authority.

V. Description of the Final Regulation and Comments and Responses

A. Introduction

We received about 100 comments to the docket for the proposed rule. In addition to the comments specific to this rulemaking that we address in this section, we received many general comments expressing support or opposition to the rule. These comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response. In this section, we have grouped similar comments together by the topics discussed or the particular portions of the proposed rule or codified language to which they refer. To make it easier to identify comments and FDA's responses, the word ''Comment,'' in parenthesis, appears before the comment's description, and the word, ''Response,'' in parenthesis appears before FDA's response. Each comment is numbered to help distinguish among different comments, and the number assigned is purely for organizational purposes and does not signify value or importance. Similar comments are grouped together under the same comment number. In this section we also describe changes we made to the final rule following our consideration of the comments and other information.

As described in more detail in this section, following our consideration of these comments, we have made changes to proposed §§ 1107.10, 1107.12, 1107.18, 1107.19, 1107.22, 1107.40, 1107.44, 1107.46, 1107.48, and 1107.50. The changes are largely intended to clarify areas of confusion or address concerns raised by the comments, and we describe in detail the changes made to each of these provisions in the following paragraphs. Following our review of the comments, we are not making changes to other sections included in the proposed rule and are finalizing those sections without change. In addition, we received no comments on the proposed change to add language to § 16.1(b)(2) (21 CFR 16.1(b)(2)) regarding rescission (as included in the proposed rule), and we are finalizing § 16.1(b)(2) without change.

B. Description of General Comments and FDA Responses

(Comment 1) Some comments object to the proposed rule, stating that the rule violates the statute because the rule would not create a viable pathway to market products that qualify for the SE pathway that is more streamlined than the PMTA pathway. For example, one comment objects to the proposed rule and states that FDA has ''exceeded Congressional intent by over-complicating the [premarket] pathways, ignoring the first prong of the SE standard and making the second prong nearly as burdensome as the PMTA pathway.'' Another comment states that regardless of whether an SE Report cites the first or second prong for determining substantial equivalence, ''the SE pathway is intended to be significantly less burdensome than the PMTA pathway,'' and the SE pathway should ''require the least information and be the simplest to implement while the PMTA pathway, with its focus on the 'protection of public health' would require the more extensive information and data.'' Other comments also object to the rule and state the SE pathway should be much more like a ''notification'' process than the PMTA pathway.

(Response 1) We disagree with these comments. We have received thousands of premarket applications, including SE Reports, and we developed this rule based on our experience with those SE Reports and the framework for substantial equivalence under sections 905(j) and 910 of the FD&C Act. The statutory requirements related to substantial equivalence differ from the statutory framework and requirements for a PMTA, and each pathway has different standards for authorization. The rule will provide applicants with additional clarity and understanding of the information needed in an SE Report for FDA to make a determination under the statutory requirements related to substantial equivalence (sections 905(j) and 910(a) of the FD&C Act). Notably, under the SE pathway, the applicant must receive an order prior to marketing the new tobacco product (unless it has received authorization through a different premarket pathway or it is a provisional tobacco product); the FD&C Act does not authorize a ''notification process'' as an alternative to receiving an SE order. As appropriate, however, we have developed mechanisms to lessen the burden for submitting data that are more streamlined by allowing for certifications when the data between the new and predicate tobacco products are identical (see, *e.g.,* § 1107.18(*l*)).

(Comment 2) Some comments suggest FDA adopt an approach similar to the substantial equivalence process FDA applies to devices under sections 510(k) and 513(i) of the FD&C Act (21 U.S.C. 360(k) and 360c(i)), for example, by permitting a notification process. Other comments reference guidance documents related to the 510(k) process for devices as examples of how to

implement the SE pathway for tobacco products.

(Response 2) We disagree with these comments. FDA's interpretation of SE with respect to medical devices is based on different statutory sections from those applicable to tobacco products and, due to the differences in the statutory provisions underlying the 510(k) premarket pathway, it has limited utility as a model in considering SE for tobacco products. As described in the preceding response and also in section IV below, sections 905(j) and 910(a) of the FD&C Act set out the substantial equivalence provisions that are specifically applicable to tobacco products, and reflect the differences in these regulated products. For example, the medical device provisions involve considerations related to the safety and effectiveness of medical devices. In comparison, the statutory provisions relating to SE for tobacco products focus on the characteristics of the new tobacco product, and where there are differences, whether such differences cause the new tobacco product to raise different questions of public health.

(Comment 3) Some comments object that the proposed rule would require behavioral information in an SE Report that the FD&C Act requires only for a new product subject to a PMTA. One comment notes that because the ''SE process is an exception to PMTA requirements, designed to determine whether the product should have to undergo the full PMTA process, [r]equiring manufacturers to submit PMTA-level evidence . . . is illogical.''

(Response 3) We disagree with the suggestion that behavioral information, such as initiation and cessation information, can never be relevant in the evaluation of an SE report. Congress broadly delegated to FDA the authority to specify what should be included in an SE Report and imposed no constraints of the type the comments suggest. (See section 905 (j)(1) of the FD&C Act (''report to the Secretary [of Health and Human Services] (in such form and manner as the Secretary shall prescribe)'')). As many comments point out, where the new tobacco product has different characteristics than the predicate tobacco product, the information submitted in the SE application must ''contain information, including clinical data if deemed necessary by [FDA], that demonstrates . . . [that] the product does not raise different questions of public health.'' (Section 910(a)(3)(A)(ii) of the FD&C Act.) Congress included findings in the Tobacco Control Act that make clear that one of the public health purposes of the legislation was to reduce dependence on tobacco. For example, Congress stated that the Tobacco Control Act's ''purposes'' include ensuring that FDA has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco and promoting cessation to reduce disease risk and the social-costs associated with tobacco-related diseases. (see Tobacco Control Act sections 3(2) and (9)). In addition, Congress defined substantial equivalence to mean that the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health. (See FD&C Act 910(a)(3)(A)(ii).) The reference to ''this section'' is a reference to the PMTA pathway. Because one of the bases for FDA finding that a product is appropriate for the protection of public health (*i.e.,* the PMTA ''standard'') includes the increased or decreased likelihood that existing users will stop using and new users will initiate use of such products, it is reasonable to examine those same considerations under the SE standard to determine whether the differences between the predicate and the new product show that the product should be reviewed under the PMTA pathway.

As a result, in determining whether a new tobacco product raises different questions of public health, FDA considers potential impacts on initiation and cessation of tobacco use. If the SE Report lacks this information, then we may be unable to determine that the product is substantially equivalent.

(Comment 4) A number of comments assert that the proposed regulation does not provide enough specificity to adequately guide industry. For example, one comment states that the proposed rule lacked clarity regarding the scope, type, and amount of testing and other information needed in SE Reports for smokeless tobacco products and the comment requests that FDA include more specific requirements regarding the content of SE Reports for smokeless tobacco products. Other comments suggest the rule requires too much information or the wrong information.

(Response 4) We disagree with these comments. The rule provides content and format information that will be applicable across a range of categories and subcategories of tobacco products, including smokeless tobacco products (see, *e.g.,* § 1107.19). In addition, after reviewing the comments received in response to our invitation to comment on design parameters for cigars, Electronic Nicotine Delivery Systems (ENDS), and other tobacco products, the final rule now includes design parameter information for these products. Based on our experience, we believe that the requirements in this rule are necessary for FDA to determine whether a product is substantially equivalent.

(Comment 5) One comment suggests that FDA should apply the rule to currently pending SE Reports.

(Response 5) As the proposed rule explained, the requirements included in the rule apply only after the effective date of this rule. Accordingly, the requirements do not apply to an SE Report for a provisional tobacco product or to any SE Report submitted before the effective date of this rule. This does not prevent applicants with pending SE Reports or those preparing SE Reports from referring to this rule for guidance on how to submit amendments to pending SE reports or prepare their SE Report prior to the effective date of this rule. Please note that we will continue to evaluate currently pending SE Reports and those submitted prior to the effective date as we have evaluated those thousands of SE Reports in the years since the Tobacco Control Act was enacted. Importantly, our previous SE evaluation experience helped aid in the development of this final rule. In practical effect, this means that an applicant submitting an SE report before this rule goes into effect has an opportunity to benefit from its contents but FDA will not refuse to accept an application for lacking information first required in this rule (*i.e.,* information not already required by regulation or statute). For example, for an application received before this rule is in effect, FDA would not retroactively refuse to accept an application that lacks information required for acceptance under this rule that was not already required by regulation or statute. Likewise, if an application submitted before the effective date of this rule lacks information necessary to enable FDA to determine whether or not the product meets the statutory standard as articulated in this rule (*e.g.,* lack of data to show that the new product is SE), FDA would not rely on this rule to deny the application—instead FDA generally intends to evaluate SE reports and communicate with applicants consistent with its review process to date.

(Comment 6) At least one comment suggests that FDA revise or withdraw SE-related guidance documents when the Agency issues the final SE regulation to reduce confusion and because the guidance documents would

no longer be warranted. Other comments suggest that FDA issue new guidance, including guidance documents with decision trees (*e.g.,* similar to 510(k) process for devices).

(Response 6) FDA agrees that revision or withdrawal of guidance documents is appropriate if the recommendations are no longer relevant or could be confusing. Following issuance of this final rule, we intend to review SE-related guidance documents to determine whether to revise or withdraw any guidance documents. More specifically, we intend to consider whether the recommendations or information included in those guidance documents are outdated due to this final rule, and we will update or withdraw those guidance documents as appropriate. Similarly, we will consider whether new guidance documents should be developed or whether updates should be made to existing guidance documents. FDA will make any changes or withdrawals or issue new guidance documents promptly pursuant to the procedures in 21 CFR 10.115.

C. Comments on Subpart B—General and FDA Responses

1. Scope (§ 1107.10)

This part establishes the procedures and provides information for the submission of an SE Report under sections 905 and 910 of the FD&C Act, the basic criteria for establishing substantial equivalence, and the general procedures FDA intends to follow when evaluating SE Reports. We are finalizing § 1107.10 (Scope) with one change from the proposed rule to reflect that this part applies to new tobacco products ''other than 'premium' cigars as defined in § 1107.12.'' In the following paragraphs, we discuss the comments related to this section, including comments on the scope of products covered.

(Comment 7) Several comments on the proposed rule discuss ''premium'' cigars. These comments included requests that FDA exempt ''premium'' cigars from premarket requirements, create a different premarket pathway for ''premium'' cigars, or delay the effective date for submitting premarket applications for ''premium'' cigars. Other comments flag concerns with specific requirements included in the proposed rule, such as concerns related to co-packaging requirements (the comments state that ''premium'' cigar packaging does not have the potential to alter or affect the performance, composition, constituent, or other physical characteristics of the product); concerns related to the applicability of ''product quantity'' change for ''premium'' cigars as these are sold individually; and concerns related to the ''significant natural and inherent variability'' in handmade ''premium'' cigar products (the comments state these products cannot be manufactured by hand consistently enough to permit manufacturers to ''fully characterize'' them in any meaningful way to permit a traditional SE comparison). Other comments raise issues related to the applicability of proposed requirements in § 1107.19 to ''premium'' cigars, such as the proposed requirement that information on ''[t]he type of tobacco, including grade and variety'' be submitted in an SE Report, that harmful and potentially harmful constituents (HPHC) data be submitted, given the variety of cigars and lack of smoke testing methodologies for ''premium'' cigars, costs of HPHC testing, and insufficient lab capacity, or that stability information be provided given the characteristics of the product. Many of these comments describe differences between ''premium'' cigars and other cigars, *e.g.,* mechanized versus handmade processes, and state that these differences make it more difficult for ''premium'' cigars to comply with SE requirements.

(Response 7) FDA received a range of comments related to ''premium'' cigars.[2] A recent court decision, *Cigar Ass'n of Am., et al.* v. *Food and Drug Admin., et al.,* ''remand[ed] the [deeming final rule] to the FDA to consider developing a streamlined substantial equivalence process for premium cigars'' and ''enjoin[ed] the FDA from enforcing the premarket review requirements against premium cigars . . . until the agency has completed its review.'' [3] Under the terms of the court's order, a ''premium'' cigar is defined as a cigar that meets all of the following eight criteria:

1. Is wrapped in whole tobacco leaf;
2. contains a 100 percent leaf tobacco binder;
3. contains at least 50 percent (of the filler by weight) long filler tobacco (*i.e.,* whole tobacco leaves that run the length of the cigar);
4. is handmade or hand rolled; [4]
5. has no filter, nontobacco tip, or nontobacco mouthpiece;
6. does not have a characterizing flavor other than tobacco;
7. contains only tobacco, water, and vegetable gum with no other ingredients or additives; and
8. weighs more than 6 pounds per 1,000 units.

As directed by the court in the *Cigar Ass'n of Am.* decision, FDA is further considering the comments submitted to the deeming rule docket that requested FDA create a streamlined SE process for ''premium'' cigars. Additionally, FDA notes that a Committee of the National Academies of Science, Engineering, and Medicine is conducting a study on such products. FDA intends to review the findings of that Committee as well as any additional research specific to ''premium'' cigars (as defined in the preceding paragraph) and their health effects, patterns of use (such as frequency of use and usage patterns among underage persons), and other factors. All such information will inform the Agency's regulatory policy with respect to premarket review of ''premium'' cigars.

Because these are ongoing efforts, at this time, FDA is not finalizing the proposed SE rule with respect to ''premium'' cigars. Rather, FDA will take appropriate action once it has further considered the comments submitted to the deeming rule docket that suggested FDA create a streamlined SE process for ''premium'' cigars, as well as the results from additional research. As such, the codified language has been revised to exclude ''premium'' cigars from the scope of this final rule, and the *Cigar Ass'n of Am.* court's definition of ''premium'' cigars has been added to § 1107.12.

(Comment 8) One comment suggests that FDA add a definition for pipe tobacco and create a different SE premarket pathway for pipe tobacco, for example, more aligned with the 510(k) process for medical devices.

(Response 8) We interpret this comment to be a request that FDA consider streamlined options within the three premarket pathways available to pipe tobacco seeking authorization: PMTA, SE, and exemption from SE, as provided in sections 905 and 910 of the FD&C Act. Generally speaking, within the construct of the SE premarket pathway, there are options for more

[2] Cigars are subject to Chapter IX of the FD&C Act as a result of regulations enacted by FDA (Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 FR 28974, May 10, 2016 (''deeming final rule'')). The deeming final rule extended FDA's regulatory authority to all tobacco products (excluding accessories of such products). These products include all cigars, pipe tobacco, waterpipe tobacco, electronic nicotine delivery systems (ENDS), and other novel tobacco products.

[3] *Cigar Ass'n of Am., et al.* v. *Food and Drug Admin., et al.,* Case No. 1:16–cv–01460 (APM), (D.D.C. Aug. 19, 2020), Dkt. No. 214 (*Cigar Ass'n of Am.*).

[4] A product is ''handmade or hand rolled'' if no machinery was used apart from simple tools, such as a scissors to cut the tobacco prior to rolling.

streamlined submissions, that will still provide the agency with the information we need to determine whether the new tobacco product is SE, which this final rule reflects. For example, where appropriate, certain requirements (*e.g.,* design parameters) are tailored by type of product. In addition, the rule generally provides options to certify that certain characteristics are identical in lieu of providing data for each characteristic of the new and predicate tobacco product (§ 1107.18(*l*)). This option may be helpful to applicants as a means of minimizing the content to be submitted, when appropriate. Finally, because we are still considering how best to define ''pipe'' tobacco, we are not including a definition of the term, but intend to undertake further actions to define the term, if needed, at a future time. However, we do not think a formal definition of ''pipe'' tobacco is needed to continue regulating the product or to conduct an SE review.

(Comment 9) Some comments request that FDA clarify which changes may proceed through the SE exemption pathway and those which may not. The comment requests that FDA define the term ''minor modification'' to help manufacturers understand which changes would qualify for the SE exemption pathway. For example, the comments request that changes to maintain product consistency or changes made by suppliers to components be considered as changes eligible for the SE exemption pathway.

(Response 9) Requests for information on which changes would qualify under the SE exemption pathway or for further information on the term ''minor modification,'' relate to 21 CFR 1107.1 (see *https://www.federalregister.gov/documents/2011/07/05/2011-16766/tobacco-products-exemptions-from-substantial-equivalence-requirements*). Please note that additional information related to exemption requests may be found at *https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/exemption-substantial-equivalence*; FDA also maintains information on exemption requests that FDA has granted at: *https://www.fda.gov/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se*.

2. Definitions (§ 1107.12)

Proposed § 1107.12 listed terms and definitions used in the proposed rule. In this final rule, we have added a definition of ''premium'' cigars, as well as updated several definitions on our own initiative to clarify the meaning or to reflect current premarket review processes or to help the definitions apply across product categories.

As discussed in section V.C.1 of this final rule, we are adding the *Cigar Ass'n of Am.* court's definition of ''premium'' cigars to § 1107.12. That definition is:

- ''*Premium*'' cigars means a type of cigar that: (1) Is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains at least 50 percent (of the filler by weight) long filler tobacco (*i.e.,* whole tobacco leaves that run the length of the cigar); (4) is handmade or hand rolled (*i.e.,* no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); (5) has no filter, nontobacco tip, or nontobacco mouthpiece; (6) does not have a characterizing flavor other than tobacco; (7) contains only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weighs more than 6 pounds per 1,000 units.

The updates to § 1107.12 are to the following terms:

- *Brand* to add an ''s'' following ''brand name'' in the definition;
- *Constituent* to add ''(*e.g.,* smoke, aerosol, droplets),'' to delete ''or any chemical or chemical compound in mainstream or sidestream tobacco smoke,'' to add ''or part'' following component, and to replace ''smoke'' with ''emission'';
- *Finished tobacco product* to move ''separately'' to follow ''consumers'' and to add ''or in the final form in which it is intended to be sold to consumers'' to better clarify what is meant by finished;
- *Harmful and potentially harmful constituent* to add the phrase ''including as an aerosol or any other emission'' in paragraph (1);
- *Heating source* to change ''a'' to ''the'';
- *Other features* to delete ''and are necessary for review''; and
- *Submission tracking number* to add ''voluntary'' and to more closely track the statutory language by substituting ''that a tobacco product was commercially marketed in the United States as of February 15, 2007'' for ''grandfathered.''

We also received comments on several definitions included in the proposed rule, and we describe and respond to those comments in the following paragraphs. Following consideration of these comments, we have added a definition of ''commercially marketed.'' In addition, we have made changes to the definition of commercial distribution and predicate tobacco product, as well as removing the definition ''grandfathered tobacco product,'' as discussed in the following paragraphs related to those terms. Please note that if there were no comments on a definition included in the proposed rule, there is no discussion related to that definition. We are finalizing all other definitions without change from the proposed rule.

- Accessory

(Comment 10) One comment supports the definition of accessory, noting that it reflects the definition included in the deeming final rule.

(Response 10) We agree and note the final rule includes this definition without change from the proposed rule.

- Commercial Distribution

We proposed to define commercial distribution as: To mean any distribution of a tobacco product to consumers or to another person through sale or otherwise, but does not include interplant transfers of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for consumption or resale. ''Commercial distribution'' does not include the handing or transfer of a tobacco product from one consumer to another for personal consumption. For foreign establishments, the term ''commercial distribution'' has the same meaning, except that it does not include distribution of a tobacco product that is neither imported nor offered for import into the United States.

In the following paragraphs, we discuss comments we received on the proposed definition of commercial distribution. After considering the comments related to this proposed definition, we have made several changes to this definition that are included in the final rule. Specifically, we are: (1) Adding ''whether domestic or imported'' to clarify the distribution, (2) changing ''another,'' to ''any,'' (3) deleting ''through sale or otherwise'' as unnecessary; (4) deleting ''registered'' as a modifier to ''establishment,'' (5) adding ''personal'' as a modifier to ''consumption,'' and (6) striking some of the language related to what commercial distribution does not include as other changes to the definition now clarify this point.

(Comment 11) One comment states that the definition of commercial distribution included in the proposed rule is overly broad and unworkable. This comment notes that including the phrase ''any distribution of a tobacco product to consumers *or to another person* through sale or *otherwise*'' (emphasis in comment) renders the definition open-ended and potentially

includes any movement of a finished product that does not fit within one of the enumerated exclusions, even if the product is not available for consumption or resale. The comment notes that if FDA is concerned with distribution of tobacco products that may be used for sampling purposes, then FDA should tailor the definition to specify sampling (or to an activity that either is a sale or promotes the sale of a product).

(Response 11) FDA agrees that the definition of commercial distribution included in the proposed rule required additional refinement. We have thus removed ''through sale or otherwise'' from the definition to clarify that commercial distribution is not limited to the sale of tobacco products to the consumer. However, ''any person'' is necessary to capture movement such as that between a manufacturer, importer, and distributor. As described in the preceding paragraph, however, FDA has made minor revisions to the definition for clarification to help in understanding the scope of this term.

(Comment 12) At least one comment objects to the use of ''registered'' establishments in the definition of commercial distribution, stating that FDA should not require that interplant transfers be between registered establishments to be excluded from the scope of commercial distribution. This comment also notes that because only domestic establishments are currently required to register, interplant transfers with a company's foreign manufacturing facilities (that are not registered) would be considered commercial distribution under the proposed definition.

(Response 12) We agree that ''registered'' should be deleted, and we have updated the definition in this final rule to reflect this deletion. Furthermore, as we previously noted in the proposed rule, the term commercial distribution excludes the providing of a tobacco product for product testing where such products are not made available for personal consumption or resale. Additionally, FDA does not intend this term to include the handing or transfer of a tobacco product from one consumer to another for personal consumption (consumer to consumer transfers).

(Comment 13) One comment requests that FDA use the same definition for commercial distribution and commercial marketing and proposes that the definition be revised to recognize that commercial marketing and commercial distribution may occur from the time of sale from a foreign manufacturer to a U.S. distributor. The comment suggests that this approach would better reflect that many pipe tobaccos are sold as private label items to a specific retailer with a limited geographical footprint.

(Response 13) We decline to make a change to combine these definitions because, although the terms have some overlap, they are also distinct, as reflected in the statute. Thus, it would not be appropriate to combine the terms. As we discuss in the paragraphs related to the definition of ''new tobacco product,'' following our review of comments, we have decided to include a definition of commercially marketed in this final rule. In response to the comment related to pipe tobacco sales, we note that with respect to the sale from a foreign manufacturer to a U.S. distributor, the final rule's definitions of commercially marketed and commercial distribution include a sale from a foreign manufacturer to a U.S. distributor and sale of tobacco products to a specific retailer with a limited geographical footprint. Applicants or others who have questions as to whether a specific activity falls within these terms should contact FDA.

- Component or Part

We proposed to define component or part as ''any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.'' In the following paragraphs, we summarize the comments we received on this proposed definition of component and part, which we are finalizing without change. We also received comments on the inclusion of ''container closure system'' as a subset of component or part, and we address those comments in the paragraphs related to the definition of container closure system.

(Comment 14) Some comments express concern about the definition of component and part noting, for example, that using the terms interchangeably can be confusing and that FDA should either define each separately or settle on one term and use that term. Another comment supports the definition of component and part noting that the term and definition are consistent with language in the deeming final rule.

(Response 14) We agree that it is appropriate in this context to remain consistent in defining terms across tobacco product regulations. Thus, this final rule maintains the definition that was included in the proposed rule and which reflects the definition included in the deeming final rule (see, *e.g.,* 21 CFR 1100.3). We disagree with comments suggesting the definition is too broad or that we should break ''component or part'' into two definitions at this time. Although we appreciate the concern about confusion, the rule makes clear that both component and part share the same definition, and applicants can apply the terms accordingly. Should FDA determine at some future point that a distinction between the terms is necessary, we would undertake notice and comment rulemaking on the issue before we would apply any changes.

(Comment 15) One comment requests that FDA exercise enforcement discretion for the submission of SE Reports for smoking pipes. The comment acknowledges that the deeming final rule states that smoking pipes are components and parts of tobacco products (81 FR 28974 at 29042) but notes that FDA has exercised enforcement discretion for the submission of ingredient reports for smoking pipes and suggests FDA do the same for SE requirements.

(Response 15) As the comment states, FDA has established compliance policies related to other FD&C Act requirements for smoking pipes. We decline to extend or establish such a premarket compliance policy for smoking pipes because pipes can impact the risk profile of the tobacco product with which the pipe is used, *e.g.,* by increasing HPHC exposure. We note that the rule includes options to certify that certain characteristics are identical in lieu of providing data for each characteristic of the new and predicate tobacco product (§ 1107.18(*l*)). This option may be helpful to applicants as a means of minimizing the content to be submitted, when appropriate. We also encourage potential applicants to reach out to FDA to discuss questions related to preparing an SE Report.

- Container Closure System (CCS)

We proposed to define ''container closure system'' as ''any packaging materials that are a component or part of a tobacco product.'' As described in the following paragraphs, we received several comments related to the definition of container closure system included in the proposed rule, as well as comments on the discussion of co-packaging that was included in the proposed rule. After considering the comments, we are finalizing this definition without change from the proposed rule.

(Comment 16) Some comments object to the definition of container closure

system as ''any packaging materials that are a component or part of a tobacco product,'' stating it is inconsistent with the FD&C Act (as amended by the Tobacco Control Act) and ''an impermissible back door effort'' to subject packaging changes to SE review. One comment adds that the definition transforms packaging into a ''component or part'' of a tobacco product contrary to a D.C. District Court decision (*Philip Morris USA Inc.* v. *FDA,* 202 F. Supp 3d 31 (D.D.C. 2016)) (*Philip Morris* decision). These comments also state that although the FD&C Act provides FDA with authority to regulate packaging under sections 903(a) and 905(i) of the FD&C Act, that authority does not provide FDA with the ability to include packaging under the definition of component or part and thereby subject packaging to premarket review.

(Response 16) FDA is not requiring that an applicant include information on all aspects of the packaging, but the requirements of the final rule do require information on the CCS as a component or part of the tobacco product. As explained in the proposed rule, a container closure system is a component or part of a tobacco product because of its potential to alter or affect the performance, composition, constituents, or other physical characteristics of the product. We are including this requirement in the final rule because, as discussed in the proposed rule, treating this distinct subset of packaging as a component or part furthers the fundamental purpose of the Tobacco Control Act to protect the public health. Some examples include CCS where substances in the CCS are intended or reasonably expected to affect product moisture, or when menthol is applied to inner foil to become incorporated into the consumed product (Ref. 1). FDA can require the applicant to demonstrate that the change in the container closure system does not cause the new tobacco product to raise different questions of public health where such information is needed to demonstrate substantial equivalence.

(Comment 17) Other comments assert that the definition of container closure system and the preamble discussion in the proposed rule improperly provide that a container closure system ''is'' considered a component or part ''categorically, without regard to whether the container closure system somehow changes the tobacco product in any way.'' The comments contend this approach is also contrary to the *Philip Morris* decision and that the plain meaning of component and part ''pertains to something that is or can be expected to become incorporated into the tobacco product itself, meaning a piece or portion of a larger whole tobacco product.'' The comments state that container closure systems are not components or parts because the package is external to the tobacco product. The comments disagree with the examples that FDA included in the preamble to the proposed rule, such as the soft pack for cigarettes, stating these are examples of packaging that are outside the scope of components and parts.

(Response 17) As described in detail in the proposed rule, FDA defines ''component or part'' as any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Packaging that constitutes the container closure system is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product (*e.g.,* leaching substances that are then incorporated into a tobacco product), and is thus a component or part of a tobacco product. Where a change in the container closure system could affect the chemistry of the product, FDA could require the applicant to demonstrate that the change in the container closure system does not cause the new tobacco product to raise different questions of public health.

Packaging that is not the container closure system is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product and is therefore not a component or part of a tobacco product. As such, packaging that is, for example, the box around a blister pack, is not a CCS if it is not intended or reasonably expected to alter or affect the performance, composition, constituents, or characteristics of the tobacco product within the blister pack.

For example, packaging materials constitute a container closure system if substances within that packaging are intended or reasonably expected to affect product moisture, *e.g.,* when the manufacturer changes the package of a moist snuff from plastic to fiberboard, which can affect microbial stability and tobacco-specific nitrosamine (TSNA) formation during storage. Another example of this is when menthol or other ingredients are applied to the inner foil to become incorporated into the consumed product (Ref. 1). Packaging materials may also be intended or reasonably expected to affect the characteristics of a tobacco product by impacting the rate of leaching into, and ultimately, the amount of substances found in, the consumable tobacco product. In fact, it has been demonstrated that compounds in packaging materials may also diffuse into snuff and affect its characteristics (Ref. 2). Thus, for example, packaging material that affects the characteristics of a tobacco product by impacting the moisture level or shelf life of a tobacco product is a container closure system (*e.g.,* a plastic versus a metal container of smokeless tobacco). A difference in tobacco moisture is reasonably expected to affect microbial growth in the product, extraction efficiency, and total exposure to nicotine or the carcinogens N-nitrosonornicotine (NNN) or 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) (Ref. 3).

Considering a distinct subset of packaging (*i.e.,* container closure system) to be a component or part is consistent with the FD&C Act and furthers the fundamental purpose of the Tobacco Control Act to protect the public health. For example, section 900(1) of the FD&C Act (21 U.S.C. 387(1)) defines an ''additive'' as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substance intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical. Congress specifically included a broad definition of additive that encompasses not just substances that do in fact have such effects but also may reasonably be expected to. Similarly, if FDA were to adopt a narrow construction of ''tobacco product'' to exclude these materials, the Agency's ability to evaluate whether the differences between the new and predicate tobacco product cause the new tobacco product to raise different questions of public health would be impeded, thereby leaving the Agency unable to fully execute its mission to protect the public health. The definition of ''package'' in section 900(13) of the FD&C Act does not dictate a contrary result, and can be reasonably interpreted to mean that a distinct subset of packaging is also a component or part of a tobacco product.

Contrary to one of the comments, the court's decision in *Philip Morris* does

not necessitate a different interpretation than the one FDA has adopted and described above. First, the court was presented with a challenge relating to FDA's regulation of product labels and changes in product quantities. It was not asked to decide on—and the Agency did not brief—the validity of FDA's interpretation of container closure system. Second, FDA is not seeking to incorporate into the SE evaluation any packaging that is not intended nor reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the product itself. As noted above, for example, the packaging around a blister pack is not part of the SE review process if it is not intended or reasonably expected to alter or affect the performance, composition, constituents, or characteristics of the tobacco product within the blister pack. The court's opinion in *Philip Morris* emphasizes the importance of looking to whether the ''physical attributes of the product itself'' have changed in determining whether a tobacco product is new. *Philip Morris,* 202 F. Supp. 3d at 51. By limiting our review to changes to the CCS, we are only looking at packaging that is intended or reasonably expected to affect or alter the performance composition, constituents, or characteristics of the tobacco product—in other words, we are looking at changes that could affect the ''physical attributes'' of the product. Such an interpretation is consistent with the *Philip Morris* decision, and, as explained above, consistent with the Tobacco Control Act's purpose and treatment of other definitions within the FD&C Act.

(Comment 18) One comment states that a container closure system should only qualify as a component or part of the product when it is designed or reasonably expected to change the characteristics of the tobacco product, and not when it is designed to maintain or preserve the characteristics of the product. Other comments state that FDA should not require an SE Report for a change to a CCS because a product's packaging does not impact its characteristics.

(Response 18) If aspects of packaging of a tobacco product are intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product, we consider that packaging to be a CCS that is a component or part of the product. A change to the CCS would require a premarket submission. Packaging that is intended or reasonably expected to maintain or preserve the characteristics of the product could be reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the product. For example, as described in the preceding response, packaging material that affects the characteristics of a tobacco product, including cigars, by impacting the moisture level or shelf life of a tobacco product is a container closure system (*e.g.,* a plastic versus a metal container of smokeless tobacco) (Refs. 1–3).

(Comment 19) Some comments object to the discussion in the proposed rule that stated that ''co-packaging two or more tobacco products within the same container closure system results in a new tobacco product.'' The comments assert that this ''new category of packaging'' created by the proposed rule has no basis in the FD&C Act and that it is improper to regulate co-packaged tobacco products as part of SE review. Accordingly, the comments request FDA to exclude co-packaged tobacco products from the scope of new tobacco products. The comment argues that as long as each separate product is legally marketed, co-packaging of the products does not create a new tobacco product requiring SE review. Other comments state that changes to the container closure system of co-packaged products should only result in a new product when they intend or reasonably expect to change the physical characteristics of the product.

(Response 19) We agree that changing the packaging of co-packaged tobacco products only results in a new tobacco product where such packaging is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product. Under section 910(a)(1)(B) of the FD&C Act, new tobacco products include those that are new because they have been rendered new through any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. Therefore, if two or more products are proposed to be co-packaged together within a single container closure system, that results in a new tobacco product requiring premarket authorization. However, as explained in the proposed rule, co-packaging two or more legally marketed tobacco products, where there are no changes, including no change to the container closure system(s), does not result in a new tobacco product.

• ''Grandfathered'' Tobacco Product

We proposed to include a definition of ''grandfathered tobacco product'' as ''a tobacco product that was commercially marketed in the United States as of February 15, 2007, and does not include a tobacco product exclusively in test markets as of that date.'' Such a product would not be subject to the premarket requirements of section 910 of the FD&C Act. We received several comments on this definition, as well as related comments on the definition of new tobacco product, and we respond to those comments in the following paragraphs and in the paragraphs related to ''new tobacco product.'' We are removing this definition because the term is no longer used in the codified text. In this preamble, we have changed the term from ''grandfathered tobacco product'' to ''Pre-Existing tobacco product'' because it more appropriately describes these products, by using the more precise ''Pre-Existing'' in place of ''grandfathered.'' FDA received several comments regarding the definition of ''Pre-Existing tobacco product,'' [5] which are discussed as follows.

(Comment 20) Several comments suggest that we consider alternative dates to February 15, 2007, as the date after which premarket review would be required for deemed tobacco products, such as the effective date of the deeming final rule (*i.e.,* August 8, 2016).

(Response 20) As indicated in the deeming final rule, FDA lacks the authority to change the February 15, 2007, date for any tobacco products, including deemed tobacco products.[6] This date is explicitly prescribed in the statute. Section 910(a)(1)(A) of the FD&C Act states, in pertinent part, that the term ''new tobacco product'' means, in part, any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007. For purposes of the SE pathway, the statute also clearly states that a predicate product must be commercially marketed (other than for test marketing) in the United States on February 15, 2007, in both section 910(a)(2)(A) and section 905(j)(1) of the FD&C Act.

[5] While comments were submitted regarding the term ''grandfathered tobacco product,'' we describe them using the new term, ''Pre-Existing tobacco product,'' throughout this document for the sake of clarity.

[6] Note that for the purposes of this final rule, ''deemed tobacco products'' are those tobacco products subject to the deeming final rule.

• Harmful and Potentially Harmful Constituent (HPHC)

We proposed to define ''harmful and potentially harmful constituent'' as any chemical or chemical compound in a tobacco product or tobacco smoke or emission that: (1) Is or potentially is inhaled, ingested, or absorbed into the body and (2) causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products. We received comment on this definition, which we respond to in the following paragraphs. We are finalizing this definition to clarify that HPHCs include chemicals or chemical compounds that are potentially inhaled, ingested, or absorbed into the body ''as an aerosol or any other emission'' as described in the preamble to the proposed rule.

(Comment 21) At least one comment supports the proposed definition, noting it is consistent with the criteria applied in formulating the HPHC list and includes both substances that are or potentially could be inhaled, ingested, or absorbed into the body (77 FR 20034, April 3, 2012).

(Response 21) We agree with the comment and note the definition is included in the final rule, with the change as noted, which we made to ensure consistency with other regulatory documents.

• Ingredient

We proposed to define ''ingredient'' as tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing. We received a comment on this definition, which we respond to in the following paragraph. We are finalizing this definition without change.

(Comment 22) One comment disagrees with the proposed definition of ''ingredient,'' stating that ''compounds reasonably expected to be formed through a chemical reaction during manufacturing are not properly identified as ingredients'' and that the proposed definition ''is imprecise'' and will ''inevitably be subject to varying interpretations.''

(Response 22) We disagree that this definition should not include ''compounds reasonably expected to be formed through a chemical reaction'' as information on these ingredients is needed to aid FDA in making an SE determination. However, we note that the phrase ''compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing'' should be interpreted as compounds formed through well-known chemical reactions, for example, reactions of sugars which could lead to the formation of related alcohols, ketones, aldehydes, and esters (Refs. 4 and 5) and reactions of nicotine which could lead to the formation of related N-nitrosamines (Ref. 6).

• New Tobacco Product

In the proposed rule, we included the statutory definition of ''new tobacco product,'' which is defined as: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. (See section 910(a)(1) of the FD&C Act.) The final rule continues to include this statutory definition. In the following paragraphs, we respond to comments related to the definition of ''new tobacco product'' generally.

In addition, FDA received many comments related to our invitation to comment on the terms ''test marketing'' and ''commercially marketed,'' which are terms included in the statutory definition of new tobacco product. In subsequent paragraphs, we describe and respond to these comments on test marketing and commercially marketed. Following our consideration of these comments, we are adding a definition of ''commercially marketed,'' to the final rule, which states ''commercially marketed means selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States.'' We also describe this definition below.

(Comment 23) One comment requests that FDA clarify that, under the definition of new tobacco product, a modification to an existing product's label does not require an SE Report. This comment cites the *Philip Morris* decision.

(Response 23) A modification to an existing product's label standing alone does not require an SE Report.

(Comment 24) Some comments address FDA's interpretation that a tobacco product exclusively test marketed as of February 15, 2007, is considered a new tobacco product under section 910 of the FD&C Act. Other comments indicate FDA's interpretation is correct, and one of these comments also notes that a tobacco product that was test marketed as of February 15, 2007, cannot serve as a predicate tobacco product under section 905(j) of the FD&C Act.

(Response 24) Following our consideration of these comments, we agree with the comment indicating that a tobacco product test marketed in the United States as of February 15, 2007, is not a new tobacco product. Section 910(a)(1)(A) defines a ''new tobacco product'' to include ''any tobacco product (including those in test markets) that was not commercially marketed in the United States as of February 15, 2007.'' The parenthetical ''including those in test markets'' in section 910(a)(1)(A) of the FD&C Act modifies the phrase directly before it—''any tobacco product''—and is intended to clarify that tobacco products commercially marketed in test markets in the United States as of February 15, 2007, should be treated the same way as any other tobacco product that was commercially marketed as of February 15, 2007, *i.e.,* they are not ''new tobacco products.'' We also agree with the comment that states that under section 905(j) of the FD&C Act, a tobacco product that was solely in a test market as of February 15, 2007, despite being a Pre-Existing tobacco product, cannot serve as a predicate tobacco product, which is consistent with the position taken in the proposed rule. Section 905(j)(1)(A)(i) describes products that can serve as valid predicate tobacco products: A tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that the Secretary by delegation to FDA has previously determined, pursuant to subsection (a)(3) of section 910, is substantially equivalent. Here, the parenthetical ''other than for test marketing'' explains a product solely sold in test markets as of February 15, 2007, cannot serve as a valid predicate tobacco product. Therefore, a product cannot serve as a predicate if it was exclusively sold in a test market as of February 15, 2007.

(Comment 25) Another comment disagrees with FDA's interpretation that the phrase ''as of'' means ''on'' arguing that ''[i]f Congress has intended that [Pre-Existing tobacco] products must have been commercially marketed on the singular date of February 15, 2007, it would have used the word 'on' in the statute,'' but, instead, ''Congress used the phrase 'as of,' which, in this context, plainly communicates marketing on or before February 15, 2007'' (emphases

omitted). This comment references a dictionary definition of ''as of now'' as meaning up to the present time and also notes that Congress used the term ''on'' in other places in the Tobacco Control Act (*e.g.,* section 904(c)(1) use of ''on June 22, 2009''). The comment argues that ''as of'' should be interpreted as ''on or before.''

(Response 25) As discussed in the proposed rule, FDA's longstanding interpretation is that ''as of'' means that the tobacco product was commercially marketed in the United States ''on February 15, 2007'' (see the final guidance entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' (79 FR 58358, September 29, 2014)). Contrary to the comment, the term ''as of'' does not have a plain meaning. The dictionary definitions of ''as of'' include: ''on; at'' (Webster's II New Riverside University Dictionary, 1988); ''beginning on; on and after'' (Webster's Unabridged Dictionary Random House 1997); ''from, at, or until a given time'' (The American Heritage Dictionary of Idioms 2003); ''on, at, from—used to indicate a time or date at which something begins or ends'' (Merriam Webster's Online Dictionary). As evidenced from these varying definitions, the term is ambiguous. ''[A]s of'' could be interpreted either as ''at any time prior to and not necessarily including on the particular date'' (in short referred to as the ''on or before'' interpretation) or as ''at any time up to and necessarily including on the particular date'' (in short referred to as the ''on'' interpretation). Interpreting ''as of'' to mean ''on'' gives a firm line of demarcation that provides clarity. Additionally, reading ''as of'' to mean ''on or before'' would mean that obsolete, abandoned, or discontinued tobacco products could return to the market without any premarket review and could serve as predicates under the substantial equivalence provision. It is reasonable to conclude that Congress did not intend to allow an immeasurable number of obsolete, abandoned, or discontinued tobacco products that were marketed before February 15, 2007, to return to the market without any premarket review or serve as predicates under the substantial equivalence provision, but rather intended to confine this number to those tobacco products that were commercially marketed in the United States on February 15, 2007. Thus, we decline to change to the interpretation the comment suggests.

• Test Marketing and Commercially Marketed

In the preamble to the proposed rule, we explained that FDA was considering whether to add the following definition of test marketing: ''test marketing'' means distributing or offering for sale (which may be shown by advertisements, etc.) a tobacco product in the United States for the purpose of determining consumer response or other consumer reaction to the tobacco product, with or without the user knowing it is a test product, in which any of the following criteria apply: (1) Offered in a limited number of regions; (2) offered for a limited time; or (3) offered to a chosen set of the population or specific demographic group. In addition, the proposed rule stated we were considering whether to add a definition of commercially marketed, such as ''offering a tobacco product for sale to consumers in all or in parts of the United States.''

After reviewing the comments we received in response to the invitation to comment, we have determined that further discussion of the scope of ''test marketing'' is needed before we issue a definition of this term; however, following our consideration of comments, we have decided to codify a definition of ''commercially marketed.'' The proposed rule stated we were considering whether to add a definition of commercially marketed, such as ''offering a tobacco product for sale to consumers in all or in parts of the United States.'' The final rule now includes a definition of ''commercially marketed'' as selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States. This addition clarifies that tobacco products that are not sold or offered for sale in order to reach consumers within the United States, such as tobacco products sold solely for export fall outside of the definition of commercial marketing.

We describe the comments and our responses on these terms in the following paragraphs.

(Comment 26) Several comments provide suggestions on how to define commercially marketed and test marketed, and some comments request that FDA not define these at all, finding the discussion in the proposed rule confusing. One comment suggests that FDA define ''commercially marketed'' and ''test marketing'' as meaning the same thing. Those comments addressing test marketing indicate that manufacturers may distribute and market tobacco product in limited regions for a set period of time without test marketing the products. Some comments suggest that ''test marketing'' should not be based on time or geographical region, but rather should be based on manufacturer intent. One comment suggests that consumer response is an inherent part of marketing any product, for testing purposes or otherwise.

Comments addressing the term ''commercially marketed'' as discussed in the proposed rule, suggest that if defined, it should be defined as ''offered for sale in the United States to any individual or entity by advertising or by any other manner used to communicate that the tobacco product is available for purchase.'' One comment states FDA has never required firms to demonstrate that a product was offered for sale to consumers, and, in fact, many manufacturers do not market or sell directly to consumers, to establish that their tobacco product is a Pre-Existing tobacco product. Other comments suggest either that a product sold wholly within one state would be commercially marketed or that anything other than a nationwide product launch could constitute test marketing.

(Response 26) Following our consideration of the responses to the proposed rule's invitation to comment on these terms, we agree that further discussion and experience on the term test marking is needed in order to more accurately capture the scope of this term. As we stated previously, we are accordingly not including a definition of test marketing in the final rule. However, after reviewing the comments related to commercially marketed, we have added a definition of this term to the final rule, which reflects the input we received. Specifically, we added a definition stating that ''commercially marketed'' means selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States. Examples of products that may not be covered by the definition of commercially marketed include investigational tobacco products and free samples. Examples of documentation of commercial marketing may include dated bills of lading, dated freight bills, dated waybills, dated invoices, dated purchase orders, dated advertisements, dated catalog pages, dated promotional material, dated trade publications, dated manufacturing documents, inventory lists, or any other document demonstrating that the product was commercially marketed in the United States as of February 15, 2007.

Importantly, as we explain in a preceding response, we also note that although a ''solely'' test marketed product may not be considered ''new'' under section 910 of the FD&C Act, it cannot serve as a predicate product under section 905(j) of the FD&C Act. Test marketed products may include, for example, products that were sold or offered for sale to consumers to determine the commercial viability of a product through the collection of consumer reaction data.

(Comment 27) One comment requests that any definition of a test marketed product include an alternative pathway for the test marketed product to come to the market without having to file an SE Report. This comment proposes a ''less cumbersome process by which products may be test marketed, in order that companies may develop data on shelf-life, HPHC changes, if any, over time, changes in nicotine content, etc.'' This comment proposes allowing the filing of a report advising FDA of a manufacturer's desire to test market a product without the manufacturer having to submit a premarket application.

(Response 27) This comment appears to provide suggestions more closely concerned with research or investigational tobacco products. Such products are outside of the scope of this rulemaking. In general, any tobacco product (including products in test markets) that was not commercially marketed in the United States as of February 15, 2007, is considered a ''new tobacco product'' under section 910(a)(1) of the FD&C Act. As such, manufacturers of test marketed products that were not commercially marketed in the United States as of February 15, 2007, are required to first submit to FDA a PMTA under section 910 for the new tobacco product, and FDA must issue an order authorizing the commercial distribution of the new tobacco product; or submit an SE Report under section 905(j) of the FD&C Act, and FDA must issue an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act); or FDA must find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act, before the product may be introduced into commercial distribution. If any new tobacco product, including a test marketed product, enters into interstate commerce for commercial distribution without an order or a finding of exemption from substantial equivalence, it is adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act and subject to enforcement action.

- Package or Packaging

We proposed to define ''package or packaging'' as a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers. Although there were no comments to the definition included in the proposed rule, there were comments that discussed packaging in the context of CCS. We address those comments in the discussion of the definition of CCS. We are finalizing the definition of package or packaging without change.

- Predicate Tobacco Product

We proposed to define ''predicate tobacco product'' as a tobacco product that is a Pre-existing Tobacco Product or a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the FD&C Act. We received some comments related to this term, which we discuss in the following paragraphs (see also comments to § 1107.18(f) for related discussion). We are finalizing this definition with changes to more closely mirror the statutory language. Thus, the definition in the final rule states that ''predicate tobacco product'' means a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the FD&C Act.

(Comment 28) Some comments request that FDA expand the definition of predicate tobacco product to allow a product for which FDA issues a marketing order under the PMTA pathway to serve as a predicate tobacco product. Other comments suggest that tobacco products authorized through the SE exemption pathway could serve as valid predicates.

(Response 28) The FD&C Act establishes which tobacco products may serve as eligible predicate tobacco products for the SE premarket pathway. These products are limited to tobacco products that were commercially marketed (other than for test marketing) in the United States as of February 15, 2007, and products that were previously found SE by FDA. (See section 905(j)(1)(A) of the FD&C Act.)

- Substantial Equivalence

In the proposed rule, we proposed to include the statutory definition of substantial equivalence, which states:

> Substantially equivalent or substantial equivalence means, with respect to a new tobacco product being compared to a predicate tobacco product, that FDA by order has found that the new tobacco product:
>
> (1) Has the same characteristics as the predicate tobacco product; or
>
> (2) Has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to require premarket review under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health.

(See section 910(a)(3) of the FD&C Act.)

In the proposed rule, we did not propose definitions of ''same characteristics'' and ''different characteristics'' under section 910(a)(3)(A) of the FD&C Act. Rather, the proposed rule explained that FDA is considering whether the ''same characteristics'' prong might be appropriate for new tobacco products that are so similar to the predicate product that FDA would not need scientific information to determine whether the new product raises different questions of public health. The proposed rule included four examples of changes between the new and predicate products that might be appropriate to proceed through the ''same characteristics'' prong, either individually or in combination, and several examples where a new product would have ''different characteristics'' because the new product was dissimilar enough from the predicate that FDA could not determine without scientific information whether the new tobacco product raised different questions of public health. We noted these examples were based on our current thinking, relying on the current state of science and the available evidence. We noted that, if evidence arises in a particular case that requires more information from an applicant, we would communicate to the applicant what information is needed to demonstrate that the new tobacco product is substantially equivalent. The proposed rule also included several factors that FDA might consider when determining if a new product raised different questions of public health. We invited comments on this discussion.

FDA received a number of comments related to this discussion. Following our consideration of these comments, we have further refined our thinking on these terms, particularly on changes that might be appropriate to proceed through the same characteristics prong. This includes adding other examples to this list. We describe our thinking on these updates in the following paragraphs.

The final rule continues to include the statutory definition of substantial equivalence, and does not include codified definitions of ''same characteristics'' or ''different characteristics.'' FDA intends to further consider the scope of these terms and will undertake further notice and comment rulemaking before moving to further define any of these terms by regulation.

Following are examples of changes that are likely to be appropriate to proceed as same characteristics at this time:

- A change in product quantity between the new and predicate tobacco products;
- a change in container closure system between the new and predicate non-moist tobacco products (*e.g.,* soft pack to hard pack of cigarettes);
- a change in container closure system between the new and predicate non-moist tobacco products where the same material is being used (*e.g.,* change from one plastic container to another plastic container, change from one metal container to another metal container) and there is no difference in flavors being added to the container closure systems that would change the characterizing flavor;
- for moist tobacco products, a change in container closure system between the new and predicate tobacco products from one type of plastic to another similar type of plastic where there is no difference in flavors being added to the container closure systems that would change the characterizing flavor and no difference in size of the container closure system;
- a change to a lower amount of total tobacco in the new tobacco product without any corresponding changes in other ingredients or characteristics in the new tobacco product;
- a change in tipping paper color from plain to cork where the target specifications of the tipping paper are identical;
- a change in adhesive in the non-combusted portion of a cigarette;
- the replacement of one filter tow with an alternate filter tow with identical target specifications (*e.g.,* vendor specifications, measured values for denier per filament, total denier);[7]
- the removal of a dye or ink from the non-combusted portion of a tobacco product or removal of printed monogram ink from the barrel of a cigarette;
- a change to replace a lower grade version of an ingredient with an equal quantity of a higher grade version of the same ingredient (*e.g.,* replacing nicotine with USP grade nicotine);
- a change to remove a single flavor ingredient, including a complex ingredient, in the new tobacco product compared to the predicate or removing an ingredient in the predicate tobacco product and replacing that ingredient with an equal quantity of water in the new tobacco product;
- for combusted tobacco products, a change in the pattern of non-ink watermark on papers or wrappers, provided the papers or wrappers have identical target specifications and the change does not alter or affect the design parameters of the paper/wrapper;
- for combusted tobacco products, a change from one paper or wrapper to a similar paper or wrapper from an alternate supplier that do not impact HPHC yields;
- a change between a new and predicate tobacco product that results in a removal of characterizing flavor (*e.g.,* removal of menthol from cigarettes, or removal of cherry flavor in smokeless tobacco), as well as removal of a flavor from a component of a finished tobacco product (*e.g.,* removal of vanilla flavored adhesive in cigars and replacement with a non-flavored adhesive);
- a change in inert tip material (*e.g.,* replacing a wood tip with a plastic tip on a cigar);
- a change from non-Fire Standard Compliant (FSC) paper to FSC paper (also known as low ignition propensity paper);
- a change from one FSC paper to an alternate FSC paper; and
- an absolute increase or decrease in ventilation of 11 percent or less between the new and predicate tobacco product (Ref. 7).

(Comment 29) Some comments note that the *Philip Morris* decision is instructive on the meaning of the term ''same characteristics.'' One comment discussing the district court decision in the *Philip Morris* (*Philip Morris,* 202 F.Supp. 3d at 54) case stated that ''same characteristics means the product has more than minor modifications to a predicate product, but less than significant modifications''. The comments state that the district court rejected FDA's interpretation that same characteristics meant that the new and predicate products had identical characteristics. Other comments note the language in the decision stating that ''the 'same characteristics' prong may encompass similar, but not necessarily identical, products, while the 'different characteristics' prong may cover significantly different products.''

(Response 29) We agree that the district court rejected FDA's interpretation that same characteristics meant that the new and predicate products had identical characteristics. As explained in the proposed rule, we view the same characteristics prong to encompass new tobacco products that are so similar to the predicate product that FDA would not need scientific information beyond identification of the changes to determine whether the new product raises different questions of public health. The examples provided in the preceding paragraphs are intended to further illustrate the changes that might be appropriate to proceed through the same characteristics prong.

(Comment 30) One comment states that FDA should limit any finding that a new tobacco product has the ''same characteristics'' as a predicate product where the characteristics are not identical and an applicant ''demonstrate[s] that the differences, both individually and collectively, cannot plausibly have an effect on individual health or population-level health.'' This comment states that at a minimum the applicant should explain all the differences in characteristics and demonstrate that the differences cannot plausibly increase the potential harm to an individual or to the population as a whole. Other comments view as inappropriate FDA's statement that the same characteristics prong would be appropriate for new tobacco products that are ''so similar'' to the predicate that FDA would not need scientific information to determine whether the new product raises different questions of public health. The comments maintain that a public health analysis should not be part of the same characteristics analysis.

(Response 30) Under the same characteristics prong, an applicant need not demonstrate that any modifications to the new product do not cause the new product to raise different questions of public health. The ''different questions of public health'' analysis arises under the different characteristics prong. An SE review is structured as a tobacco product to tobacco product comparison, which does not account for population standards. We agree, and the rule requires, that the applicant provide information on the similarities and differences in characteristics between the new and predicate tobacco products (see, *e.g.,* §§ 1107.18(d) and 1107.19). However, we disagree with the

[7] Note that the addition or removal of a filter between the new and predicate tobacco products would not likely succeed through the same characteristics prong because the addition or deletion of a filter could impact product performance or HPHC yields and result in different exposures to the consumer and population.

comments that suggest that public health considerations generally should not be considered as part of an SE review under either prong. Rather, under the SE pathway, FDA protects the public health by authorizing only new tobacco products that are substantially equivalent to a predicate tobacco product.

(Comment 31) Some comments request additional clarity on the same characteristics prong and suggest that the lack of distinct definitions for ''same characteristic'' and ''different characteristic'' creates unclear pathways for manufacturers to follow. For example, one comment finds circular FDA's suggestion that ''the 'same characteristics' analysis might be appropriate for new tobacco products that are so similar to the predicate product that FDA would not need scientific information to determine different questions of public health'' while ''different characteristics' [is] if a product were dissimilar enough from the predicate product that FDA could not determine without scientific information whether the new product raised different questions of public health.'' This comment notes that FDA should determine whether two products have the ''same characteristics,'' and, if so, find the new product substantially equivalent, and, if not, then move to the second prong to determine ''whether the new product as a whole raises different questions of public health relative to products in the same category that were on the market as of February 15, 2007.''

Similarly, another comment suggests that the ''function of the 'same characteristics' prong is to determine whether any difference in characteristics between a new product and its predicate are materially different,'' stating that materiality is determined by whether such differences raise questions of public health. The comment further argues that if the differences are not material, then the products have the same characteristics. This comment suggests that under the different characteristics prong, a product should be substantially equivalent if requiring authorization under the more demanding PMTA pathway is not appropriate because the product does not raise different questions of public health.

Other comments suggest FDA define ''same characteristics'' to mean the products being compared have similar, but not identical, materials, ingredients, design, composition, heating source or other features, and the differences are not material to a public health assessment of the new product. The comment proposes FDA might define ''different characteristics'' to mean the products being compared have material differences in materials, ingredients, design, composition, heating source or other features, such that there is a potential to raise different questions of public health.

(Response 31) The initial decision of whether to submit a change under the same characteristics or different characteristics prong in an SE Report rests with the applicant who is best positioned to understand their new tobacco product, as well as how it compares with the predicate tobacco product. However, it is possible that FDA may determine that an SE Report submitted under the different characteristics prong has the same characteristics, or that FDA may determine that an SE Report submitted under the same characteristics prong has different characteristics. Note that an applicant's failure to properly identify the type of report will not prevent further review of the SE Report. In addition, although we agree that characteristics that have material differences are likely to fall under the different characteristics prong, we do not agree that a determination as to whether any differences are ''materially different'' is necessarily a function of the same characteristics prong or that using that term adds much clarity. As noted, we view the same characteristics prong to encompass new tobacco products that are so similar to the predicate product that FDA would not need scientific information beyond identification of the changes to determine whether the new product raises different questions of public health.

The range and scope of comments received on this topic illustrate that codifying definitions that will appropriately address the spectrum of tobacco product and changes that an SE Report might include could be premature and result in inflexibility. Thus, as we discussed earlier in this section, although this final rule continues to include examples of changes that might proceed as same characteristics, we have determined at this time not to proceed with codifying definitions of same characteristics and different characteristics.

(Comment 32) Several comments address whether there are some classes of changes that would not require scientific information to determine whether the new product raises different questions of public health. Some comments note that several examples included in the proposed rule as examples of changes that could proceed as same characteristics in an SE Report should be eligible for the SE Exemption pathway. For example, some comments state that product quantity changes should be exempt from premarket review, although one comment states FDA should not allow a product quantity change to fall under the same characteristics prong of SE. Other comments request that we include additional examples of changes that might proceed as same characteristics in an SE Report, such as changes to low ignition propensity cigarette paper, tipping paper, and tipping paper adhesives, or that we provide a decision-tree.

(Response 32) FDA agrees that certain changes could proceed through either the same characteristics prong or through the SE exemptions pathway, and we disagree with the comment that suggests that product quantity changes are not appropriate for a ''same characteristics'' SE Report. At this time, based on the currently available evidence regarding consumer perception and use, changes in product quantity between a new and predicate tobacco product do not cause new tobacco products to raise different questions of public health. As explained earlier in this section of the final rule, we have added examples of changes that are likely to be able to proceed as same characteristics in an SE Report, including a change in tipping paper color from plain to cork where the tipping paper target specifications are identical, a change in adhesive, the removal of a dye or ink, or replacing filter tow with an alternate filter tow with identical target specifications. In addition, as we note above, with more review experience we intend to provide further information and clarification about the Agency's thinking about what kinds of modifications could proceed through the same characteristics prong, different characteristics prong, and/or an exemption request under section 905(j)(3) of the FD&C Act (as implemented at § 1107.1).

(Comment 33) One comment suggests that a change submitted as a same characteristics SE Report could contain all the general information outlined in proposed § 1107.18(c), a certification that all characteristics are identical between the predicate and new tobacco product except for listed changes, a side-by-side design and ingredient comparison, a health information summary statement, and a statement of compliance with any applicable product standards. The comment notes that a same characteristics SE Report should not contain comparative testing data, HPHC testing, or stability testing.

(Response 33) FDA expects that SE Reports submitted under the same characteristics prong will be for new tobacco products that are so similar to the predicate product that FDA would not need scientific information to determine whether the new product raises different questions of public health. An SE Report submitted under the same characteristics prong must contain the applicable required information set out in § 1107.18 but would not need to include the comparison information as set out in § 1107.19. If an applicant submitting an SE Report under the same characteristics prong is not able to show that the new tobacco product is eligible for the same characteristics prong, the applicant should proceed under the different characteristics prong which requires the submission of further information, such as comparison of HPHCs data.

(Comment 34) Several comments also state that requiring SE submissions for product quantity changes conflicts with an FDA memorandum that the comments suggest show that FDA has no scientific or other basis to require SE Reports for product quantity changes (this comment references the FDA memorandum, ''Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for Statutorily Regulated Tobacco Products.'' December 2017, available at: *https://www.fda.gov/media/124674/download*).

(Response 34) We disagree that product quantity changes for tobacco products do not require premarket review. Section 910(a)(1) of the FD&C Act defines a ''new tobacco product'' as: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. As explained in *Philip Morris* v. *FDA,* a change in product quantity results in a new tobacco product requiring premarket authorization. *Philip Morris,* 202 F.Supp. 3d at 55–56.

We also disagree that product quantity changes can proceed through the exemption pathway under section 905(j)(3) of the FD&C Act. The FD&C Act establishes when a modification might be exempt from substantial equivalence, stating that FDA may exempt from the requirements of section 905(j) relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 910 of the FD&C Act, tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive (section 905(j)(3) of the FD&C Act; see also § 1107.1). The statute limits the eligible modifications to changes to additives. Therefore, a change in product quantity is not eligible to use the exemption premarket pathway because a change in product quantity, even if combined with a change in additives, is not only a change in additives.

(Comment 35) Another comment requests that FDA extend the product quantity change ''streamlined approach'' to other modifications and suggests as examples ingredient changes within 5 percent of the target and the replacement of non-Generally Recognized as Safe (GRAS) to GRAS ingredients in smokeless tobacco.

(Response 35) FDA agrees in part with this comment. We agree that other types of modifications can be submitted as a ''streamlined'' SE Report. FDA has received numerous successful applications where the manufacturer described any modification(s) between the new and predicate tobacco product, and provided a certification statement that all other characteristics are identical. For these SE Reports, FDA expects the applicant to provide adequate data to support that the new tobacco product is substantially equivalent to the predicate (which, for a different characteristics report, would include data to support that the proposed modification between the new and predicate tobacco product does not cause the new tobacco product to raise different questions of public health). A change in ingredient amount within 5 percent of the target specifications of the predicate tobacco product may be found substantially equivalent. This is a case-by-case determination. For example, a change of 5 percent could raise different questions of public health if there is toxicity associated with that ingredient; therefore, scientific data would be needed to ensure that any increase in toxicity does not cause the new tobacco product to raise different questions of public health. Also, if there are ingredient changes within 5 percent of the target specifications for a large number of ingredients (*e.g.,* 30 ingredients), the totality of all modifications may raise different questions of public health.

As with any ingredient change between a new and predicate tobacco product, the applicant must provide adequate information to demonstrate the new tobacco product meets the standard for authorization through the SE pathway.

FDA has received SE Reports that have included a change from non-GRAS to GRAS ingredients. Any ingredient change where the ingredients involved are (1) chemically identical; (2) have the same or nearly the same specifications; and (3) are present in identical or lower quantities, are not expected to raise HPHC quantities. Ingredient changes from non-GRAS to GRAS meet this type of change and therefore are not expected to raise HPHC quantities. In this scenario, FDA agrees no data would be needed beyond that required to identify this change under § 1107.18(g). FDA notes that GRAS designation pertains to foods and is not determinative with respect to the substantial equivalence standard, although in some cases, a GRAS determination and data underlying that determination may be appropriately bridged to tobacco products. As indicated above, changes from one ingredient to a higher grade of that ingredient can qualify as a same characteristics SE Report (*e.g.,* a change from non-USP to USP grade nicotine).

(Comment 36) Several comments generally object to FDA's approach to the ''different'' characteristics prong stating, for example, that FDA treats every SE Report as a different characteristics SE Report. One comment states that FDA is requiring the same or similar information for both prongs, and that all SE reports in essence would have to submit under the ''different'' characteristics prong to show the new tobacco product has the same characteristics. The comments state that the approach in the proposed rule is in conflict with Congressional intent.

(Response 36) We disagree with this comment. Both the proposed rule and this final rule illustrate modifications that are likely to be able to fall under the same characteristics prong and thus would not require submission of the information required under § 1107.19, unlike modifications that fall under the different characteristics prong, which do require submission of the information in § 1107.19.

(Comment 37) Some comments state that the different characteristics prong does not make reference to a predicate tobacco product at all and suggest that the different questions of public health determination should be without reference to a predicate and instead be determined by a comparison to all tobacco products in the marketplace. For example, one comment suggests that FDA ''look only to the risks to the public that are of a different type or

magnitude from the risks present in the market for the particular category of tobacco product at issue as of the baseline date of February 15, 2007.'' Similarly, some comments state that because the FD&C Act does not include ''predicate product'' in the ''different characteristics'' prong, FDA must evaluate products by comparing the attributes of the product to a broader range of other marketed products (beyond the referenced predicate). These comments generally state that the different questions of public health language included in the second prong is intended to route to the PMTA process those new tobacco products that raise different questions of public health beyond those already recognized, *i.e.,* to identify products that have risks distinct in type or magnitude from the existing, known risks prevalent in the market as of February 15, 2007, and that this should be a ''heavy lift'' before FDA can conclude that a new product raises different questions of public health.

(Response 37) We disagree with the comment's assertion that the analysis of different characteristics should include consideration of all tobacco products in the marketplace as of February 15, 2007. Both the same characteristics and different characteristics prongs are specific to the comparison between a new tobacco product and its predicate. A marketplace range of products, or multiple predicates, as suggested by the commenter, would be inconsistent with the statutory framework Congress provided for authorization through the SE pathway. Nowhere in section 910(a)(3)(A) or 905(j) of the FD&C Act does the statute state—either explicitly or implicitly—that the SE comparison should be made to the market as a whole as of February 15, 2007. On the contrary, there are numerous references to a single predicate product throughout the sections of the FD&C Act which discuss SE. *See, e.g.,* section 905(j)(1)(A)(i) of the FD&C Act (person seeking to introduce new tobacco product via SE pathway must provide its basis for determination that the new tobacco product is substantially equivalent, within the meaning of section 910, to *a tobacco product commercially marketed* as of February 15, 2007); section 910(a)(2)(A) of the FD&C Act (a PMTA order is required unless FDA has issued an order that the new tobacco product—is substantially equivalent to *a tobacco product commercially marketed* as of February 15, 2007); section 910(a)(3)(A) (''substantial equivalence'' means, with respect to the tobacco product being compared to *the predicate tobacco product*); section 910(a)(3)(C) (a new tobacco product may not be found to be substantially equivalent *to a predicate tobacco product* that has been removed from the market or that has been determined by a judicial order to be misbranded or adulterated). There are no references in the FD&C Act that discuss any SE finding in connection with the marketplace or a marketplace range of products. In addition to being inconsistent with the FD&C Act, a comparison to all tobacco products in the ''marketplace'' would make it difficult and impractical to compare each characteristic between the new and predicate tobacco products. This approach also raises questions as to what should be considered the ''marketplace,'' such as which tobacco products should be used in determining the marketplace and whether the understanding of marketplace shifts over time.

This is in contrast to the evaluation FDA must make to authorize a product through the PMTA pathway. In order to receive authorization through the PMTA pathway, FDA must find that permitting the new tobacco product to be marketed would be ''appropriate for the protection of the public health.'' (See section 910(c)(2) of the FD&C Act.) In making this determination, FDA must evaluate the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products. (See section 910(a)(4) of the FD&C Act.) This is a much different standard and inquiry than that which is undertaken under the different questions of public health analysis under SE.

(Comment 38) One comment states that FDA's intent to judge differences in characteristics individually and in the aggregate under the different characteristics prong ''place[s] undue and unreasonable importance on every individual change to a specific ingredient, material, or characteristic, no matter how minor or unrelated to public health, and without any explanation of how FDA will weigh the differences.'' This comment argues that if true, FDA will be unlikely to determine that any new product is substantially equivalent.

(Response 38) We disagree with the assertion that we will be unable to determine that any new tobacco product is substantially equivalent. FDA has issued a high number of SE orders and a large ratio of such orders relative to not substantially equivalent (NSE) orders. As of December 31, 2019, of the orders issued for regular SE Reports, 80 percent were for an SE finding (a total of 1,009 SE orders versus a total of 209 NSE orders) (information on marketing orders related to substantial equivalence for tobacco products can be found at *https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se*). Additionally, as of December 31, 2019, FDA had closed 96% of all regular SE Reports accepted. FDA evaluates SE Reports on a case-by-case basis based on the content of the SE Report. Certain changes between the new and predicate tobacco product may affect additional characteristics or impact HPHCs in a way that would cause a new tobacco product to raise different questions of public health. For example, certain changes in design parameters can lead to an increase HPHCs. We also want to note, in response to the concern that FDA's approach places ''unreasonable importance on every individual change'', ''no matter how minor'' the change, that for changes that are minor modification to tobacco additives, the exemption from substantial equivalence pathway is available. SE Reports that include changes that FDA believes limited or no information is needed may be eligible to proceed as a ''same characteristics'' SE Report, as explained in the examples above, or via a streamlined SE Report containing limited information sufficient to demonstrate the changes subject of that SE Report do not cause the new tobacco product to raise different questions of public health.

(Comment 39) At least one comment states that the considerations included in the proposed rule related to different characteristics and different questions of public health exceed the physical characteristics of the product itself (*e.g.,* that FDA is requiring that applicants examine the potential to increase initiation, increase abuse liability, or decrease cessation). The comment further argues that, if FDA is requiring applicants to address whether every change has the potential to affect any of these outcomes, it is requiring manufacturers to meet a subjective, unmeasurable standard contrary to law, *i.e.,* FDA appears to want manufacturers to prove a negative.

(Response 39) We disagree that these considerations do not relate to the physical characteristics of a tobacco product. Rather, a modification to a tobacco product may cause the new tobacco product to have different characteristics from the predicate

tobacco product. When a new product has different characteristics, FDA evaluates whether the totality of difference(s) in characteristics do not cause the new product to raise different question of public health. Congress stated that the Tobacco Control Act's ''purposes'' include ensuring that the FDA has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco and promoting cessation to reduce disease risk and the social-costs associated with tobacco-related diseases (Tobacco Control Act sections 3(2) and (9)). In addition, as explained above, Congress defined substantial equivalence to mean that the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health. (See section 910(a)(3)(A)(ii) of the FD&C Act.) The reference to ''this section'' is a reference to the PMTA pathway. Because one of the bases for FDA finding that a product is appropriate for the protection of public health (*i.e.,* the PMTA ''standard'') includes the increased or decreased likelihood that existing users will stop using and new users will initiate use of such products, it is reasonable to examine those same considerations under the SE standard to determine whether the differences between the predicate and the new product show that the product should be reviewed under the PMTA pathway. Thus, as part of making the ''different questions of public health'' determination, FDA typically considers whether the new product has potentially higher HPHC yields, toxicity, initiation, abuse liability, or dependence relative to the predicate product.

(Comment 40) Some comments disagree with the proposed rule's discussion of the phrase ''different questions of public health'' (DQPH) and state that FDA's thinking is incorrect. Other comments note that the six identified factors included in the proposed rule for determining if a new tobacco product raises different questions of public health seem optional, non-exhaustive, and vague.

(Response 40) We agree that additional information may assist applicants in understanding DQPH. Thus, in the following paragraphs FDA is providing further information on our thinking related to this phrase. Specifically, in evaluating whether an applicant has demonstrated that a difference in characteristic does not cause the new product to raise different questions of public health, FDA may consider, among other public health considerations, whether:

- The new tobacco product has higher HPHC yields compared to the predicate tobacco product, and the difference in HPHC yields is greater than the analytical variability of the method used to detect it.[8]
- The new tobacco product has potentially higher toxicity due to an appreciable increase in an ingredient associated with adverse health effects, compared to the predicate tobacco product. For example, the evaluation of the available toxicology information may show that an increase in an ingredient between the new and predicate tobacco products demonstrates an increase in cancer risk or non-cancer hazard for users of the new tobacco product compared to those of the predicate tobacco product, and thus causes the new tobacco product to raise different questions of public health.
- The new tobacco product compared to the predicate has the potential to affect use behavior such as an increase in initiation of the product, especially among youth or other vulnerable populations; a decrease in cessation; or use by different tobacco-use status groups.
- The new tobacco product compared to the predicate has potentially higher abuse liability.
- The new tobacco product has the potential to increase dependence.

Based on these considerations, as well as other public health considerations, FDA will determine whether the applicant has demonstrated that any differences do not cause the new tobacco product to raise different questions of public health.

(Comment 41) Other comments request that FDA include a definition of the phrase ''different questions of public health'' in the final regulation. The comments assert that industry needs this information to determine the appropriate pathway for its SE submission. Some comments propose definitions of the phrase; for example, one comment proposes to define the phase ''different questions of public health'' to mean when ''the new product as a whole raises questions of public health that are significantly different in type and magnitude from those presented by [Pre-Existing tobacco products] or other legally marketed tobacco products.'' The comments contend that the analysis should look at ''different questions of public health'' as a whole rather than the implications of the particular product as compared to another product. One comment suggests that an applicant could satisfy the public health analysis by providing HPHC data for both the new and predicate products, and if none of the HPHCs for the new product are statistically higher than the predicate product, then the new product should pass the public health analysis. The comment suggests that applicants could submit a quantitative risk assessment (QRA) (defined by the comment as a magnitude of individual disease risk tool), and if the new product is of no greater risk than the predicate product then the new product should pass the public health analysis. This comment also suggests that FDA should establish a QRA framework and ''identify the number of product runs or batches necessary to generate HPHC data,'' as well as publish this data so that manufacturers can generate QRA category curves.

(Response 41) We agree that changes in characteristics could cause the new tobacco product to raise ''different questions of public health'' where ''the new product as a whole raises questions of public health that are significantly different in type and magnitude from those presented by [Pre-Existing] or other legally marketed tobacco products.'' However, instead of adopting a definition, we include additional details in the preceding paragraphs on what we may consider when determining if a new tobacco product raises different questions of public health. The public health analysis of an SE Report involves the evaluation of all toxicologically relevant changes, including HPHCs, but also non-tobacco ingredient changes that may cause the new tobacco product to raise different questions of public health. At this time, we are not recommending the inclusion of QRA with SE Reports, as they are not needed for the comparison of HPHCs from the new and corresponding predicate tobacco products. If an applicant has scientific evidence that a QRA would be supportive in evaluating the overall toxicological comparison between a new and predicate tobacco product, we strongly encourage the applicant to contact FDA and to justify the methodology and applicability of a potential QRA before an applicant voluntarily develops or submits a risk assessment, as the assessment may not

[8] In determining whether an applicant has demonstrated that any differences in characteristics do not cause the new product to raise different questions of public health, FDA will consider whether increases in certain HPHCs are offset by decreases of other HPHCs.

be needed or appropriate to support the SE Report.

(Comment 42) Another comment asserts that a definition of different questions of public health should include information that indicates a product with a low usage rate will not impact public health.

(Response 42) We disagree with the assertion that new tobacco products with low usage rates would necessarily not impact public health. Under section 905(j)(1)(A)(i) of the FD&C Act, the basis for determining substantial equivalence is through the comparison of the new tobacco product to the predicate tobacco product. Therefore, providing prevalence of use (even if it indicates low usage) of the new tobacco product without comparison to prevalence of use to a predicate tobacco product is insufficient to determine if the new tobacco product raises different questions of public health. In addition, differences in the composition of users of the new and predicate tobacco products may still raise DQPH even with low overall prevalence of use. Furthermore, FDA's assessment of the product's impact on public health goes beyond usage rate. For example, a new tobacco product that has a low usage rate, but is found to be more toxic than the predicate tobacco product (*e.g.,* a tobacco product with higher HPHCs than the predicate tobacco product) could raise different questions of public health and be found not substantially equivalent. Moreover, prevalence can change over time, and it can be difficult to predict the prevalence of a new product before it is marketed.

- Tobacco Product

We proposed to include the statutory definition of tobacco product (section 201(rr) of the FD&C Act (21 U.S.C. 321(rr))). In the FD&C Act, tobacco product is defined as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the FD&C Act is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g) (21 U.S.C. 353(g))). We discuss the comment related to this definition in the following paragraphs, and we are including this definition in the final rule without change.

(Comment 43) At least one comment disagrees with FDA's interpretation of tobacco product (*i.e.,* as encompassing the whole product and not limited to a single unit or portion) and argues that FDA's interpretation is too broad, misinterprets the FD&C Act, and is unnecessary.

(Response 43) We disagree with these objections related to the language included in the proposed rule's discussion of new tobacco product and tobacco product. Rather, as noted in the proposed rule, and supported by the *Philip Morris* decision, for purposes of determining whether a tobacco product is new under section 910 of the FD&C Act, and therefore requires premarket authorization prior to marketing, a ''tobacco product'' encompasses the whole product (*e.g.,* a pack of cigarettes or a tin of loose tobacco), and is not limited to a single unit or portion of the whole product (*e.g.,* a single cigarette or a single snus pouch). (*See Philip Morris,* 202 F. Supp. 3d at 55–57.) If an SE Report includes information on only a portion of a new tobacco product, FDA would have an incomplete understanding of the tobacco product (*e.g.,* FDA may not get information on the container closure system, which could impact the consumable product) and would not be able to determine, for example, potential impacts on initiation and cessation of tobacco use (information which may be needed for determining whether there are DQPH).

- Tobacco Product Manufacturer

We proposed to include the statutory definition of tobacco product manufacturer in the rule (section 900(20) of the FD&C Act). The statute defines tobacco product manufacturer as any person, including a repacker or relabeler, who: (1) Manufactures, fabricates, assembles, processes, or labels a tobacco product or (2) imports a finished tobacco product for sale or distribution in the United States. In the following paragraphs, we discuss the comments related to this definition. We are including this definition without change in the final rule.

(Comment 44) One comment requests that FDA clarify that ''an entity that contracts with another domestic entity to manufacture a tobacco product'' is included in this definition.

(Response 44) The rule includes the definition of tobacco product manufacturer from the FD&C Act, stating that ''tobacco product manufacturer'' includes any repacker or relabeler and any person who manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States (this term and definition are included in the final rule). Under this definition, contract entities engaged in the activities described in the definition of a tobacco product manufacturer would fall within the scope of the definition of tobacco product manufacturer.

D. Comments on Subpart C—Substantial Equivalence Reports and FDA Responses

1. Submission of an SE Report (§ 1107.16)

Proposed § 1107.16 would establish when an applicant should submit an SE Report. We received no comments on this proposed section, and we are finalizing this section without change.

2. Content and Format of an SE Report (§ 1107.18)

Proposed § 1107.18 set out the required content and format of SE Reports. This proposed section included requirements related to: (a) Overview; (b) format; (c) general information; (d) summary; (e) new tobacco product description; (f) description of predicate tobacco product; (g) comparison information; (h) comparative testing information; (i) statement of compliance with applicable tobacco product standards; (j) health information summary or statement regarding availability of such information; (k) compliance with part 25 (21 CFR part 25); and (*l*) certification statement. Proposed § 1107.18(b) and (c) also included requirements for the use of Form FDA 3964 (Tobacco Amendment and General Correspondence Report) and Form FDA 3965 (Tobacco Substantial Equivalence Report Submission) (Refs. 8 and 9).

After considering the comments, we are revising § 1107.18 in several places for consistency with other changes to the rule and to add clarity. Specifically, in § 1107.18(a), we have revised language that previously referred to ''grandfathered'' to reflect the statutory language related to what types of tobacco product can serve as predicate tobacco products. We also added in paragraph (a) a cross-reference to § 1105.10 to clarify that FDA generally intends to refuse to accept an SE Report for review if it does not comply with both §§ 1105.10 and 1107.18 to help ensure applicants are aware that the requirements of both sections must be satisfied. As we explain further below, we have made modifications to § 1107.18(g) and (h) to clarify what information is needed for acceptance for further review.

We are also revising § 1107.18(c)(4) to add ''voluntary'' as a modifier to ''request'' to further emphasize that

seeking an FDA determination relating to a potential predicate tobacco product is a voluntary process. We revised § 1107.18(c)(5) and (6) to add ''including email address'' as information the SE Report must include to help ensure we have complete contact information.

We revised § 1107.18(c)(7)(iii) (product category, product subcategory, and product properties table) to help ensure that we are able to identify and evaluate each product more accurately and efficiently for purposes of SE review. Under this revised taxonomy, some tobacco products may fit under more than one category. For example, the cigarette product category no longer lists noncombusted cigarettes as a subcategory. Instead, for purposes of SE review, a ''heated tobacco product'' category has been added to the identification tables. This SE review category should be used for (among others) tobacco products that meet the definition of a cigarette but are not combusted (products that do not exceed 350°C). Heated tobacco products (HTP) can be used with e-liquids, other types of tobacco filler, or consumable (*e.g.,* wax, oils). If, however, a tobacco product can be used only with e-liquids, it should be captured under ENDS and not the HTP category. To ensure we have all the information we need to efficiently and effectively review your application, if the product that is the subject of your application is a heated tobacco product and is not an ENDS product, you should submit information under §§ 1107.18(c)(7)(iii) and 1107.19(a)(21) under the heated tobacco product category.[9] FDA believes these product categorizations will help ensure that applications include the most relevant information for their product, which in turn will speed up FDA's review and ability to reach an authorization decision.

Other changes to § 1107.18(c)(7)(iii) include FDA's clarification under the ''cigar'' category to designate ''leaf-wrapped'' cigars as *unfiltered* to more accurately describe the product category, as ''leaf-wrapped'' cigars typically do not include filters; and under the ''waterpipe'' category, waterpipe ''diameter'' has been added to distinguish between waterpipes of different sizes (width/diameter and height) where all other uniquely identifying information is the same; under the ''pipe tobacco filler'' category, ''tobacco cut style'' has been added to distinguish between different cut pipe tobacco filler *e.g.,* standard cut, such as shag cut, bugler cut, loose cut, etc., or a pressed cut, such as flake, cube cut, roll cake, etc. or a mixture. Additionally, FDA has removed the requirement to provide tobacco cut size from the unique identification requirements for smokeless tobacco and cigar tobacco filler. A specific numerical value for this field is not necessary to uniquely identify the specific product to which the SE Report pertains, as it can be described further through identification of additional properties (*e.g.,* fine cut, long cut). However, for the purposes of determining whether characteristics related to tobacco cut size cause the new tobacco product to raise different questions of public health, information to determine tobacco cut size is required under § 1107.19 for the product categories specified in that section.

Across all product categories, the subcategory of ''co-package'' has been removed from § 1107.18(c)(7)(iii). If an applicant submits an SE Report for a co-packaged tobacco product, the unique identification of this co-packaged product would include the specific items needed to identify each product within the co-package. For example, if the co-package is a pouch of roll-your-own (RYO) tobacco filler that contains rolling papers inside the pouch, the applicant would identify the tobacco product as a co-packaged product and provide the unique identification for both RYO tobacco filler and rolling papers.

In § 1107.18(d)(2), we have added ''any differences in characteristics do not cause the new tobacco product to'' instead of ''does not'' to clarify that this part of the sentence refers to differences in characteristics.

In § 1107.18(e), we are deleting ''including the fermentation process, where applicable, with information on the type and quantity of the microbial inoculum and/or fermentation solutions'' as the SE Report does not need to include this as part of a concise overview of the process used to manufacture the new tobacco product. The information that would have been submitted under this proposed requirement would also be duplicative of the fermentation information that will be submitted as part of the SE Report under § 1107.19.

In § 1107.18(f), for the reasons explained earlier in this preamble, we have removed references to ''grandfathered'' and instead use language that reflects the statutory definition of predicate tobacco product. We are also deleting from § 1107.18 proposed paragraph (f)(2)(i), which would have required the predicate tobacco product to be in the same product category and subcategory as the new tobacco product and making corresponding renumbering edits to this subsection. As we discuss in later paragraphs, we are removing this requirement because although it will likely be difficult for an applicant to demonstrate substantial equivalence in this situation (where the new product is in a different category or subcategory as its selected predicate), it may, in rare cases, be possible for an applicant to make a showing of substantial equivalence. In § 1107.18(f)(2)(iii) (formerly (f)(2)(iv)), we have changed ''rescission order'' to ''rescission action,'' which is a more accurate description.

In § 1107.18(g), we have made some minor clarifying edits, and in § 1107.18(h) we have added ''that has been demonstrated to be fully validated'' following comparative testing, which is needed to ensure the method is fit for purpose and the measured values can be accurately compared between a new and predicate tobacco product. FDA considers full validation of a quantitative analytical procedure to include: (1) Accuracy; precision (repeatability, intermediate precision, and robustness); (2) selectivity; (3) sensitivity (limit of detection and limit of quantification); (4) linearity; and (5) range. The performance criteria typically include information such as the target analyte, an approximation of the range of concentrations of the analyte in the sample, the intended purpose of the procedure (*e.g.,* qualitative, quantitative, major component, minor component, etc.), and the number of samples to be analyzed.

We have also corrected minor typographical errors in proposed § 1107.18(g) and (k)(2). We have also removed the phrase ''as described in § 1107.19'' from § 1107.18(g) and (h) to better reflect that FDA's determination of acceptability for review is not intended to be an exhaustive review of the SE Report but rather is intended to serve as a check that the SE Report generally includes required information before FDA accepts an SE Report and proceeds to substantive review. For the same reason, we also moved the detailed requirements related to comparative testing from proposed § 1107.18(h) to § 1107.19.

Both ''same characteristics'' and ''different characteristics'' SE Reports must provide the information required by § 1107.18(g). As explained in § 1107.18(g), if the new tobacco product

[9] The categorization of HTPs as a separate category from cigarettes in this rule, as demonstrated in §§ 1107.18(c)(7)(iii) and 1107.19(a)(21), does not extend to other legal requirements beyond those associated with the SE review process.

has limited changes to a characteristic(s) when compared to the predicate tobacco product, and all other characteristics are identical (*e.g.,* a change to product quantity), the applicant must provide comparison information related to any characteristic(s) that have changed, but may certify that the other characteristics are identical under § 1107.18(*l*)(2).

Where the new tobacco product has the same characteristics as the predicate tobacco products, applicants need only explain that their SE Report is a ''same characteristics'' report to satisfy the requirement of § 1107.18(h). Furthermore, as explained in § 1107.18(h), an applicant need not provide comparative testing information for any characteristics that are identical between the new tobacco product and the predicate tobacco product, and for which the applicant has certified that the characteristics are identical under § 1107.18(*l*)(2).

The following paragraphs describe the comments we received on proposed § 1107.18 and our responses to those comments.

• Forms (§ 1107.18(b)–(c))

Proposed § 1107.18(b) and (c) included requirements that the applicant use the forms that FDA provides when submitting an SE Report. Following our consideration of the comments related to the forms, we are finalizing these requirements without change. We describe the comments to these subsections and our responses next.

(Comment 45) At least one comment states that use of the FDA forms should be optional rather than mandatory.

(Response 45) We disagree. As explained in the proposed rule, the requirements in this rule, including use of these forms, are intended to provide clarity to applicants with respect to what they must submit in an SE Report and to help ensure that an SE Report provides information necessary for FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007. Additionally, use of a standardized form allows FDA to receive information in a way that allows for faster processing and uploading of the SE Report and its contents, thereby increasing efficiency of the review process.

(Comment 46) One comment believes FDA has underestimated the time needed to complete the forms and did not explain how it arrived at these estimates.

(Response 46) FDA conducted a thorough analysis of the current paperwork burden associated with the SE program and other similar forms. After a further review of similar forms, we have adjusted Form 3965 to 45 minutes per response and Form 3964 to 10 minutes per response. Using our knowledge of elements in an SE report FDA believe we have applied the most accurate burden to the forms. Beyond entering data into the form, we conclude that the burden for searching existing data sources and gathering and maintaining the data needed, is accounted for in the burden charts. FDA notes that the commenter did not provide a recommendation for alternative estimates (see also section IX of this final rule).

(Comment 47) Another comment notes that although FDA appears to recognize that the evidence required in an SE Report depends on whether the new tobacco product has the ''same'' characteristics as the predicate product or if the new tobacco product has ''different'' characteristics than the predicate product, this distinction is not reflected in either the draft of Form FDA 3965 or the rule itself.

(Response 47) The form has been revised to include a section where the applicant would distinguish whether they are submitting a ''same characteristics'' SE Report, or a ''different characteristics'' SE Report. A ''same characteristics'' SE Report must describe the modification(s) and include all of the other information required in § 1107.18. As described in previous paragraphs, however, an SE Report submitted under the same characteristics prong would not be required to provide the information described in § 1107.19.

• General Information (§ 1107.18(c))

Proposed § 1107.18(c) listed the information that the SE Report would be required to include. This information included general administrative information specifying the type of submission (*e.g.,* SE Report or amendment to a report); unique identification of both the new and the predicate tobacco products, as well as contact information. Following our consideration of comments, we are finalizing § 1107.18(c) with changes to reflect updates to § 1107.18(c)(7)(iii) (related to product category, product subcategory, and product properties).

(Comment 48) Several comments request clarity regarding the proposed requirement that an SE Report include information about the product's characterizing flavor. Specifically, the comments request FDA to clarify the requirement or include a definition of the term, or seek to understand if the purpose of the requirement is simply to see how the applicant identifies the product (*e.g.,* ''no characterizing flavor'' or a ''particular flavor''). Some comments note that the only information available is in an FDA memorandum, and they disagree with how the memorandum explains that characterizing flavor should be indicated by factors including chemical composition or olfactory response (the comment cites an FDA document, entitled, ''Unique Identification of Tobacco Products,'' November 2016, which is available at: *https://www.fda.gov/media/124658/download*). Other comments request that FDA consider only the toxicological effects rather than the effect on user behavior, when considering the differences in characterizing flavor between the new and predicate tobacco products.

(Response 48) This final rule does not define characterizing flavor. As part of uniquely identifying a new and predicate tobacco product, the SE Report must include product property information on whether the products have a characterizing flavor or not. The SE Report may state, for example, that a new cigarette has ''none'' for the product property of characterizing flavor. In addition, this information is needed as part of fully characterizing a new tobacco product to aid FDA during the review process and in making an SE determination. When considering the differences in characterizing flavor between the new and predicate tobacco products, FDA considers both the toxicological effects and the effects on user behavior.

(Comment 49) At least one comment indicates general disagreement that a change in characterizing flavor should require submission of an SE Report. The comment states that, if a new product includes a different flavoring from the predicate, FDA should not require that an SE Report be submitted for that new or different flavor but that, if an SE Report is required, the product should not ''fail'' SE review ''unless the addition of flavor alters the chemistry of the product such that it increases the inherent risks of tobacco-related diseases in an individual user either through the introduction of new or greater HPHCs.'' A comment also states FDA has not explained why a change in characterizing flavor would require submission of an SE Report for a product with different characteristics.

(Response 49) We disagree that an SE Report should not be required for a change in characterizing flavor. Section 910(a)(1) of the FD&C Act establishes that any modification results in a new tobacco product. A change to or

addition or deletion of ingredients that make up a characterizing flavor renders a tobacco product ''new.'' For FDA to make an SE finding, the SE Report must demonstrate that the new tobacco product is substantially equivalent to the predicate tobacco product. As we explain in previous paragraphs related to the definition of substantial equivalence, at this time, an SE Report for the removal of a characterizing flavor is likely to be able to come in as a same characteristic SE Report as FDA has found such a change does not require scientific data to show that the change does not cause the new tobacco product to raise different questions of public health.

• New Tobacco Product Description (§ 1107.18(e))

(Comment 50) Several comments object to requiring any manufacturing information, such as the ''concise overview of the process used to manufacture the tobacco product'' as provided in this subsection as unnecessary in an SE review. These comments note that FDA should address manufacturing procedures through manufacturing practice regulations issued under section 906(e) of the FD&C Act (21 U.S.C. 387f). Another comment disagrees with these comments, stating that information on manufacturing practices is important to ensure that products are consistently produced.

(Response 50) We agree with the comment suggesting that information on manufacturing practices can be relevant to an SE determination. Note, however, that a concise overview of the process used to manufacture the new tobacco product is only needed where the manufacturing process for the new tobacco product could affect the characteristics of the new tobacco product beyond what is described elsewhere in the SE Report. If the manufacturing process for the new tobacco product does not affect the characteristics of the new tobacco product beyond what is described elsewhere in the SE Report, an applicant must state that to satisfy § 1107.18(e)(3).

As explained in the proposed rule, this overview would not need to be an exhaustive discussion but enough information to enable FDA to fully understand and compare the characteristics that can be affected by the manufacturing process of the new tobacco product and the predicate tobacco product. FDA has found during reviews of SE Reports that changes in manufacturing may impact the characteristics of the tobacco product, *e.g.,* the quantities of nicotine (total and free), as well as HPHCs such as TSNAs. Such changes could cause the new product to raise different questions of public health, *e.g.,* an increase in TSNAs may increase the risk for certain types of cancer (Ref. 10).

We disagree with the comments that suggest this information would be more appropriately required through manufacturing practices regulations issued under section 906 of the FD&C Act. Section 906 authorizes FDA to issue regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice. Such regulations could include comprehensive requirements on purchasing controls, production and process controls, and requirements related to acceptance activities and nonconforming products (see, *e.g.,* 21 CFR part 820). In comparison, § 1107.18(e)(3) requires only a ''concise overview'' of the process used to manufacture the new tobacco product'' to aid FDA in understanding in how the manufacturing process might affect the characteristics (or, if the manufacturing process does not affect the characteristics of the new tobacco product beyond what is described elsewhere in an SE Report, an applicant may simply state that). The requirement for a concise overview is vastly different from the manufacturing information that may be required under a tobacco products manufacturing practices regulation under section 906 of the FD&C Act. Moreover, the purpose of the requirement in § 1107.18(e)(3) is not for the purposes described in section 906 of the FD&C Act but, rather, is to help ensure enough information to enable FDA to fully understand and compare the characteristics that can be affected by the manufacturing process of the new tobacco product and the predicate tobacco product.

• Description of the Predicate Product (§ 1107.18(f))

As described in an earlier paragraph in this section, we have made changes to this subsection for consistency with changes that we made to the definition of predicate tobacco product and other clarifying edits. We also removed the requirement that a tobacco product to which a new tobacco product is compared be in the same category and subcategory of product as the new tobacco product. In the following paragraphs, we describe the comments we received on this subsection and our responses.

(Comment 51) Some comments object to the proposed requirement that the new and predicate products be in the same category and subcategory. The comments state, ''there is nothing in the statute to prohibit the attempted use of cross-category comparisons in an SE submission'' and also refer to the deeming final rule as suggesting such a comparison is appropriate. The comments state that while cross-category comparisons may be more burdensome or require more information, the comparison may be appropriate and, therefore, applicants should be permitted to attempt it.

(Response 51) After careful review of the comments submitted and our own experience, we agree and are no longer requiring that the new and predicate products be in the same category and subcategory. We note that it would likely be difficult for an applicant to demonstrate substantial equivalence where the new product is in a different category or subcategory as its selected predicate, but it may, in rare cases, be possible for an applicant to make a showing of substantial equivalence. For example, an applicant may be able to compare a new snus tobacco product to a pouched moist snuff predicate tobacco product.

It continues to be critical, however, that an applicant select an appropriate predicate tobacco product and provide the scientific evidence demonstrating the new tobacco product is substantially equivalent to that predicate. Even where there are differences in the category or subcategory between the new and predicate tobacco products, FDA could issue an SE order if the applicant provides scientific evidence that demonstrates to FDA that differences between the new product and the predicate product do not cause the new tobacco product to raise different questions of public health. Comparison of a new and predicate tobacco product is much easier, and more likely to result in a finding of SE, if the new and predicate tobacco products are of the same category and subcategory, as the basic characteristics of the predicate and new products are likely to be more similar. For example, manufacturers of ENDS may find it difficult to show that their product is substantially equivalent to a combusted cigarette or a smokeless tobacco product because of the differences in product properties.

If an applicant chooses to compare a new and predicate tobacco product that are not in the same category or subcategory, for FDA to be able to conduct a review of the SE Report, the

applicant should provide a strong scientific justification for why a product that may differ from the new tobacco product in even the most basic of characteristics and parameters is an appropriate predicate and how any differences in characteristics do not cause the new tobacco product to raise different questions of public health. For example, where the new and predicate tobacco products are not in the same category or subcategory, an applicant could provide information to demonstrate that users or likely users of the new product display very similar tobacco product use behaviors (*e.g.,* likelihood of initiation, experimentation, switching, dual-use/polyuse, or cessation, as well as actual use patterns, frequency and amount of use) in addition to information on comparison of HPHCs exposure.

(Comment 52) One comment agrees with the proposed requirement of § 1107.18(f) that an applicant include a single predicate product for comparison and that a composite predicate tobacco product would be inconsistent with the FD&C Act. Other comments disagree with FDA's proposal to require manufacturers to identify a single predicate product to compare to the new product. Several of these comments contend that manufacturers should be able to use multiple predicates in a single SE report, stating that permitting the use of multiple predicates would be more consistent with statutory design and also align with the substantial equivalence requirements for devices in sections 510(k) and 513(g) of the FD&C Act. The comments state that we have been inconsistent in our position regarding the use of predicate products and contend that the one predicate approach described in the proposed regulation would create problems for manufacturers because it does not allow for product innovation. In support of this, some comments refer to FDA webinars that suggest that use of two predicates would be appropriate, an FDA decision to permit two predicates to be used for a smokeless product, and an FDA policy memorandum that acknowledges ''multiple predicate tobacco products are identified in an SE Report'' (this comment referenced the FDA memorandum FDA, ''Use of Surrogate Tobacco Products in SE Reports,'' September 2016. Available at: *https://www.fda.gov/media/124665/download*). Some comments ask that, if the final rule maintains the single predicate approach, applicants be permitted to amend currently pending SE Reports to designate the most appropriate predicate product.

(Response 52) We disagree that the final rule should permit the use of multiple predicate tobacco products in an SE Report. There is nothing in the statutory language to support the assertion that the SE comparison can be made to a range of predicate products, and doing so would be inconsistent with the premise of SE review. Creating a new tobacco product from a range of predicate tobacco products can raise different questions of public health beyond those questions raised by the individual predicates because of the way the various additives and other features of a tobacco product interact to impact how chemicals are handled by the body. Some of the ways chemicals can interact is to alter how they are absorbed into the body, metabolized by the body, or how they bind to receptors in the body.

For example, acetaldehyde when present at a level that is below its independent reinforcing effect could boost the reinforcing effect of nicotine, the primary addictive substance in tobacco, beyond what it would be without acetaldehyde present or the sum of the two independent effects (Refs. 11 and 12). If a component from one predicate that contains nicotine is mixed with a component from another predicate that contains acetaldehyde, the synergistic effect of this mixture could raise different questions of public health beyond the separate predicates, because the addictiveness of the product could be greater than either independently or the sum of the two predicate products alone and may reduce cessation and increase initiation, thereby impacting public health.

Finally, the comments also cite instances where it appears that FDA has suggested or permitted reference to two predicate tobacco products. However, in the past, if an SE Report referenced multiple predicate tobacco products, we generally have either broken this down into multiple reports or have used a single predicate tobacco product for comparison. This approach can result in delays in processing or reviewing an SE Report, which the final rule seeks to prevent by requiring use of single predicate tobacco product. With respect to the comment that requests that FDA permit this for pending SE Reports, as explained in previous paragraphs, this rule does not apply to pending submissions.

(Comment 53) Some comments suggest that requiring that predicate tobacco products be ''fully characterized'' would be too restrictive and have an anticompetitive impact. These comments state that the level of detail required to fully characterize a predicate tobacco product would necessarily limit each manufacturer to using its own products as predicates and would become too difficult with the passage of time. The comments also suggest there is no public health purpose to requiring these data on predicates.

(Response 53) We disagree. Demonstrating substantial equivalence necessitates a comparison of physical characteristics between a new and predicate tobacco product. In the absence of predicate product characteristics, FDA is unable to conduct scientific review and fulfill its statutory obligation. If an applicant does not have access to a predicate product or wishes to use a predicate product they do not own, one option is the use of a Tobacco Product Master File (TPMF) (see, *e.g.,* the guidance entitled ''Tobacco Product Master Files, which can be accessed at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files*). A TPMF is a file that is voluntarily submitted to the Center for Tobacco Products (CTP) that contains trade secret and/or confidential commercial information about a tobacco product or component that the owner does not want to share with other persons. TPMFs are a beneficial tool for manufacturers, component suppliers, and ingredient suppliers, and can assist the tobacco product submission process. Also, as discussed in the following paragraph, if an applicant no longer manufacturers a predicate product, it can be remanufactured and tested for the purposes of SE review, or a surrogate may be appropriate for use in place of the actual predicate tobacco product.

- Comparison Information (§ 1107.18(g)) (Surrogates)

In the proposed rule, in the description of § 1107.18(g), FDA requested comment on the use of information from surrogate tobacco products where there is inadequate data available for the new or predicate tobacco product. FDA received several comments on the use of information from surrogate tobacco products.

(Comment 54) One comment states that manufacturers should not be able to use a surrogate tobacco product in the place of a predicate tobacco product. The comment argues that there is no statutory basis for allowing this, and requests FDA to remove this from the final regulation.

(Response 54) Under the statute, applicants must submit an SE Report that provides information to support that a new tobacco product is

substantially equivalent to a predicate tobacco product. The use of surrogate tobacco products in certain situations does not change those statutory requirements. Although permitting use of a surrogate tobacco product may provide an opportunity for applicants to provide stand-in information in lieu of the precise predicate product itself, it is the applicant's responsibility to provide FDA with adequate bridging information for FDA to determine that it is appropriate to extrapolate the data provided on the surrogate tobacco product to the actual predicate product. Ultimately, FDA makes a determination as to whether or not the new product is substantially equivalent to the selected, valid predicate product.

(Comment 55) Several comments request that FDA provide more information regarding the use of surrogate tobacco products, including whether these may be used for SE Reports for cigars. Some comments request that FDA define a surrogate product in the final regulation or that FDA clarify when and how surrogate data may be used, to ensure that its use is applied consistently across applicants and FDA reviewers. The comments on this topic request more clarity on the use of surrogates to assist applicants in providing sufficient information about the surrogate in their submissions.

(Response 55) Although we are not adding a definition of ''surrogate tobacco product'' to this final rule, for the purposes of an SE review, FDA considers a surrogate tobacco product to be a tobacco product, other than the predicate or new tobacco product that is the subject of the SE Report, for which data are available (or can be generated) and may be scientifically bridged or extrapolated to the predicate or new tobacco product. A surrogate tobacco product is not a fictional tobacco product, but an actual product for which there are empirical data.[10] FDA believes that, when appropriate, applicants, regardless of category of tobacco product, may use a surrogate tobacco product but should clearly designate the specific parts of the SE Report for which the surrogate tobacco product is to be used.[11] Such a surrogate tobacco product may be used, where appropriate, by an applicant looking to demonstrate the substantial equivalence of a new cigar product as compared to a valid predicate.

FDA believes it would only be appropriate to use a surrogate tobacco product when the relevant data are not available for the new or predicate tobacco product and the surrogate tobacco product data can be scientifically bridged to the new or predicate product. Data for a surrogate tobacco product may be provided in place of data for the new or predicate tobacco products, but applicants should provide a scientific justification for why it is reasonable to use the surrogate data and then bridge between the surrogate data and the new or predicate tobacco product. For example, if stability data for a smokeless predicate product are not available, but there is a smokeless surrogate product for which there is stability testing data that can be bridged to the predicate (*e.g.,* through data on the water content and activity, tobacco (blend and format), ingredients, and container closure), these data could be used for the missing predicate stability data. Similarly, if smoking regimen data (intense and non-intense) for the predicate tobacco product are not available, test data from a surrogate tobacco product could be appropriate if the predicate and surrogate tobacco products can be bridged through data (*e.g.,* ventilation, paper, tobacco blend, filtration). However, surrogate products should not be used for the purpose of extrapolating *target* specifications and *range limits* from a surrogate product to a new product (emphasis added). This is because target specifications and range limits should be specified by the manufacturer for the new tobacco product. If an applicant chooses to use a surrogate tobacco product, we recommend an SE Report include the following information related to the surrogate product:

- The tobacco product to which data on the surrogate product is to be bridged (*e.g.,* predicate product);
- A detailed description of the ingredients in the surrogate product, noting any difference(s) in ingredients from the bridged tobacco product (*i.e.,* the new tobacco product or predicate tobacco product);
- Design parameters of the surrogate product (*e.g.,* cigarette paper base paper porosity, ventilation, tobacco cut or particle size);[12]
- An identification in a side-by-side list of the specifications for ingredients and additives, and materials and design parameters, that differ between the surrogate and the tobacco product to which data (*e.g.,* HPHC or stability) on the surrogate product is to be bridged, including tobacco blend or other ingredients, design parameters, and materials such as pouch, filter tow, or paper. To facilitate review and reduce FDA requests for clarification, FDA recommends that side-by-side comparisons of the surrogate and corresponding predicate or new product be provided in tabular format. Where any difference in the characteristics of the products has the potential to impact the use of test data between the surrogate and predicate or new tobacco product, a scientific justification that explains how the surrogate data may be bridged to the predicate or new product will help FDA evaluate whether the surrogate is appropriate. We recommend that the SE Report include supporting information, *e.g.,* publications to show that bridging is appropriate (this may be provided in an appendix);
- Testing procedures used to measure and obtain data on the surrogate tobacco product that may be used in lieu of data on the predicate product;
- Surrogate tobacco HPHC yields or quantities (these would not be needed when the new or predicate tobacco product is available for testing);
- Method validation reports of analytical testing (*e.g.,* accuracy,

[10] Note that a predicate tobacco product that is no longer being manufactured may be reproduced using the design parameters, tobacco blend, structural materials, and ingredients that are identical to those of the predicate tobacco previously produced, and, in this case, FDA would consider the reproduced predicate product to be the predicate product. But if the reproduced predicate product differs from the predicate product in any characteristic, FDA would consider the product to be a surrogate and the applicant would have to supply appropriate bridging information to the selected predicate product. For example, if the reproduced predicate product has the same tobacco blend (percentage of tobacco type) and tobacco curing process as the predicate product, FDA would consider the reproduced predicate product to be the predicate product, even if the crop years are different. If, however, there is any change in the amount of ingredients, including grade and purity or in materials or design parameters, including any change to a manufacturing process that would affect design parameters, FDA would consider the reproduced product to be a surrogate tobacco product.

[11] Surrogate products are not predicate tobacco products. Evidence of commercial marketing for surrogate products is not appropriate to determine whether the predicate tobacco product is a tobacco product commercially marketed (other than for test marketing) as of February 15, 2007.

[12] For example, if an applicant submits HPHC data from a surrogate combusted filtered cigarette in lieu of HPHC data from a predicate combusted filtered cigarette, the applicant could explain that the surrogate data are appropriate for FDA to consider because the surrogate and predicate tobacco products are identical with the exception of tobacco blend differences. The SE Report also should include data that show those differences are not expected to cause the surrogate tobacco product to yield significant differences in HPHC when compared to the predicate product. Please note that this is just one approach, and FDA expects that the scientific justification for use of the surrogate tobacco product may vary from case to case and depend on the type of differences (*e.g.,* in tobacco blend, design features) between the surrogate tobacco product and the new or predicate tobacco product.

repeatability, limit of detection, limit of quantification).

(Comment 56) One comment asks whether one product could be a surrogate for another product if the products contain an identical blend, but one product is wrapped in cellophane and the other is not.

(Response 56) While it may be possible to use a surrogate product in this instance, because the answer to this comment depends on more specific information than is provided, we recommend that for this or any other specific question related to the use of surrogates, the applicant contact the Agency.

(Comment 57) A few comments reference the comparison requirements (in § 1107.19) stating these unreasonably restrict the use of surrogate products and do not promote clarity and efficiency.

(Response 57) As we discuss in detail in preceding paragraphs, FDA is allowing the use of surrogate tobacco product data in specific scenarios and has provided a more robust description on how a surrogate can be utilized in an SE Report. Section 1107.19 does not place limitations on the type of scientific data an applicant may provide surrogate information for in lieu of the actual new or predicate tobacco product.

• Statement of Compliance With Applicable Tobacco Product Standards (§ 1107.18(i))

In the proposed rule, we invited comment on how we should handle SE Reports that are pending at the time a final product standard issues with respect to the requirement that the SE Report include a statement of compliance with any applicable standard. We received some comments in response, which we discuss and respond to in the following paragraphs.

(Comment 58) One comment suggested that FDA should continue its review of the SE Report through final determination, and, if the product is determined to be substantially equivalent, FDA could condition the marketing of that product on the manufacturer establishing compliance with the product standard that went into effect while the SE Report was under review. The comment also states that, as part of issuing a standard, FDA should establish the process for bringing legally marketed products into compliance with the standard. Another comment suggests that applicants be permitted to modify their prior statements regarding compliance, and that compliance with the standard be considered during review of the pending SE Report.

(Response 58) We appreciate the information provided in response to our invitation to comment. FDA agrees with the comments that suggest that this issue should be considered as part of issuing a standard under section 907 of the FD&C Act (21 U.S.C. 387g). Additionally, the regulatory process that FDA must follow to issue a product standard under section 907 of the FD&C Act is lengthy and would provide applicants with notice of proposed requirements well in advance of any change becoming effective.

• Compliance With Part 25 (§ 1107.18(k))

(Comment 59) Some comments urge FDA to either remove the requirement that manufacturers include an environmental assessment (EA) in their SE Reports or establish categorical exclusions for SE reports. The comments find the EA process unnecessarily burdensome without legitimate purpose. One comment objects that requiring EAs for deemed tobacco products that are still on the market is inconsistent with FDA's categorical exclusion for provisional SE Reports (those products on the market as of February 15, 2007) (see 80 FR 57531, September 24, 2015). The comment asserts FDA's different treatment of these categories of products is arbitrary and capricious. Other comments state that EAs are burdensome, with some noting greater difficulty for cigar manufacturers, and that FDA could alleviate some of these costs by allowing multiple products to be addressed in one EA or allowing the use of EA-specific master files for all products manufactured at the same facility.

(Response 59) We disagree with the assertion that the requirement of EAs is unnecessarily burdensome. FDA is required to examine the environmental impacts of issuing marketing orders under the National Environmental Policy Act of 1969 (NEPA) (FDA's implementing regulations are at title 21 CFR, part 25). Part 25 requires EAs as a means of assessing the potential environmental impacts from tobacco products, which may present environmental issues during manufacturing (*e.g.,* release of chemicals), use (*e.g.,* smoke and aerosol may impact air quality), and disposal (*e.g.,* litter, which persists in the environment and is toxic to different organisms). Per § 25.20, an EA is normally required for the issuance of an SE order, except that provisional SE reports that receive an SE order are categorially excluded under § 25.35(a). SE Reports for which an NSE is issued are also categorically excluded from having an EA under § 25.35; however, that outcome is not known until review of an SE Report is complete.

FDA also disagrees with the assertion that the requirement of EAs for deemed tobacco products still on the market is inconsistent, arbitrary, or capricious in comparison to the requirements for provisional products. In issuing the categorical exclusion for provisional products, FDA provided an estimate of the environmental impacts of all FDA-regulated tobacco products on the market, including products marketed after February 15, 2007, and before March 22, 2011, and pre-Existing tobacco products (tobacco products that were commercially marketed in the United States as of February 15, 2007) (79 FR 3742 at 3746). FDA currently lacks the information to conduct such an analysis for deemed tobacco products still on the market. Unlike provisional products, deemed tobacco products include products whose environmental impacts are largely unknown, with the potential to result in greater or different impacts on the environment compared to other tobacco products. Because there is no basis for such a categorical exclusion at this time, NEPA and its implementing regulations require FDA to examine the potential environmental impacts from the issuance of an SE order; therefore, EAs are required for deemed tobacco products to comply with NEPA.

We disagree with the suggestions that a single EA be submitted for multiple products or that an EA-specific master file be permitted. Additionally, FDA is required by regulation to evaluate the environmental impact individually from one proposed action (§ 25.40(a)). An aggregated impact from multiple products is not sufficient under NEPA to determine whether the individual proposed action has a significant impact on the human environment.

• Certification Statement (§ 1107.18(l))

(Comment 60) Some comments assert that FDA has no authority to impose the certification requirement or that it invites imprecision and falsification particularly when certifying that characteristics are identical without supporting test data. Other comments suggest there is no need for this ''additional assurance.'' Two comments suggest that an applicant should be permitted to submit a certification stating that all characteristics of the new and predicate tobacco products are identical except for those identified. Alternatively, other comments support

the certification approach and request that we permit applicants of currently pending SE Reports to submit such a certification without waiting for the final rule to become effective. One comment states that any certification that some or all characteristics are identical must be fully supported by actual test data.

(Response 60) We disagree that FDA does not have the authority to impose the certification requirement, that it invites imprecision or falsification, or is unnecessary. Section 905(j)(1) of the FD&C Act authorizes FDA to issue regulations prescribing the form and manner of SE Reports, and we have included this requirement based on that authority. Notably, as some comments indicate, these certifications can help minimize the burden on applicants by providing an opportunity to certify when characteristics are identical (§ 1107.18(*l*)(2)). With respect to the concern related to ensuring there is underlying support for a certification, the certification is intended in part to ensure that an applicant is prepared to support their SE Report with further information, if needed (for example, the certification in § 1107.18(*l*)(2) provides that the company ''will maintain records to support the comparison information in § 1107.19 that substantiate the accuracy of this statement''). Moreover, after careful consideration of this concern, we also have included in § 1107.18(*l*)(2) a requirement that a justification for the certification be included. Such a justification could include, for example, the type of test data that was compared between the new and predicate tobacco products and/or a description of the quality control checks that were conducted, which demonstrate the characteristics being certified are identical. The certification also is intended to provide FDA with assurance that the applicant has fully considered the SE Report and its contents, believes there is a basis for making the findings required by section 910(a)(2) of the FD&C Act, and understands the potential consequences of submitting false information to the U.S. Government.

Thus, contrary to what some of the comments suggest, the certification is an important, but also simple, means of helping ensure that the authorized representative is aware of and understands the recordkeeping requirements, that the submission is truthful and accurate, and the representative is authorized to submit the SE Report on behalf of the applicant. For a certification under § 1107.18(*l*)(2), the certification also helps ensure that the authorized representative is aware of and understands that, in lieu of providing data for each characteristic of the new and predicate tobacco products, the applicant is choosing to certify that the characteristics of the products are identical and that records will be maintained to support this determination. With respect to the comment that requests FDA permit this for pending SE Reports, as explained in preceding paragraphs, this rule does not apply to pending submissions.

3. Comparison Information (§ 1107.19)

Proposed § 1107.19 set out the comparison information that would be required in an SE Report. It also set forth the manner in which the comparison section of the SE Report would be required to be organized, and explained that applicants who make a comparison of a new product to a predicate product may also need to provide information to demonstrate that the new tobacco product is substantially equivalent to the original predicate tobacco product. Following our consideration of the comments, which we describe and respond to in detail in this section, we are clarifying in this preamble and in changes to the codified that § 1107.19 applies to ''different characteristics'' SE Reports. ''Same characteristics'' SE Reports do not need to include the information in this section. In reviewing an SE Report, FDA may request additional information if needed to make an SE determination.

On our own initiative, we have revised the introductory text in § 1107.19 so that it no longer states ''The comparison section of the SE Report must be organized in the following manner'' as not all of the subsections require information to be submitted in an SE Report, and instead added ''as described in this section.'' Following our consideration of comments and based on our increased experience reviewing SE Reports, we are finalizing with changes § 1107.19(a) (comparison of product design). These changes include the addition of design parameters for cigars, pipes, waterpipes, ENDS, and heated tobacco products, as described in detail in the product design paragraphs that follow.

In addition, we have made clarifications in § 1107.19(c) (product composition), including replacing ''material'' with ''ingredient'' in paragraph (c)(2)(iv) due to a typographical error; adding examples of the type of tobacco to be identified and striking ''grade and variety'' in paragraph (c)(3)(i) because tobacco grading is not uniform throughout the industry, which reduces the utility of this information in application review, and FDA does not need to characterize the tobacco type to the level of detail of tobacco variety for the purposes of an SE evaluation; adding a requirement that information on the type of curing method be submitted as paragraph (c)(3)(ii) because the curing method is known to influence the formation of TSNAs and other select HPHCs and this information will allow FDA to fully characterize the tobacco (Refs. 13 and 14); adding ''of each type'' following quantity in paragraph (c)(3)(iii), and striking proposed paragraph (c)(3)(iii) to clarify we need this for each type of tobacco since many tobacco products are made from blends of different tobacco types.

To § 1107.19(d)(1)(ii)(F) we have added a requirement that full validation reports for each analytical method be included because, as noted in the earlier discussion in this rule, this information is needed to ensure the method is fit for purpose and the measured values can be accurately compared between a new and predicate tobacco product.

In addition, we added that reference product datasets be included (if applicable) in § 1107.19(d)(1)(ii)(J). A reference product is a product of known physical and chemical composition and is typically accompanied by a Certificate of Analysis that states the attributes of the reference product. A suitable reference product is one that is compositionally and functionally representative of the test samples in the study, and laboratories may use a reference product for proficiency testing to demonstrate that the laboratory is capable of accurately measuring tobacco chemicals of interest and as a control sample during instrument calibration, method validation, and sample analysis. Thus, reference product datasets are used to demonstrate that the test results obtained from testing of tobacco products are reliable. Because of the addition of reference product datasets to the final rule, we have renumbered proposed § 1107.19(d)(1)(ii)(J) to § 1107.19(d)(1)(ii)(K). In the final rule, we also are adding to § 1107.19(d)(1)(ii)(K) ''Test data for combusted or heated tobacco products must reflect testing conducted using both intense and nonintense smoking or aerosol-generating regimens, where established'' (Refs. 15 and 16). The proposed rule explained that for combusted tobacco products constituent smoke yields from the new and predicate tobacco products would need to be determined using intense and nonintense smoking regimens, but the proposed codified did not specifically reference these regimens (see 84 FR

12740 at 12763). Following our consideration of comments on this issue (see later paragraphs in this section for a discussion of comments), we added codified text to ensure the understanding that this is required for these products. Because heated tobacco products present issues similar to combusted tobacco products, the final rule also specifies that test data for heated tobacco products reflect testing conducted using both intense and nonintense smoking or aerosol-generating regimens, where established. The final rule also now includes a § 1107.19(d)(1)(ii)(L) that clarifies that the applicant must include in the SE Report a complete description of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable.

In addition, we have reorganized and modified proposed § 1107.19(e) for clarity. We also added a requirement for information on the heat treatment process (if applicable), which is a tobacco processing method that could potentially reduce the microbial load of the tobacco product and result in lower levels of carcinogenic TSNAs, thereby altering product composition (*i.e.,* product characteristics) in § 1107.19(e)(2) (Refs. 17 and 18). For better organization, we moved the stability information in proposed § 1107.19(e) to § 1107.19(f); moved the testing information from proposed § 1107.18(h) to § 1107.19; and renumbered proposed § 1107.19(f) to § 1107.19(g) and proposed § 1107.19(g) to § 1107.19(h) in this final rule.

Following our consideration of comments, we are finalizing the stability testing in § 1107.19(f) with some changes. First, we are expanding the types of tobacco products that will need to submit information on stability and shelf life. The proposed rule would only have required stability testing information for smokeless tobacco products and tobacco products that contained fermented tobacco, including naturally fermented tobacco. As explained in the proposed rule, stability information is a particular concern with smokeless tobacco products and other tobacco products that contain fermented tobacco because the characteristics of these products can be affected by the manufacturing process, storage conditions, and length of time on a shelf.

Upon further consideration, the final rule will require information on stability and shelf life for all tobacco products, except RYO tobacco products and cigarettes that are not HTPs.[13] Information obtained through stability testing and shelf life is important for FDA to consider during its review to ensure that the tobacco products are microbiologically and chemically stable during storage and do not result in different questions of public health. Fermentation of tobacco (including natural fermentation) affects the microbial content, which could potentially affect TSNA content and product stability (Refs. 19–24). In addition, based on our experience, HTPs can contain high levels of humectants, which can affect product stability; therefore shelf life and stability information is required to support an SE report for HTPs. Humectants function to keep a product moist, thereby impacting the moisture content and water activity of the product, which in turn may impact microbial growth and product stability (Ref. 25).

Based on FDA's experience with cigarettes and RYO tobacco products under the SE pathway and because the vast majority of cigarettes and RYO tobacco products do not contain fermented tobacco, these products do not have the same stability concerns. However, we lack similar experience with more novel tobacco products, such as ENDS and HTPs, and thus need stability information for these types of products to determine whether there is a difference in microbial factors or HPHC quantities over time. The proposed rule did not specify that this information was needed for novel tobacco products because we did not expect many substantial equivalence reports to be submitted for novel tobacco products. In reviewing the PMTA rule and its stability requirements, though, we recognized the possibility that a novel product manufacturer may pursue authorization through the SE pathway and we wanted to make sure that both the PMTA and SE regulations would require applicants to provide the Agency with the necessary stability information. FDA believes information regarding these products' shelf life and stability over time is needed to ensure FDA fully understands the microbial and chemical stability of the new and predicate tobacco products throughout their stated shelf life, and will thus have the needed information to make the SE determination.

Second, stability testing requirements have been updated to remove identification of microbiological organisms by genus and species and remove testing for pH, moisture content, nitrate and nitrite levels, and preservatives and microbial metabolic inhibitors. In addition, if a tobacco product does not have a defined shelf life, stability data will need to be provided over a specified amount of time with a justification for why that time period is appropriate.

Section 1107.19(f)(2) of the proposed rule (now § 1107.19(g)(2)) stated that, when an applicant states that its new tobacco product has different characteristics than the predicate tobacco product, the applicant must also include an explanation as to why a difference in any of the following characteristics do not cause the new product to raise different questions of public health: Product design (§ 1107.19(a)); heating source (§ 1107.19(b)); materials and ingredients (§ 1107.19(c)); and other features (§ 1107.19(d)). In addition, to demonstrate that a new tobacco product with different characteristics is substantially equivalent, an applicant must also explain why any difference in the manufacturing process between the new tobacco product and the predicate tobacco product does not raise different questions of public health (§ 1107.18(e)). Similarly, for smokeless tobacco products, an applicant must explain why any difference in stability between the new tobacco product and the predicate tobacco product does not raise different questions of public health (§ 1107.19(e)). In the final rule, we have updated this subsection to remove repetitive language (*i.e.,* ''with different characteristics''), add clarifying language (''would not change the characteristics of the new tobacco product such that the new tobacco product could'' and ''cause the new tobacco product to''), and after ''smokeless tobacco'' add ''and tobacco products that contain fermented tobacco as these tobacco products have similar stability considerations.''

We have also updated § 1107.19(i) to reflect the updated definition of predicate tobacco product, as described in the definitions section of this final rule.

- Product Design (§ 1107.19(a))

In the following paragraphs, we describe in more detail the changes to § 1107.19(a)and we describe the comments submitted on § 1107.19(a) and our responses to those comments.

We have revised § 1107.19(a) so that it does not require test data, target specifications and range limits be submitted in all instances, as the proposed rule would have required.

[13] See the discussion in section V.D.2, about how products should be categorized for purposes of SE review.

Instead, § 1107.19(a) requires that SE Reports include test data (including test protocols, quantitative acceptance criteria, data sets (*i.e.,* measured values), and a summary of the results) only when the target specification or range limits of the new tobacco product differ from the predicate tobacco product. We have also clarified that test data would need to be submitted for both the new and predicate tobacco products. Additionally, FDA has clarified that for tobacco cut size or particle size, when target specifications and range limits are not available, the following alternative information may be submitted in place of this information: A description of the tobacco cutting process (including a complete description of the milling, cutting, and sifting process; the control parameters of the miller or cutter; and any sift specifications) or the measured particle size distribution for the new and predicate tobacco products. This alternative may be used, for example, if an applicant does not set target specifications or range limits for tobacco cut size. In this case, they could submit information about the tobacco cutting process of the new and predicate tobacco products to demonstrate that the products are substantially equivalent.

Applicants may also choose to submit the necessary design parameter information using a Manufacturing Data Sheet Specification (MDSS) document. The MDSS is a document typically maintained by manufacturers, describing all the parameters that are controlled by the manufacturer during manufacture of their tobacco products. However, there will be cases where the design parameters on the MDSS will not directly translate into one of the product-specific design parameters required in § 1107.19. In these cases, additional information would need to be submitted to provide the complete characterization necessary. Additionally, FDA will not require test data for all parameters for which target and range are required. For example, for parameters that are observational (*e.g.,* number of waterpipe holes), FDA would not seek test data on that parameter. Also, some design parameters are machine settings (*e.g.,* tobacco cut size), calculated (*e.g.,* denier per filament), provided by suppliers (*e.g.,* Certificate of Analysis for base paper porosity), or can be extrapolated from other design parameter test data (*e.g.,* filter pressure drop test data is more informative than filter length test data). FDA has clarified alternative terminology for ''porosity'' understanding that applicants may refer to this term as ''permeability'' for several design parameters, as well as adding units of measure for several design parameters.

Following our review of comments, we have revised the tables of design parameters required for certain product categories as described here:

Cigarettes: As discussed in section V.D.2 above, tobacco products that meet the definition of cigarette but are heated tobacco products should be categorized as heated tobacco products (HTPs) for purposes of SE review. Accordingly, this section discusses cigarettes that are not HTPs. Section 1107.19(a) has changed certain proposed requirements under target specification and range. These changes include: (1) Removal of the proposed requirement for applicants to provide cigarette draw resistance as FDA determined that requiring this as distinct parameter was unnecessary and not as informative as filter pressure drop because draw resistance could be modified by the user by puffing more or less intensely; (2) removal of cigarette paper base paper basis weight as it provides duplicative information that is already captured by the submission of ingredient levels (*e.g.,* a higher basis weight might be due to the inclusion of more cellulose and more calcium carbonate); (3) addition of tobacco cut size as this parameter has an influence on the chemical concentration in the combusted portion of the cigarette, combustion temperature, and affects the particle size and distribution of particles; (4) FDA has clarified terminology for cigarette paper band porosity, as applicants may refer to this term as permeability, and also provide an alternative to providing cigarette paper band porosity or permeability. Band diffusivity, while not preferred, is an acceptable alternative if it is currently not part of an applicant's practice to specify cigarette paper band porosity. Regardless of whether porosity or diffusivity is specified, the same parameter must be provided for both the new and predicate tobacco products to conduct a meaningful comparison. While there are minor differences (porosity is more relevant during active puffing, whereas diffusivity is more relevant during smoldering), the addition of diffusivity as an alternative parameter allows flexibility to applicants who do not directly measure porosity or permeability while still providing FDA with the information it needs to make the substantial equivalence finding (Ref. 26).

FDA has revised certain proposed parameters for test data which include: (1) Removal of puff count as this was duplicative of information that an applicant would submit with smoke constituent data because puff count is determined in a smoking machine using either the International Organization for Standardization or Health Canada Intense smoking regimen or other applicable regimen (Refs. 27 and 28); (2) removal of cigarette draw resistance as explained above; (3) removal of cigarette paper base paper basis weight as explained above; (4) addition of tobacco filler mass as this has a direct influence on smoke constituents (Ref. 29); and (5) the option to provide oven volatiles instead of moisture as this provides similar information to FDA (Ref. 30) [14] and allows the applicant flexibility to provide either parameter based on the specific manufacturing processes they employ.

Smokeless Tobacco: Section 1107.19(a) has changed certain proposed requirements under target specification and range. These changes include: (1) Removal of portion thickness as it is an unnecessary parameter because it is the pouch effective area that may result in an increase of the release level of nicotine, unprotonated nicotine, and could affect TSNA levels and the pouch effective area can be calculated from other required design parameters, *i.e.,* pouch length and pouch width; (2) addition of pouch material thickness as this parameter influences the release level of nicotine and can affect TSNA levels; [15] (3) addition of nicotine dissolution rate because it is a measure of how much free nicotine a user could be exposed to and differences in nicotine dissolution can have an impact on addiction and nicotine uptake (Refs. 31, 32, 85); and (4) clarification of requiring certain parameters ''if applicable'' for portioned product properties (*i.e.,* portion length, portion width, and portion mass, ''if applicable'' has been removed) because these parameters are needed for all portioned smokeless products. However, not all portioned products are pouched, so the pouch-specific

[14] Please note that the term ''moisture,'' has widely varying and conflicting definitions and terminology in use within the tobacco industry. It is common for ''moisture'' or ''moisture content'' to be used to refer to water content of a material but in relation to the tobacco industry it is necessary to differentiate between ''moisture'' as water content and ''moisture'' as oven volatiles. *https://www.coresta.org/sites/default/files/technical_documents/main/PTM-CTR_MoistureWaterOvenVolatiles_July2014%282%29.pdf.*

[15] See, *e.g.,* Gale, N., G. Errington, and K. McAdam, Group Research & Development, British American Tobacco, ''Effects of Product Format on Nicotine and TSNA Extraction from Snus Pouches,'' Presentation at the 67th Tobacco Science Research Conference, Williamsburg, VA, September 15–18, 2013. Available at: *https://www.researchgate.net/publication/299854728_Effects_of_Product_Format_on_Nicotine_and_TSNA_Extraction_from_Snus_Pouches.*

properties should only be reported if applicable, and thus FDA has added ''if applicable'' to pouch material porosity or permeability and pouch material basis weight.

Roll-your-own tobacco, rolling papers: Section 1107.19(a) has changed a proposed requirement under target specification, range, and test data. This change includes the option to provide diffusivity in lieu of cigarette paper band porosity (also described as permeability) for the reasons explained above under *Cigarettes.*

Roll-your-own tobacco, non-filtered tubes: Section 1107.19(a) has changed certain proposed requirements under target specification and range. These changes include the addition of: (1) Clarification of terminology changing ''total mass (mg)'' to ''tube mass (mg);'' (2) the option to provide tube diameter as an alternative to tube circumference as FDA is able to obtain the information necessary from other required design parameters; and (3) the option for the applicant to provide diffusivity in lieu of cigarette paper band porosity or permeability as described above. This alternative is also provided under test data for this product category.

Roll-your-own tobacco, filtered tubes: Section 1107.19(a) has changed certain proposed requirements under target specification and range. These changes include the addition of: (1) Clarification of terminology changing ''total mass (mg)'' to ''tube mass (mg);'' (2) the option to provide tube diameter as an alternative to tube circumference as FDA is able to obtain the information necessary from other required design parameters; (3) the option for the applicant to provide filter efficiency as an alternative to denier per filament, total denier, or filter density (Ref. 33); and (4) the option for the applicant to provide diffusivity in lieu of cigarette paper band porosity or permeability as described above. These alternatives (filter efficiency and diffusivity) are also provided under test data for this product category.

Roll-your-own tobacco: Section 1107.19(a) has changed certain proposed requirements under target specification, range, and test data. This change includes the removal of the requirement for the applicant to provide filler mass as this is provided as part of unique identification of the tobacco product under § 1107.18.

In addition, in the proposed rule, we invited comments and information on the parameters that may be needed to support an SE Report for tobacco products that were not specifically included in the proposed rule, such as cigars and ENDS. Based on the comments and information we received, we have added design parameters to § 1107.19(a) for cigar tobacco products, pipe tobacco products, waterpipe tobacco products, ENDS tobacco products, and heated tobacco products, as described in the following paragraphs.

Cigars. Cigarettes (outside the category of heated tobacco products) and cigars are generally similar in design and principles of operation as they are both cylinders filled with a blend of processed tobacco that is generally smoked. Both are generally lit with a fire source, which burns the tobacco as the user inhales at one end; thus, they are consumed and deliver nicotine in a similar manner. A main difference between cigarettes and cigars is that cigars are either wrapped in a tobacco leaf (wrapper and binder) or a material containing tobacco, whereas non-HTP cigarettes are wrapped in paper (cigarette paper) or a material that does not contain tobacco. Additionally, cigars come in a wider variety of sizes and may be thicker in diameter and contain more tobacco filler than cigarettes. Despite these differences, for both types of tobacco products, no matter the size, air is pulled through the tobacco column, which aids in tobacco combustion and nicotine delivery. Cigarette paper commonly has an established porosity or permeability, that is set during manufacturing, while cigar wrapper properties are based on the tobacco used as the wrapper. Although cigars and cigarettes may be wrapped in different materials, both cigar wrappers and binders, as well as cigarette papers, have inherent permeabilities/porosities, which may affect smoke constituent yields. Cigars may be filtered (containing filter tow or other materials), unfiltered, or unfiltered with tips made of wood or plastic, while most cigarettes have filters (containing filter tow) and do not contain tips. If a cigar does contain a filter, it will be similar to cigarette filters and contain tow. Based on FDA's experience with cigarettes, many design parameters required to assess public health impacts for cigarettes will also be needed to assess public health impacts for cigars. The following paragraphs describe in more detail the required parameters for each subcategory of cigars.

Filtered, sheet-wrapped cigars: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize filtered, sheet-wrapped cigars and how changes to these parameters may impact public health, as described next:

- Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 34).
- Cigar puff count can directly affect smoke constituent yields (Ref. 34).
- Cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 35).
- Tobacco filler mass may affect smoke constituent yields (Ref. 34).
- For cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper and binder basis weight may affect puff count and smoke constituent yields (Refs. 36 and 37).
- For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper and binder width and wrapper length may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields.
- Cigar wrapper porosity may affect smoke constituent yields (Refs. 37 and 38).
- For cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 39 and 40). Similarly for cigars, the tobacco rod density may modify burn properties and smoke constituent yields.
- For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for cigars, the tobacco moisture or oven volatiles may affect puff count.
- For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 42). Similarly for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.
- For cigarettes, the band porosity may affect smoke constituent yields (Ref. 43). Similarly for cigars, the wrapper or binder band porosity or permeability may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the paper during active puffing.
- For cigarettes, the band width may affect smoke yields (Ref. 44). Similarly for cigars, the wrapper band width and binder band width may affect ventilation and, in turn, smoke constituent yields.
- For cigarettes, the band space may affect puff count (Ref. 45). Similarly for cigars, the wrapper band space and binder band space may affect ignition propensity and, in turn, puff count.

○ For cigarettes, the filter parameters can impact smoke yields (Ref. 33). Similarly for cigars, the filter diameter, filter mass, and filter tow crimping index, denier per filament, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields.

○ For cigarettes, the filter pressure drop affects smoke yields (Ref. 46). Similarly for cigars, the filter pressure drop may affect smoke constituent yields.

○ For cigarettes, tipping paper length may affect smoke constituent yields (Ref. 47). Similarly for cigars, the tipping paper length may affect smoke constituent yields.

○ Ventilation may affect smoke constituent yields (Ref. 34).

○ For cigarettes, the diameter can affect the smoke yields (Ref. 46). Similarly for cigars, the cigar maximum and minimum diameter may affect rod density, which modifies the burn properties and smoke yields; FDA needs this information to characterize the diameters as shapes of cigars can differ with the tips being narrower than the center of the cigar. This may result in multiple rod densities used to test the smoke and influence smoke yields depending on what part of the cigar is tested.

○ For cigarettes, the paper porosity may affect smoke constituents (Ref. 43). Similarly for cigars, the binder porosity may affect or may further limit air flow into and out of the cigar which may affect smoke yields.

Unfiltered, sheet-wrapped cigars: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize unfiltered, sheet-wrapped cigars and how changes to these parameters may impact public health, as described next:

○ Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 34).

○ Cigar puff count can directly affect smoke constituent yields (Ref. 34).

○ Cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 35).

○ Tobacco filler mass may affect smoke constituent yields (Ref. 34).

○ For cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper and binder basis weight may affect puff count and smoke constituent yields (Refs. 36 and 37).

○ For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper and binder width and wrapper length may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields.

○ Cigar wrapper porosity may affect smoke constituent yields (Refs. 37 and 38).

○ For cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 39 and 40). Similarly for cigars, the tobacco rod density may modify burn properties and smoke constituent yields.

○ For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for cigars, the tobacco moisture or oven volatiles may affect puff count.

○ For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 42). Similarly for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.

○ For cigarettes, the band porosity may affect smoke constituent yields (Ref. 43). Similarly for cigars, the wrapper or binder band porosity or permeability may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the paper during active puffing.

○ For cigarettes, the band width may affect smoke yields (Ref. 44). Similarly for cigars, the wrapper and binder band width may affect ventilation and, in turn, smoke constituent yields.

○ For cigarettes, the band space may affect puff count (Ref. 45). Similarly for cigars, the wrapper and binder band space may affect ignition propensity and, in turn, puff count.

○ Cigar tip mass, length, and inner diameter dimensions directly influence the overall cigar draw resistance and in turn, puff count (Ref. 48).

○ For cigarettes, the diameter can affect the smoke yields (Ref. 46). Similarly for cigars, the cigar maximum and minimum diameter may affect rod density, which modifies the burn properties and smoke yields; FDA needs this information to characterize the diameters as shapes of cigars can differ with the tips being narrower than the center of the cigar. This may result in multiple rod densities used to test the smoke and influence smoke yields depending on what part of the cigar is tested.

○ For cigarettes, the paper porosity may affect smoke constituents (Ref. 43). Similarly for cigars, the binder porosity may affect or may further limit air flow into and out of the cigar which may affect smoke yields.

Unfiltered, leaf-wrapped cigars: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize unfiltered, leaf-wrapped cigars and how changes to these parameters may impact public health, as described next:

○ Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 34).

○ Cigar puff count can directly affect smoke constituent yields (Ref. 34).

○ For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar binder and wrapper length and wrapper width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields.

○ Cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 35).

○ For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for cigars, the tobacco moisture or oven volatiles may affect puff count.

○ For cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper and binder basis weight may affect puff count and smoke constituent yields (Refs. 36 and 37).

○ For cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 39 and 40). Similarly for cigars, the tobacco rod density may modify burn properties and smoke constituent yields.

○ For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 42). Similarly for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.

○ Tobacco filler mass may affect smoke constituent yields (Ref. 34).

○ For cigarettes, the diameter can affect the smoke yields (Ref. 46). Similarly for cigars, the cigar maximum and minimum diameter may affect rod density, which modifies the burn properties and smoke yields; FDA needs this information to characterize the diameters as shapes of cigars can differ with the tips being narrower than the center of the cigar. This may result in multiple rod densities used to test the smoke and influence smoke yields depending on what part of the cigar is tested.

Cigar filler:[16] Section 1107.19(a) describes the design parameters that

[16] These design parameters are for an SE Report where ''cigar filler'' is the new tobacco product (not

must be contained in an SE Report to fully characterize cigar filler and how changes to these parameters may impact public health, as described next:

○ For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 42). Similarly for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.

○ For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for cigars, the tobacco moisture or oven volatiles may affect puff count.

Cigar component:[17] Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize a cigar component and how changes to these parameters may impact public health, as described next:

○ For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper length and width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields.

○ For cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper basis weight may affect puff count and smoke constituent yields (Refs. 36 and 37).

○ Cigar wrapper porosity may affect smoke constituent yields (Refs. 37 and 38).

Pipe. Cigarette tobacco and pipe tobacco are similar, as they are both processed tobacco that is cut, milled, and sifted before ingredients are added to control for tobacco moisture and taste. Therefore, tobacco parameters for a cigarette can be extrapolated to tobacco parameters for a pipe. Additionally, the filter in a pipe is similar to a filter in a cigarette, as they both contain tow and the length of the filter can determine the amount of suction a smoker needs to apply to the tobacco product to draw smoke through (filter pressure drop). Furthermore, the filter in a pipe can affect the filter efficiency just as a cigarette filter would. Therefore, filter pressure drop and filter parameters for a cigarette can be extrapolated to the filter parameters for a pipe. Based on FDA's experience with cigarettes, many design parameters required to assess public health impacts for cigarettes will also be needed to assess public health impacts for pipes. The following paragraphs describe in more detail the required parameters for each subcategory of pipes.

Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize a pipe and how changes to these parameters impact public health, as described next:

○ The bowl chamber inner and outer diameters allow FDA to calculate the chamber wall thickness. A thicker wall will lead to a cooler smoke and makes it less likely the user will burn themselves when holding the chamber. Additionally, the chamber inner diameter will affect temperature and tobacco capacity, meaning the greater the pipe surface area, the more leaf can be burned at once, and with increased temperature, as we have learned from our experience with other types of tobacco products (*e.g.,* cigarettes), this will affect smoke constituents.

○ The bowl chamber hole shape is important to characterize the pipe as this may affect the airflow and tobacco temperatures, which, as we have learned from our experience with other types of tobacco products (*e.g.,* cigarettes), affects the burn rate and smoke constituents delivered.

○ The bowl chamber volume affects the burn rate and temperature, which, as we have learned from our experience with other types of tobacco products (*e.g.,* cigarettes), dictates the smoke constituents delivered to users.

○ The draught hole allows the user to pull air through the tobacco to their mouth. The diameter of the draught hole affects the resistance to draw which, as we have learned from our experience with other types of tobacco products (*e.g.,* cigarettes), can impact nicotine and other toxicant delivery to the user.

○ The draught hole dimensions and geometry may affect the airflow and oxygen available at the burning tobacco for the chemical reaction and, as we have learned from our experience with other types of tobacco products (*e.g.,* cigarettes), can affect smoke constituent yields.

○ The location of the draught hole can affect airflow and tobacco temperatures, which, as we have learned from our experience with other types of tobacco products (*e.g.,* cigarettes), affects the burn rate and smoke constituents delivered.

○ The stem of a pipe delivers smoke from the bowl to the user's mouth. The length of the stem may affect the smoke temperature, which may affect how the product is consumed, while the width of the stem may affect resistance to draw which, as we have learned from our experience with other types of tobacco products (*e.g.,* cigarettes), can impact toxicant delivery to the user.

○ The shank of a pipe similarly may affect the smoke temperature (length) and resistance to draw (diameter), which, as we have learned from our experience with other types of tobacco products (*e.g.,* cigarettes), can impact nicotine and other toxicant delivery to the user.

○ For cigarettes, the filter pressure drop affects smoke yields (Ref. 46). Similarly for pipes, the pressure drop through the air valve can affect nicotine and other toxicant delivery to the user. Air flow through an air valve can affect tobacco burn rate and tobacco temperatures which in turn, may affect smoke constituent delivery to the user.

○ Some pipes may come with a filter. For cigarettes, filter diameter, denier per filament, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 33). Similarly for pipes, the filter efficiency, filter pressure drop, and filter length may affect smoke constituent yields.

Pipe tobacco. Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize pipe tobacco and how changes to these parameters may impact public health:

○ For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 42). Similarly for pipes, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.

○ For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for pipes, the tobacco moisture or oven volatiles may affect puff count.

Waterpipes: Cigarette tobacco and waterpipe tobacco are similar, as they are both processed tobacco that is cut, milled, and sifted before ingredients are added to control for tobacco moisture and taste. Therefore, tobacco parameters for a cigarette can be extrapolated to tobacco parameters for a waterpipe. Additionally, the length of the waterpipe stem affects the pressure drop in the waterpipe in a similar way as the length of the filter and filter tow causes a filter pressure drop in a cigarette: Both determine the amount of suction a smoker needs to apply to the tobacco product to draw smoke through. Therefore, filter pressure drop for a cigarette can be extrapolated to the pressure drop of a waterpipe. Based on FDA's experience with cigarettes, many design parameters required to assess

when cigar filler is a component or part of a cigar or other tobacco product).

[17] These design parameters are for an SE Report where a ''cigar component'' is the new tobacco product (not when the cigar component is a component or part of a cigar or other tobacco product).

public health impacts for cigarettes will also be needed to assess public health impacts for waterpipes. The following paragraphs describe in more detail the required parameters for each subcategory of waterpipes.

Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize waterpipes and how changes to these parameters may impact public health, as described next:

- Hose dimensions (length and diameter) are directly proportional to air infiltration and affects toxicant yields (Ref. 49).
- Hose material may affect hose permeability, which may affect smoke constituent yields (Ref. 49).
- Water filtering efficiency is directly proportional to mainstream smoke and can increase exposure to HPHCs (Ref. 50).
- For cigarettes, the filter pressure drop affects smoke yields (Ref. 46). Similarly for waterpipes, the pressure drop may result in differences in the difficulty of pulling air through the waterpipe and, in turn, affect smoke constituent yields.
- Waterpipe components or parts, including stem, bowl, windscreen (foil), and purge valve, impact puffing behavior and toxicant exposure; therefore, the foil dimensions and ventilation may affect smoke constituent yields (Ref. 51).
- The shape and size (diameter and volume) of the base can affect the pressure drop or difficulty of pulling air through the waterpipe hose (Ref. 51).
- The head dimensions (height, top diameter, bottom diameter, volume, and number of holes) affect how long a smoke session lasts by controlling how much tobacco can be used during a session. Head dimensions can also affect airflow beneath and through the tobacco to make heat transfer more effective, prolonging smoking sessions (Ref. 51).
- The head materials could aid in heat transfer, prolonging the heating of the tobacco and causing the tobacco to reach temperatures that affect smoke yields (Ref. 52).

Waterpipe heating source: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize a waterpipe heating source and how changes to these parameters may impact public health, as described next:

- When combusted, heating sources such as charcoal or wood cinders expose the user to high yields of toxicants such as carbon monoxide and polycyclic aromatic hydrocarbons. Therefore, the heating source mass, density, and temperature may affect smoke constituent yields (Ref. 53).

Waterpipe filler: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize waterpipe filler and how changes to these parameters may impact public health, as described next:

- For cigarettes, the tobacco cut size may result in more particulate matter (Refs. 41 and 42). Similarly for waterpipe filler, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter. Finer tobacco cut size may result in a decrease in filling power and in turn, a larger amount of tobacco in the bowl.
- For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for waterpipe filler, the tobacco moisture or oven volatiles may affect puff count. Moisture contributes to packing density, thus decreasing void volume.

Waterpipe foil: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize waterpipe foil and changes to these parameters may impact public health, as described next:

- Waterpipe components or parts, including the windscreen (foil) impact smoke's puffing behavior and toxicant exposure. Therefore, the foil dimensions such as length, width, diameter, and foil thickness may affect smoke constituent yields (Ref. 51).
- The aluminum foil perforation pattern (diameter and number of holes) impacts the path of hot gases through the tobacco mixture, which may affect smoke constituent yields (Ref. 51).

Waterpipe head: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize a waterpipe head and how changes to these parameters may impact public health, as described next:

- Waterpipe components or parts, including stem, bowl, windscreen (foil), and purge valve, impact puffing behavior and toxicant exposure; therefore, the foil dimensions and ventilation may affect smoke constituent yields (Ref. 51).

ENDS: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize ENDS and how changes to these parameters may impact public health, as described next:

- The air flow rate of the ENDS can affect the coil/heating element temperature, e-liquid consumption, and aerosol characteristics such as particle number concentration, count median diameter, and particulate matter (PM)2.5, which impact aerosol exposure (Ref. 54).
- Coil/heating element resistance may affect overall heating element resistance, thereby influencing heating element temperature. The coil/heating element's resistance, material and the voltage [18] determine the current flow and heating element temperature. Because the coil/heating element temperature is not constant, coil/heating element resistance can be used to characterize the coil temperature over time. The heating element temperature and temperature duration may affect toxicant emissions and nicotine delivery (Refs. 55–59).
- Coil/heating element resistance and battery output voltage determine power delivery unit (PDU) wattage. PDU wattage determines the amount of heat produced by the atomizer. PDU wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 57 and 59).
- An increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions may lead to greater exposure to toxicant emissions (Ref. 58).
- The temperature of the coil/heating element can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in coil/heating element temperature can increase HPHC levels in the aerosol, therefore, maximum coil/heating element temperature and temperature control deviation from this maximum coil/heating element temperature can affect toxicant emissions and nicotine delivery (Refs. 56–59).
- Number of coils/heating element present can affect overall atomizer resistance and distribution of heat dissipation (Ref. 60).
- The position of the coil/heating element can increase the possibility of dry puff conditions and subsequent increased toxicant emissions (Ref. 57).
- Atomizer and cartridge components of e-cigarettes may be heated repeatedly and aerosolized and can contribute to increased toxicant emissions (Ref. 55).
- Puff count can differ depending on other puff topography (*e.g.,* puff duration and puff flow rate), e-cigarette and atomizer design, and e-liquid parameters. Puff count can also affect total puff volume, which in turn can

[18] Voltage, current, and resistance are used to ensure the battery and the ENDS are operating within the ''normal operating range.'' The battery manufacturer sets the normal range of the voltage and current. Understanding the resistance allows FDA to assess whether the coil is drawing more current than the battery is designed for.

affect total toxicant emissions (Ref. 61). In addition, information on the puff count of ENDS helps FDA assess how the product compares with other products.

- E-liquid capacity of the atomizer tank/cartridge can affect total puff volume, which in turn can affect total toxicant emissions (Refs. 61 and 62).
- Battery/PDU voltage or voltage operating range may affect the heating element temperature, thereby affecting toxicant emissions and nicotine delivery (Refs. 56–59).
- Battery wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 57 and 59).
- Coil/heating element resistance and battery output voltage determine PDU wattage. PDU wattage determines the amount of heat produced by the atomizer. PDU wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 57 and 59).
- PDU wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 57 and 59).
- The temperature of the coil/heating element can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in coil/heating element temperature can increase HPHC levels in the aerosol, therefore, maximum coil/heating element temperature and temperature control deviation from this maximum coil/heating element temperature can affect toxicant emissions and nicotine delivery (Refs. 56–59).
- Coil/heating element resistance, number of coils/heating element, coil/heating element gauge, and coil/heating element configuration may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery (Refs. 55–59).
- Battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63).
- Battery power impacts the delivery of nicotine and the total emissions of volatile aldehydes (Refs. 64 and 65).
- Battery and PDU voltage impacts the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 65).
- The draw resistance of the ENDS impacts the ease of drawing air into the ENDS to produce aerosol, which can affect nicotine and other toxicant delivery to the user (Ref. 66). For cigarettes, we evaluate filter pressure drop since it is more informative than draw resistance; however, for ENDS, there is no filter pressure drop or other similar parameter that could be used in place of draw resistance.
- PDU current cutoff is an electrical cutoff and a safety feature, that interrupts electric current when a specific condition is met (temperature, current, etc.) to protect the user. (Refs. 55 and 63).
- Inhaled aerosol temperatures can be damaging or uncomfortable to users who inhale aerosol above a certain temperature (Ref. 67).

E-liquid. Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize e-liquids and how changes to these parameters may impact public health, as described next:

- The e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Refs. 61 and 62).
- Aerosol parameters such as particle number concentration, count median diameter, and $PM_{2.5}$ are used to characterize the amount and size of particles to which the user is exposed. Epidemiological and clinical studies have shown that exposure to large amounts of small particles can impair lung function and is correlated with cardiovascular disease (Refs. 68 and 69).
- E-liquid viscosity and boiling point impact the proportion of nicotine that is aerosolized (Ref. 70). E-liquid viscosity can also affect the e-liquid absorbency through the wick and wicking rate, possibly leading to dry puff conditions and increased toxicant emissions. Also, the e-liquid viscosity can affect the electronic cigarette nicotine and other toxicant delivery to the user (Refs. 60 and 61).
- The e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Refs. 61 and 62).

Heated tobacco products (HTP): HTPs currently sold in global markets can function in ways that are similar to products in other product categories. For example, some HTPs can function like ENDS products by aerosolizing e-liquids or using a battery and PDU to power the product. Other HTPs can contain tobacco filler, like a non-HTP cigarette or cigar, but are heated instead of combusted. For these reasons, the properties of HTPs vary widely but are comparable to the properties of other tobacco product categories. Based on FDA's experience with other similarly characterized tobacco products, many design parameters required to assess public health impacts for those products will also be needed to assess public health impacts for HTPs. The following paragraphs describe in more detail the required parameters for each subcategory of HTPs.

Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize HTPs and changes to how these parameters may impact public health, as described next.

- For cigars, the length, diameter, and mass can affect smoke constituent yields (Ref. 35). Similarly for HTPs, dimensions (mass, length, width, height, and diameter) can directly affect the amount of tobacco that is heated and, in turn, affect smoke constituent yields.
- For ENDS products, the draw resistance can affect nicotine and other toxicant delivery to the user (Ref. 66). Similarly for HTPs, the draw resistance can impact the ease of drawing air into the product to produce aerosol, which can affect smoke constituent yields.
- For ENDS, puff count can affect total toxicants emissions (Ref. 61). Similarly for HTPs, the puff count can affect puff volume, which in turn can affect total toxicant emissions.
- For ENDS, e-liquid capacity of the atomizer tank/cartridge can affect total toxicant emissions (Refs. 61 and 62). Similarly for HTPs, the product volume (capacity of the cartridge) can affect total puff volume, which, in turn, can affect total toxicant emissions.
- For ENDS, airflow rate can impact aerosol exposure (Ref. 54). Similarly for HTPs, the airflow rate allows air to flow from the heating element to the user's mouth; some products allow the user to manually change the airflow while others have a minimum airflow that activates the product. Overall, airflow rate will impact aerosol exposure.
- For cigars, ventilation may affect smoke constituents yields (Ref. 34). Similarly for HTPs, ventilation may affect smoke constituent yields.
- For ENDS, the battery and PDU voltage can impact volatile aldehydes emission (Ref. 65). Similarly for HTPs, the battery and PDU voltage impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes.
- For ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs the temperature sensor is a safety feature that allows the product power to be cut

off to ensure the product does not get too hot, causing the battery to vent or harm the user.

○ For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 36). Similarly for HTPs, the material wrapper length and width may directly influence the area through which the air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields.

○ For cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 36). Similarly for HTPs, the material wrapper basis weight may affect puff count and smoke constituent yields.

○ For cigars, the cigar wrapper porosity may affect smoke constituent yields (Refs. 37 and 38). Similarly for HTPs, the material porosity may affect smoke constituent yields.

○ For ENDS, the heating element configuration and the temperature it reaches based on the type of heating element and its configuration, can affect the chemical and physical characteristics of the aerosol delivered to the user (Refs. 56–59). Similarly, for HTPs, different heating element sources, such as coils, can reach different temperatures, which affects the chemical and physical characteristics of the aerosol delivered to the user.

○ For ENDS, the temperature of the heating element can affect the chemical and physical characteristics of the aerosol delivered to the user (Refs. 56–59). Similarly for HTPs, the temperature of the heating element (heating element temperature range, operational temperature, maximum temperature) can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in heating element temperature can increase HPHC levels in the aerosol; therefore, maximum heating element temperature and temperature control deviation from this maximum heating element temperature can affect toxicant emissions and nicotine delivery.

○ For ENDS, the heating element temperature may affect toxicant emissions and nicotine delivery (Ref. 59). Similarly for HTPs, the heating element can have a direct effect on the heat transfer to the e-liquid or tobacco, and in turn, affect the smoke constituent yields.

○ For ENDS, the heating element configuration may affect toxicant emissions and nicotine delivery (Refs. 55–59). Similarly for HTPs, the heating element configuration may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery.

○ For ENDS, the heating element dimensions may affect toxicant emissions and nicotine delivery (Refs. 55–59). Similarly for HTPs, the heating element dimensions, such as length, influence the overall surface area, which affects heating element resistance, which influences the heating element temperature.

○ For ENDS, the heating element mass may affect toxicant emissions and nicotine delivery (Refs. 55–59). Similarly for HTPs, the heating element mass influences the power delivery of the battery, and in turn, the heat applied to the e-liquid or tobacco, which affects the smoke constituent yields and in turn, affects the smoke constituent yields.

○ For ENDS, the heating element location may affect toxicant emissions and nicotine delivery (Refs. 55–59). Similarly for HTPs, the heating element location can affect nicotine emissions.

○ For ENDS, the number of heating elements may influence the heating element temperature thereby affecting toxicant exposure and nicotine delivery (Ref. 60). Similarly for HTPs, the number of coils/heating elements present can affect overall resistance and distribution of heat dissipation.

○ For ENDS, the heating element diameter or gauge may affect toxicant emissions and nicotine delivery (Refs. 55–59). Similarly for HTPs, the larger the diameter of the heating element, the lower its resistance, and vice versa. Heating element resistance may influence heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery.

○ For ENDS, the heating element resistance may affect toxicant emissions and nicotine delivery (Refs. 55–59). Similarly for HTPs, the heating element resistance may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery.

○ For cigars, tobacco filler mass may affect smoke constituent yields (Ref. 34). Similarly for HTPs, the tobacco filler mass may affect smoke constituent yields.

○ For cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 39 and 40). Similarly for HTPs, the tobacco rod density may modify burn properties and smoke constituent yields.

○ For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for HTPs, tobacco moisture or oven volatiles may affect puff count.

○ For cigarettes, tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 42). Similarly for HTPs, tobacco filler manufacturing and processing as well as tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.

○ For e-liquids, the e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Refs. 61 and 62). Similarly for HTPs, the e-liquid volume can affect the delivery of nicotine and other toxicants to the user.

○ For e-liquids, the e-liquid viscosity can affect the electronic cigarette nicotine and other toxicant delivery to the user (Refs. 60, 61, and 70). Similarly for HTPs, the e-liquid viscosity and boiling point impact the proportion of nicotine that is aerosolized (Ref. 70). The e-liquid viscosity can affect the nicotine and other toxicant delivery to the user.

○ For ENDS, an increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions may lead to greater exposure to toxicant emissions (Ref. 58). Similarly for HTPs the battery capacity is a measure of the charge stored by the battery. The higher the mAh rating, the higher the capacity of the battery and the longer it will last between charges. The longer the battery lasts, the more the user can inhale smoke constituents.

○ For ENDS the battery and PDU voltage operating range and wattage effects volatile aldehydes emission (Ref. 65). Similarly for HTPs, the battery and PDU voltage operating range or wattage impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes.

○ For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs the battery current range gives an indication of the safe zone for the battery to charge and what is considered its normal operating region; if the battery levels go beyond the safe zone while charging, the battery could be damaged, which could cause harm to the user.

○ For ENDS, the battery and PDU voltage impacts the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes

(Ref. 65) Similarly for HTPs, the battery voltage indicates how much current the battery can send out to the heating element. For the same resistance, a higher voltage will send more current (and more watts) to the heating element and it will produce more vapor. There is a link between voltage and capacity because vaping at a higher wattage will produce a higher current and that will reduce the amount of time you can vape between charges. In addition, the voltage will influence the vapor temperature, and in, turn smoke yields.

- For ENDS, an increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions may lead to greater exposure to toxicant emissions (Ref. 58). Similarly for HTPs, the battery capacity rating is a measure of the average amount of current the battery releases over time under normal use. Current may influence the heating element temperature, which in turn affects toxicant emissions and nicotine delivery. In addition, battery mAh rating provides an understanding of how long a battery will last and thus the product stability.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the battery charging temperature limits give insight on the safe range for battery charging temperatures and testing will show if the software of the battery can keep the battery in the safe zone.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the battery discharge temperature limits give insight on the safe range for battery discharging temperatures and testing will show if the software of the battery can keep the battery in the safe zone.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU and battery current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the end of discharge voltage is the level to which the battery voltage or cell voltage can fall before affecting the load. This helps to establish the life cycle of the battery.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU and battery current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the maximum current at which the battery can be charged continuously is usually defined by the battery manufacturer in order to prevent excessive charge rates that would damage the battery or reduce its capacity. Damage to batteries is a hazard to users.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU and battery current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the maximum current at which the battery can be discharged continuously is usually defined by the battery manufacturer in order to prevent excessive discharge rates that would damage the battery or reduce its capacity. Damage to batteries is a hazard to users.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the battery upper limit charging voltage is important to limit the maximum battery voltage during charging to prevent damage to the battery, which is a hazard to users.
- For ENDS, the battery and PDU voltage range may influence volatile aldehydes emissions (Ref. 65). Similarly for HTPs, the battery and PDU voltage impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes.
- For ENDS, the Battery and PDU current operating range and wattage range may influence the toxicant emissions (Refs. 57 and 59). Similarly for HTPs, the PDU current operating range and wattage operating range may influence the heating element temperature thereby affecting toxicant emissions.
- For ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the PDU temperature cutoff is an electrical safety product that interrupts electric current when heated to a specific temperature to protect the user.
- For ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the current cutoff is an electrical cutoff, which is an electrical safety product that interrupts electric current when a specific condition is met (temperature, current, etc.) to protect the user.
- For ENDS, the battery and PDU current operating range may influence the toxicant emissions (Refs. 57 and 59). Similarly for HTPs, the batteries should have a normal operating current range so as to not overheat the product and cause it to become a hazard to the user. In addition, this current range has a direct impact on the heating element, which in turn affects the smoke constituent yields.
- Inhaled aerosol temperatures can be damaging or uncomfortable to users who inhale aerosol above a certain temperature (Ref. 67).
- For e-liquids, aerosol parameters such as particle number concentration, count median diameter, and $PM_{2.5}$ are used to characterize the amount and size of particles to which the user is exposed (Refs. 68 and 69). Similarly for HTPs, the aerosol parameters such as particle number concentration, count median diameter, and $PM_{2.5}$ are used to characterize the amount and size of particles to which the user is exposed. Clinical studies have shown that exposure to large amounts of small particles can impair lung function and is correlated with cardiovascular disease.
- For cigarettes, filter pressure drop may affect smoke constituent yields (Ref. 46). Similarly for HTPs, the filter pressure drop may affect smoke constituent yields.
- For cigarettes, filter diameter, denier per filament, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 33). Similarly for the HTPs, the filter diameter, denier per filament, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields.

(Comment 61). Some comments provide information in response to the proposed rule's request for comment on the appropriate design parameters for cigars and pipe tobacco. These comments suggest the following list as appropriate design parameters to be addressed for cigars: Cigar length; ring gauge; total tobacco mass (including wrapper mass, binder mass, and filler mass); and filter ventilation (if applicable). One comment provided this list of appropriate design parameters for pipe tobacco: Tobacco filler mass (mg); tobacco cut size (mm); and tobacco moisture (%). One comment suggests that without design parameters or testing information related to cigar, hookah, pipe tobacco and other comments, the rule is deficient and further states that the final rule must include content requirements for each product category and subcategory.

(Response 61) As discussed earlier in this section, following consideration of these comments, FDA has added design parameters for cigars, pipes, waterpipes, and other tobacco products to this section. Note that FDA does not consider a tobacco product to be ''new'' if there are variations that fall within the product's specifications. So long as the product is manufactured within specified parameters, FDA would not consider variations within these parameters to be a design change that would result in a new tobacco product. It is also important to note that at this time, FDA does not intend to enforce the premarket requirements of sections 910 and 905(j) for tobacco blending changes required to address the natural variation of tobacco (*e.g.,* blending changes due to variation in growing conditions) in order to maintain a consistent product. FDA agrees with the commenter's suggested list of appropriate design parameters for pipe tobacco.

• Comparison of Heating Sources (§ 1107.19(b))

In the following paragraphs, we describe the comments and our responses on § 1107.19(b). We are finalizing this subsection without change.

(Comment 62) One comment states that the information required by proposed § 1107.19(b), which states that the SE Report must include a description of the heating source for the new and predicate tobacco products and identify any differences, or the report must state that there is no heating source in the product, is similar to the previously submitted ingredient listing information. The comment asserts that requiring manufacturers to submit this information a second time is unnecessary and would lengthen FDA's review of the SE Report.

(Response 62) Section 910(a)(3)(B) of the FD&C Act specifically identifies the heating source as one of the characteristics of a tobacco product that FDA must consider in determining whether a new tobacco product is substantially equivalent to a predicate tobacco product. We disagree that information describing the heat source of the products being compared in an SE Report is similar to or duplicative of previously submitted ingredient listing information. Although there will likely be some overlap, the ingredient listing requirement under section 904 of the FD&C Act (21 U.S.C. 387d) is a separate requirement from the requirement to submit ingredient information in a premarket application. It is necessary to receive ingredient information in an SE Report because a finding of substantial equivalence is based on a side-by-side listing of quantitative and qualitative comparisons of all product characteristics that differ between a new and predicate tobacco product.

• Comparison of Product Composition (§ 1107.19(c))

In the following paragraphs, we describe the comments and our responses on § 1107.19(c). As discussed in the introductory paragraphs to § 1107.19, we are finalizing this subsection with minor clarifying changes.

(Comment 63) Two comments took issue with the requirement in § 1107.19(c) that information on ''[t]he type of tobacco, including grade and variety'' be submitted in an SE Report. These comments assert that the Department of Agriculture grading system would not be useful because they claim that it is not uniformly used by farmers and manufacturers. Instead, they noted that each farmer and manufacturer has its own unique grading system and that a written record may not exist for such system.

(Response 63) FDA has decided to remove the requirement in § 1107.19(c) that applicants provide information regarding the grade and variety of tobacco type in their SE Reports. FDA agrees with the comments that tobacco grading is not uniform throughout the industry, which reduces the utility of this information in application review. In addition, FDA does not need to characterize the tobacco type to the level of detail of tobacco variety for the purposes of an SE evaluation. Instead, information regarding the tobacco curing process is more useful to FDA to characterize and analyze the tobacco used in the tobacco products and tobacco products in general. FDA is still requiring that the tobacco type (*e.g.,* Bright, Burley, Oriental) and curing process (*e.g.,* fire-cured, flue-cured, air-cured) be provided in SE Reports. As described in the proposed rule, the tobacco type impacts the characteristics of the products as different types have different smoke constituent profiles, including potentially different HPHC profiles (Refs. 71 and 72). The curing process also can impact HPHC profiles (Ref. 73).

• Comparison of Other Features (§ 1107.19(d))

In the following paragraphs, we describe the comments and our responses § 1107.19(d). We are finalizing this subsection with the minor clarifying changes as described in the introductory paragraphs to § 1107.19.

(Comment 64) Section 1107.19(d) lists the other features that must be included in an SE Report. One such other feature listed in § 1107.19(d) are HPHCs. Several comments express concern with the proposed requirement that data from two smoking regimens be submitted for combusted tobacco products. They state that this requirement would lead to an unnecessary and significant increase in testing burden with no corresponding benefit. However, one comment contends that, if constituent yields were reported from a single smoking regimen only, FDA would have limited and potentially misleading information about constituent yields produced by a given product.

(Response 64) We disagree that mainstream smoke data from two smoking regimens (non-intense and intense) should not be required. Each of these regimens provides unique information on the HPHCs generated by the tobacco product under different pyrolysis conditions (*i.e.,* varying amounts of oxygen due to smoker use). Studies have shown identical tobacco products smoked using a non-intense smoking regimen differ in the formation of volatile organic compounds (VOCs) and aldehydes than when smoked using an intense smoking regimen. A non-intense smoking regimen can provide the upper range of aldehydes generated from smoking while an intense smoking regimen can provide the upper range of VOCs generated from smoking. Exposure to VOCs and aldehydes results in an increased risk of cancer and respiratory disease, and for some of these VOCs and aldehydes tobacco smoke is the primary source of non-occupational exposure in the U.S. population (Ref. 74). Aldehydes, such as

formaldehyde, have been classified as class 1 carcinogens by the International Agency for Research on Cancer. A 2018 study (Ref. 75) shows aldehyde (formaldehyde, acrolein, acetaldehyde, and crotonaldehyde) formation may increase nonlinearly, up to six times more in a non-intense smoking regimen than in an intense smoking regimen. Another study showed there is a disproportionate increase in monoaromatic VOCs under a smoking regimen where the filter ventilation is blocked (*i.e.,* intense smoking regimen) compared to a non-intense smoking regimen (Ref. 76). Thus, the current state of science indicates: (1) There is a nonlinear correlation between the smoke data obtained by a non-intense compared to an intense smoking regimen and (2) due to variations in the oxygen environment during pyrolysis, different VOCs and aldehydes are formed in a non-intense smoking regimen than those formed in an intense smoking regimen.

Finally, considering smoke data from only one smoking regimen would result in an incomplete assessment of smoker exposure. A non-intense and intense smoking regimen provides an upper and lower range of HPHCs that are generated during the use of a combusted tobacco product; consequently, it is necessary that FDA evaluate smoke data obtained by both intense and non-intense smoking regimens.

(Comment 65) Several comments expressed concern regarding the requirement in proposed § 1107.19(d) that HPHC data be submitted, particularly as it relates to cigars, given the variety of cigars and the variability of several smoke HPHCs in filler HPHC data, the lack of smoke testing methodologies, for example, for pipes and cigars, costs of HPHC testing, and insufficient laboratory capacity. One comment also notes that FDA has not clarified which HPHCs will be required to be reported for any cigars. A few comments also maintain that FDA has not provided substantial evidence that the testing will yield meaningful results. In addition, one comment claims that FDA should not require that HPHC testing be included in an SE Report because the FD&C Act does not require it be included. One comment encourages FDA to ensure that analytical methods are appropriately validated.

(Response 65) We disagree that HPHC data should not be required in an SE Report. In determining whether a new tobacco product is substantially equivalent, it is important for FDA to understand what is placed into the product (*e.g.,* ingredients), as well as what comes out of the product and what is, or potentially is, inhaled, ingested, or absorbed in the body (*e.g.,* HPHCs). HPHCs are of particular importance, as they may be carcinogens and/or respiratory, cardiovascular, and/or reproductive or developmental toxicants.

With respect to the comments on the lack of smoke testing methodologies, we note that there are some cigar smoking methods that are applicable to many commercially available products, including larger cigars.[19] The cost of testing will be dependent upon a variety of factors related to the new tobacco product, including the product characteristics and proposed modifications (*e.g.,* minor changes to ingredients may need no or limited testing information while more significant changes to tobacco blend or ingredient changes in higher quantities may require a higher number of HPHCs tested or more voluminous data). In general, the cost of testing information necessary to submit with an SE Report to determine substantial equivalence is not disproportionate for any product category. FDA acknowledges that applicants may rely on third party laboratories, the SE program has been in existence for many years, and FDA has received thousands of SE Reports, including SE reports containing information obtained from third party laboratories. Additionally, we anticipate laboratory capability and capacity will continue to expand over time to meet the needs of future applicants.

- Shelf Life and Stability Information (§ 1107.19(f))

In the following paragraphs, we describe the comments and our responses on § 1107.19(f) (in the proposed rule, this was proposed as § 1107.19(e), stability information). We are finalizing subsection (f) with the changes described in the introductory paragraphs to § 1107.19.

(Comment 66) Proposed § 1107.19(e) (now subsection (f)) requires the submission of stability information for smokeless tobacco products and any other tobacco product that contains fermented tobacco. Several comments dispute that stability information is a relevant testing parameter. The comments also claim that FDA cannot require stability testing without substantial evidence regarding its necessity, and that FDA has not met this requirement.

(Response 66) We disagree. TSNAs are carcinogenic compounds that are present at very low levels in freshly harvested tobacco leaves but can increase dramatically during tobacco processing and storage (Refs. 10, 19–21, 77, 78). TSNA production is critically influenced by the microbial communities associated with the tobacco. Microbial-mediated reduction of nitrate results in production of nitrite, which further reacts with alkaloids present in tobacco to produce the carcinogenic TSNAs (Refs. 17, 18, 20, 79–82). Therefore, TSNA content in the finished tobacco products is greatly affected by a variety of factors such as tobacco processing method(s) (*e.g.,* curing, aging, sweating, fermentation, heat treatment), product composition (*e.g.,* humectants, preservatives), container closure system, and product storage conditions (*e.g.,* temperature, humidity), all of which could potentially alter microbial activity and, in turn, affect the stability of the tobacco product over the shelf life. Since bacterial communities and constituents in tobacco products can potentially change over the shelf life (Refs. 17, 83, 84), information obtained through stability testing is important for FDA to consider during its review to ensure that the tobacco products are microbiologically and chemically stable during storage and do not result in an increased risk to public health as the product sits in storage as compared to the predicate tobacco product.

- Comparison to Original Predicate Tobacco Product (§ 1107.19(h))

In the following paragraphs, we describe the comments and our responses on § 1107.19(h) (proposed § 1107.19(g)). We are finalizing this subsection with the changes described in the introductory paragraphs to § 1107.19, including changes for consistency with the updated definition of predicate tobacco product.

We received several comments related to this proposed subsection. In the proposed rule, we explained that FDA may request that the applicant include information related to the ''original'' predicate tobacco product (a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007), even if the original predicate tobacco product is back several

[19] See, *e.g.,* the following CORESTA standards: CORESTA Reference Method (CRM) 65: Determination of Total and Nicotine-Free Dry Particulate Matter using a Routine Analytical Cigar-Smoking Machine—Determination of Total Particulate Matter and Preparation for Water and Nicotine Measurements; CRM 66: Determination of Nicotine in the Mainstream Smoke of Cigars by Gas Chromatographic Analysis; CRM 67: Determination of Water in the Mainstream Smoke of Cigars by Gas Chromatographic Analysis; CRM 68: Determination of Carbon Monoxide in the Mainstream Smoke of Cigars by Non-Dispersive Infrared Analysis.

predicate tobacco products. Due to the removal of the definition of ''grandfathered,'' we are no longer using the term grandfathered tobacco product in this section. We describe the comments and responses on this subsection in the following paragraphs.

(Comment 67) One comment states that FDA has underestimated the burden that would be imposed by the proposed requirement that a new tobacco product be compared to the original predicate tobacco product. Other comments object to the proposed requirement arguing that it could foster anti-competitive competition and create an imbalance in the industry in favor of large manufacturers that can afford to maintain a large pool of tobacco products. In addition, they assert that smaller companies will risk non-compliance given the costs associated with complying with the rule and that the cost of compliance may cause companies to raise prices on their goods. Instead of requiring this information, the comments suggest FDA should instead rely on data the Agency currently has including data from previously submitted SE Reports. Another comment suggests that this interpretation also is inconsistent with FDA's position that only a single predicate can be used as the basis for an SE determination because the interpretation suggests that applicants that use as a predicate a tobacco product that was previously found SE ''must demonstrate multiple levels of substantial equivalence and support multiple comparisons in a single application.''

(Response 67) We disagree that this requirement should or even could be deleted. This is because, as explained in the proposed rule, although an applicant can support a showing of SE by comparing the new tobacco product to a predicate tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or that FDA has previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act). This statutory provision helps FDA ensure that new tobacco products using the substantial equivalence pathway and relying on predicate tobacco products previously found SE do not vary so much from the original predicate tobacco product that the new product would actually raise different questions of public health compared to the original predicate tobacco product. New products with differences that may appear only incremental when a new tobacco product is compared to a predicate tobacco product previously found SE can lead to product ''creep,'' which could result in the new tobacco product actually having significant changes when compared to the original predicate tobacco product. Issuance of an order under section 910(a)(2)(A)(i)(I) of the FD&C Act would undermine the public health purposes of the Tobacco Control Act (section 3) by permitting significant product evolution over time that raises different questions of public health. Such products should be submitted for premarket authorization through the PMTA pathway, which requires an applicant to demonstrate that their product is ''appropriate for the protection of the public health.'' FDA would only request the information described in § 1107.19(h) when necessary to ensure that any order issued by the Agency complies with section 910(a)(2)(A)(i)(I) of the FD&C Act. Before requesting this information from the applicant, FDA would review other relevant SE Reports in the chain, for example, the first SE Report that received an SE order using the original predicate tobacco product as a predicate product, to make this finding. If FDA is unable to make the finding required by section 910(a)(2)(A)(i)(I) of the FD&C Act based on the information in its files, and the applicant does not provide the needed information when requested, FDA would not be able to issue an order authorizing the new tobacco product. We disagree with the comments suggesting this requirement favors large companies or would lead to anti-competitive behavior as we expect that companies, regardless of size, maintain records such as these as part of their business practices. We note that FDA expects to be able to make the finding required by section 910(a)(2)(A)(i)(I) of the FD&C Act based on the information in its files in the vast majority of circumstances, and thus only expects applicants to need to provide additional information in unusual circumstances. In response to the comment that suggests that FDA's ''look-back'' approach effectively implements an SE process relying on multiple predicates, we note that where FDA must compare the new product to the original predicate tobacco product in addition to the selected predicate, each of those comparisons involves an evaluation comparing a singular new product to a singular predicate.

(Comment 68) One comment states that FDA's proposed requirement means that specifications and measurements for the original predicate tobacco products be submitted, and because those data were not required at the time the original predicate tobacco product was originally manufactured, would essentially be requiring the manufacturer to retroactively adopt certain design and manufacturing requirements for products. Other comments state that applicants would have to manufacture the original predicate tobacco products in order to comply with the proposed requirements. One comment added that the requirement would decrease clarity, efficiency, and predictability during the SE review process. Some comments state that while it is appropriate to ''compare key design parameters'' to determine whether a new product has the same or different characteristics as a predicate tobacco product, the FD&C Act does not give FDA the authority to retroactively impose design requirements on tobacco products, especially for provisional tobacco products that were designed, manufactured, and marketed before the Act required submission of SE Reports. Instead, the comments assert that FDA must issue a regulation under section 906(e) to impose design criteria and that such regulation must be independent of the SE framework. One comment instead proposes a framework that would require the manufacturer to provide the specifications employed in designing the new and predicate product, confirm that those specifications were met in manufacturing the product for HPHC testing, and then compare the output to determine whether there is a difference in disease risk posed.

(Response 68) We disagree that this section requires applicants to retroactively adopt or impose certain design and manufacturing requirements for original predicate tobacco products. FDA is not imposing design parameters on original predicate tobacco products and section 906(e) of the FD&C Act does not apply here. Rather, this section is intended to make applicants aware that in certain cases FDA may need to request information related to the original predicate tobacco product when necessary to ensure that any order issued by the Agency complies with section 910(a)(2)(A)(i)(I) of the FD&C Act. As explained in a preceding response, before requesting this information from the applicant, FDA would review its own files for other relevant SE Reports in the chain, for example, the first SE Report that received an SE order using the original

predicate tobacco product as a predicate product to make this finding.

(Comment 69) Some comments object to the proposed requirement that, if an applicant is using as a predicate a tobacco product found SE by FDA, and not one that is considered the original predicate tobacco product, FDA may request information related to the original predicate tobacco product. The comments dispute that applicants should have to comply with FDA's ''look back'' approach because under section 905(j) of the FD&C Act, an applicant may compare a new tobacco product to either a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a product previously found to be substantially equivalent. The comments also claim that the proposed requirement allowing FDA to request this information is in conflict with Congressional intent, and presents other issues, including preventing tobacco products from evolving by locking products into their 2007 composition, difficulty for applicants in obtaining data on the 2007 product, and inconsistency with FDA's proposed requirement that applicants maintain records for four years since this provision would require records in perpetuity if FDA could reach back to the 2007 product.

(Response 69) We disagree with these objections as manufacturers have been on notice since the passage of the Tobacco Control Act that FDA is required to make the comparison between the new tobacco product and the original predicate tobacco product, and, in doing so, may need to rely on previously submitted SE Reports, including those submitted by a different manufacturer. As discussed in the proposed rule, the statute permits an applicant to compare its new tobacco product to either a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or one that FDA has previously found SE (section 905(j)(1)(A)(i) of the FD&C Act). However, the statute also requires FDA to make an SE determination by comparing the new tobacco product to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007 (section 910(a)(2)(A)(i)(I) of the FD&C Act). Therefore, to meet its statutory obligation, FDA may need to look back to previously submitted SE Reports in the SE chain that relied on the original predicate tobacco product in order to issue an SE order. This statutory provision helps FDA ensure that new tobacco products using the substantial equivalence pathway and relying on predicate tobacco products previously found SE do not vary so much from the original predicate tobacco product that the new product would actually raise different questions of public health compared to the original predicate tobacco product. New products with differences that may appear only incremental when a new tobacco product is compared to a predicate product previously found SE may actually have had significant changes when compared to the original predicate tobacco product. Should this be the case, such that FDA cannot issue the determination required under section 910(a)(2)(A)(i)(I), the statute also provides alternative premarket pathways.

(Comment 70) Another comment supports the proposed requirement to include the information regarding the original predicate tobacco product in the SE Report. The comment states that successive iterations of SE Reports, each referencing a predicate product that is not itself the original predicate tobacco product, would attenuate the relationship between the new tobacco product and the original predicate tobacco product, thereby introducing products that are not substantially equivalent to any product actually commercially marketed (other than for test marketing) on February 15, 2007.

(Response 70) We agree with this comment and have maintained this requirement without change from the proposed rule.

• Other Comments on Comparison Information

(Comment 71) A few comments request that we provide further clarity on the comparison information required to be submitted for cigars and ENDS, and particularly more clarity with respect to required HPHC information. Some comments suggest specific cigar design parameter information that should be included, such as cigar length, circumference, wrapper mass, binder mass and filter ventilation. Another comment states that is inappropriate for FDA to require cigar manufacturers to include wrapper material as part of the product properties information to be submitted since whole leaf tobacco is the wrapper material.

(Response 71) FDA is providing additional clarity related to comparison information for deemed tobacco products in this final rule. Following our consideration of the comments and based on our experience, FDA has added information to § 1107.19 to address these concerns, including as suggested by at least one comment, cigar parameter information (cigar length, circumference, wrapper mass, binder mass, and filter ventilation) as well as additional product parameters that vary based on cigar construction (*e.g.,* unfiltered, hand rolled). We disagree that it is inappropriate to require information on wrapper material as part of the reported cigar product properties, as the composition of the wrapper will contribute to changes in smoke constituent delivery to the user.

With respect to HPHC information, as defined in this rule and discussed in the proposed rule, HPHCs are a subset of the chemical and chemical compounds in the tobacco product, including cigars, or its tobacco smoke or emission and, accordingly, the SE Report for a cigar must include the HPHC information necessary to provide a complete comparison between the new and predicate tobacco products. CORESTA [20] has established and published methods on how to generate cigar smoke in order to quantitatively compare HPHCs found in cigar smoke. We also recommend that applicants that wish to submit a premarket application for a new ENDS, cigar, or other tobacco product consider the final guidance entitled ''Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act'' (76 FR 5387, January 31, 2011; revised guidance issued August 2016, see *https://www.fda.gov/media/80109/download*), which FDA intends to update in the future. Although this guidance document does not break out the information for those specific tobacco product categories, this guidance document may still provide useful information for these products; additionally, applicants may request a meeting to discuss these and other issues and, as noted in the proposed rule, FDA will make every attempt to grant requests for meetings to resolve important issues (see, *e.g.,* the guidance entitled ''Meetings with Industry and

[20] CORESTA standards that applicants might consider include CORESTA Reference Method (CRM) 46: Atmosphere for Conditioning and Testing Cigars of all Sizes and Shapes; CRM 47: Cigars—Sampling; CRM 64: Routine Analytical Cigar-Smoking Machine—Specifications, Definitions and Standard Conditions; CRM 65: Determination of Total and Nicotine-Free Dry Particulate Matter using a Routine Analytical Cigar-Smoking Machine—Determination of Total Particulate Matter and Preparation for Water and Nicotine Measurements; CRM 66: Determination of Nicotine in the Mainstream Smoke of Cigars by Gas Chromatographic Analysis; CRM 67: Determination of Water in the Mainstream Smoke of Cigars by Gas Chromatographic Analysis; CRM 68: Determination of Carbon Monoxide in the Mainstream Smoke of Cigars by Non-Dispersive Infrared Analysis.

Investigators on the Research and Development of Tobacco Products'' (May 25, 2012, 77 FR 31368; revised guidance issued July 2016, see *https://www.fda.gov/media/83420/download*)).

4. Amendments (§ 1107.20)

We proposed in § 1107.20 to establish how and when applicants may submit amendments to an SE Report, including information on when a redacted copy of the amendment might need to be submitted. The proposed section provided that an applicant could not amend an SE Report to change the predicate tobacco product and that an applicant could not amend an SE Report after FDA closed the report under proposed § 1107.44 or the report was withdrawn under proposed § 1107.22. The proposed provision also stated that amendments would generally be reviewed in the next review cycle as described in proposed § 1107.42. Following our review of comments on this section, we are finalizing the section without change. We describe the comments on this section in the following paragraphs.

(Comment 72) One comment disagrees with the proposed requirement that an applicant could not amend an SE Report to change the predicate after the report is accepted for review. This comment states that permitting applicants to change a predicate prior to the initiation of scientific review is important for products covered by FDA's current compliance policy for deemed new tobacco products that were on the market on August 8, 2016, as withdrawal of a timely submitted SE Report would impact the marketing status of the product.

(Response 72) We disagree that applicants should be permitted to change the predicate tobacco product identified in an SE Report that FDA has accepted for review. As stated in the proposed rule, changing the predicate product changes the fundamental basis of the analysis, as the comparison between the new and predicate tobacco products is the crux of the SE determination. Unless FDA refuses to accept the SE Report (§ 1107.40), FDA intends to issue an acceptance for review letter and then begin to review the SE Report . Therefore, there is no time to change the predicate tobacco product between FDA's acceptance of an SE Report for review and FDA's initiation of the review. If an applicant determines that a predicate change is necessary, they should withdraw the initial SE Report and resubmit it as a new SE Report with the information related to the new predicate tobacco product.

5. Withdrawal by Applicant (§ 1107.22) and Change in Ownership of an SE Report (§ 1107.24)

Proposed § 1107.22 would establish when and how an applicant may withdraw an SE Report. We received no comments on this proposed section, and we are finalizing the section with one substitute of ''part 20'' for § 20.45. Proposed § 1107.24 would establish the procedures for transferring ownership of an SE Report. We received no comments on this proposed section, and we are finalizing the section without change.

E. Comments on Subpart D—FDA Review and FDA Responses

In this subpart, FDA proposed requirements related to FDA review of an SE Report, including how FDA would communicate with an applicant, review cycles, and FDA's actions on an SE Report, including issuance of orders and rescission of orders. Following our review of the comments, we are finalizing § 1107.40 with a minor change to reflect that, after receiving an SE Report, FDA will either refuse to accept the report for review or issue an ''acceptance for review'' letter rather than an ''acknowledgement'' letter, as proposed. We revised § 1107.44(a) to add a reference to § 1105.10 (refuse to accept). We revised §§ 1107.42, 1107.44, 1107.46, and 1107.48 for consistency with the updates to the definition of predicate tobacco product. We also revised § 1107.42(c) to replace a ''will'' with ''generally intends to'' to provide the Agency with some discretion following receipt of a deficient SE Report. We also revised § 1107.50 pertaining to the opportunity for a hearing in a rescission action, and we describe those revisions in more detail in the paragraphs related to that section.

We note that in addition to the general comments we received on this subpart, in the proposed rule, FDA invited comment on two issues: The appropriate amount of time to allow applicants to respond to a deficiency letter and when extensions of time should be granted. In response, some comments discuss FDA's review process generally, and many of these comments recommend that FDA change the timeframes for review and response.

In the following paragraphs, we describe the comments we received on this proposed subpart and our responses.

1. Comments on Communications Between FDA and Applicants (§ 1107.40)

Proposed § 1107.40(a) provided for general principles regarding communications between applicants and FDA and the form of these communications, *e.g.,* phone conversations, letters, email. Proposed § 1107.40(b) addressed the purpose of meetings and that FDA would make every attempt to grant meeting requests for important issues. Proposed § 1107.40(c) described how FDA would acknowledge an SE Report, and proposed § 1107.40(d) stated that FDA would make reasonable efforts to communicate to applicants the deficiencies found in an SE report and any additional information needed for FDA's review. This section also stated that applicants must provide additional comparison information under proposed § 1107.19 if requested by FDA. Following our review of comments to this proposed section, we are finalizing the section by replacing ''acknowledgement'' with ''acceptance for review'' in paragraph (c).

(Comment 73) Some comments state that FDA should grant meetings with industry while an SE Report is pending and when FDA requests scientific information or testing in the pending SE Report. The comments reason that meetings during the review process serve to clarify and improve the quality of information required, and improve the timelines for future actions. Another comment notes that a phone conversation could help advance the review process for a request for a determination that a product was commercially marketed in the United States as of February 15, 2007 (Pre-Existing tobacco product).

(Response 73) FDA agrees that opportunities can be helpful to clarify the information being requested, *e.g.,* in a deficiency letter with an applicant. In addition, FDA intends to use a variety of methods to communicate with applicants depending on the circumstances and issues, including but not limited to, telephone conversations, letters, and/or emails, and, therefore, in many cases a formal meeting may not be necessary. If there are complex scientific issues that require discussion, an applicant may request a meeting to discuss these and other issues and, as noted in the proposed rule, FDA will make every attempt to grant requests for meetings to resolve important issues. However, fundamental scientific issues should be the subject of meeting requests prior to submitting an SE Report (see, *e.g.,* the guidance entitled

''Meetings with Industry and Investigators on the Research and Development of Tobacco Products'').

(Comment 74) One comment argues that FDA should communicate deficiencies in SE Reports to applicants prior to issuing an NSE order. A comment requests that FDA establish dispute resolution procedures that include a mechanism for stay of an NSE order for a provisional tobacco product, and that during this period of time, FDA should be barred from making it known that the product was found to be NSE given the potentially serious business consequences of such a disclosure.

(Response 74) We note that § 1107.42(b) provides for the use of multiple review cycles allowing FDA to communicate procedural, administrative, or scientific deficiencies found during a review, rather than issuing an NSE order. There may be cases where it is in FDA's and/or the applicant's interest to not issue deficiency letters but rather issue an NSE order, and, as customary, FDA generally intends to outline the deficiencies that are the basis for the decision. This will allow applicants to consider the deficiencies and consider the best course to address the deficiencies identified in their NSE order letter. An applicant has the option to request a meeting with FDA, if they choose, and FDA intends to make every effort to grant pre-submission meetings with applicants to discuss the scientific principles in their NSE determination and how best to prepare a subsequent premarket application. In addition, the scope of this rule is SE Reports for new, non-provisional products, which should not be on the market during FDA's review. FDA intends to comply with the requirements related to disclosure of information in 21 CFR part 20 and § 1107.60. If an applicant wishes to dispute the issuance of an NSE order, they may request supervisory review of FDA decisions under § 10.75 (21 CFR 10.75).

2. Comments on Review Cycles (§ 1107.42)

Proposed § 1107.42 addressed review cycles and explained what an initial review cycle is, as well as when additional review cycles would occur and what would happen if FDA issued a deficiency notification. Following our review of comments, we are finalizing this section with a minor change to add ''(other than for test marketing)'' following commercially marketed in paragraph (a).

(Comment 75) Several comments state that FDA should set clear deadlines for the review process. One comment suggests that FDA's rule should establish a 90-day review timeline noting that Congress directed that FDA review ''the more rigorous PMTA applications for new and novel products'' ''no later than 180 days after receiving the application.''

(Response 75) FDA agrees that review timeframes are important for both FDA and industry. Thus, in general, FDA intends to review SE Reports and either issue a deficiency letter or make a final determination within 90 calendar days of receipt of the SE Report or amendment as proposed in § 1107.42(a).

(Comment 76) One comment disagrees with the review cycles set out in the proposed rule (initial review, at least one scientific Advice/Information request, and one preliminary finding letter), which could mean that review could take 270 days. Some comments support the proposed review process of three review-cycles, noting it provides appropriate time and resources for industry and FDA.

(Response 76) We agree with those comments that support the three review-cycle process as providing appropriate timeframes. Although the FD&C Act does not require FDA to provide multiple review cycles, FDA has provided this framework to help applicants. This final rule provides additional predictability to this review process by establishing timeframes for both FDA's review and the applicant's response. As the proposed rule explained, FDA's intent is to complete review of an SE Report submitted under § 1107.18 within a maximum of 270 review days (*i.e.,* three 90-day review cycles). Based on FDA's review experience, an SE Report should be resolved within three review cycles, sometimes fewer. If fewer review cycles are needed, FDA intends to decide in a shorter time period, and we expect that this rule will result in a decrease in the average number of review cycles needed to issue an order. As the tobacco industry and we continue to gain experience with submitting and reviewing, respectively, our goal would be to complete SE reviews in shorter timeframes.

It is ultimately the applicant's responsibility to provide a complete SE Report that supports a scientific finding of substantial equivalence. If the applicant receives a deficiency letter and cannot respond within the specified timeframe, they have the option to withdraw and resubmit the SE Report with the required content.

(Comment 77) Some comments propose that FDA issue a notice of refusal to accept an SE Report for review within five business days of receipt of the report. Other comments propose that an acknowledgement or refusal to accept letter should be issued within 10 business days, and that applicants have a reasonable period of time to respond, such as 30 or 60 days, with a request that for the first five deficiencies, FDA provide 60 days to respond. The comments also assert that the time permitted to respond to a deficiency letter should be based on factors such as the size of the company submitting the SE report and the type or number of deficiencies identified by FDA. Some comments state that FDA should provide 180 days for applicants to respond to deficiency letters without regard to the type or number of deficiencies. The comments propose a similar approach to extension requests, noting that the extensions should be given on a case-by-case basis, with consideration given to the nature of the request.

(Response 77) The rule will provide predictability to the review process with timeframes for both FDA review and applicant response. As already stated, it is the applicant's responsibility to provide a complete SE Report that supports a scientific finding of substantial equivalence. With respect to issuance of a refuse to accept letter, FDA has established performance goals of 21 calendar days. This action closes the SE Report; therefore, an applicant would need to submit a new SE Report in order to obtain premarket authorization through the SE pathway. For an SE Report that is accepted for review, and for which the applicant receives a deficiency letter to which it cannot respond within the specified timeframe, the applicant has the option to withdraw and resubmit the SE Report with the required information. With respect to deficiency timeframes being based on the size of the manufacturer or the number of deficiencies involved, FDA is committed to following a consistent and transparent process for all submitters of SE Reports. As an SE Report should be complete upon submission to the Agency, if an applicant is unable to respond to the number of deficiencies in the timeframe provided in the letter, the applicant has the option to withdraw and resubmit the SE Report with the required information. FDA will review all subsequent applications without prejudice.

3. FDA Action on an SE Report (§ 1107.44) and Issuance of an Order Finding a New Tobacco Product Substantially Equivalent

Proposed § 1107.44 listed the actions FDA could take after receipt of an SE

Report. We received no comments on this proposed section, and we are finalizing the section with a minor change to add ''for review'' and a reference to § 1105.10 (to ensure applicants are aware of that provision). Proposed § 1107.46 explained when FDA would issue an order finding a new tobacco product substantially equivalent. We received no comments on this proposed section, and we are finalizing the section without change.

4. Issuance of an Order Denying Marketing Authorization (§ 1107.48)

Proposed § 1107.48 explained when FDA would issue an order that the new tobacco product cannot be marketed. After considering the comment on this proposed section, we are finalizing the section without change. We describe the comment and our response in the following paragraphs.

(Comment 78) One comment requests that FDA include a dispute resolution mechanism for those applicants that seek to challenge an adverse decision by FDA. The comment asserts that manufacturers whose products are removed from the market while NSE orders are pending appeal are harmed when the Agency does not have a formal mechanism to challenge the decision beyond 21 CFR part 10.

(Response 78) As discussed in previous paragraphs, this rule applies to new, non-provisional SE Reports, not provisional SE Reports. In general, tobacco products that are the subject of non-provisional SE reports should not be on the market prior to FDA making an SE or NSE determination. Therefore, no products would need to be removed from the market during supervisory review of an NSE determination. Applicants who wish to dispute an NSE finding can use § 10.75.

5. Rescission of an Order and FDA Response (§ 1107.50)

Proposed § 1107.50 set out the grounds for rescinding an SE order and providing notice of the opportunity for a hearing related to the Agency's intention to rescind. We are finalizing this section with some clarifications to reflect the updated definition of predicate tobacco product, as well as additions related to when notice of an opportunity for a hearing will be offered. As described in the proposed rule, FDA will generally rescind an order only after notice of an opportunity for a hearing under 21 CFR part 16 (hereinafter a Part 16 hearing). However, also as described in the proposed rule, FDA may rescind an order prior to notice of an opportunity for a hearing if it finds that there is a reasonable probability that continued marketing of the tobacco product presents a serious risk to public health. In that case, FDA will provide the manufacturer a notice of an opportunity for a hearing as soon as possible after the rescission. In addition, FDA has revised § 1107.50(b) to add paragraphs (i)–(iii) as a means of more clearly explaining that FDA may rescind an order without notice of an opportunity for a Part 16 hearing where an entity that has, on its own initiative, identified a mistake, notified the Agency of the mistake, and agreed to a rescission of the marketing order of the tobacco product without the need for a Part 16 hearing. In this narrow circumstance, providing notice of an opportunity for a hearing is an unnecessary procedural step as the applicant has already informed the Agency that they would not request a Part 16 hearing. Other than these two circumstances, FDA will offer notice of an opportunity for a Part 16 hearing prior to rescission, as described in § 1107.50(b). We received comments on this proposed section, and we respond to those in the following paragraphs.

(Comment 79) Some comments object to § 1107.50 of the proposed regulation which provides the grounds for rescinding an SE order. The comments state that FDA was not granted authority to rescind an SE order, in contrast to FDA's express authority to withdraw a PMTA or modified risk tobacco product order. One comment objects to FDA's reliance in the proposed rule on *Ivy Sports Med. LLC* v. *Burwell,* 767 F.3d 81, 86 (D.C. Cir. 2014) (hereinafter *Ivy Sports*) as misplaced because Congress did not confer rescission authority for SE orders. This comment notes that Congress ''plainly intended to displace any [rescission] authority here'' as it provided misbranding, adulteration, and recall authorities to address SE orders based on false information or unanticipated safety issues. Other comments state that if the rescission provision is maintained, FDA should include clear definitions and specific time limits.

(Response 79) We disagree with the comments that suggest FDA cannot or should not rescind SE orders when the grounds set out in § 1107.50 exist. As explained in the proposed rule, this provision is based on our authority to issue an order when we can make the findings in section 910(a)(2)(A)(i) of the FD&C Act, as well as our authority in section 701 (related to issuing regulations for the efficient enforcement of the FD&C Act). Moreover, as explained in the proposed rule, this section is also based on FDA's inherent authority to timely revisit and reconsider prior decisions, as discussed in *Ivy Sports.* Although misbranding, adulteration, and recall authorities are important authorities that can be used to address safety and other issues related to a tobacco product, § 1107.50 will work in tandem with those authorities to protect the public health. For example, under § 1107.50, FDA may rescind a substantially equivalent order if the applicant has removed the new tobacco product from the market for a safety concern. If the applicant continued to market such a product without premarket authorization, that product would then be adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act. However, without rescission of an SE order, there is no adulteration, misbranding, or other provision in the statute to address products found SE based on false information.

As discussed in the proposed rule, FDA's initiation of rescission will occur only when the grounds described in § 1107.50 exist. We agree with comments that suggest FDA should exercise this authority in a timely and judicious way; while we are declining to set specific time limits, FDA intends to initiate a rescission action within a reasonable period of time, which will depend on the circumstances of each order. For example, we note that, in the absence of applicant malfeasance, 10 months has been held to be ''comfortably within the reasonableness standard'' in light of the particular facts. *Ivy Sports Medicine, LLC* v. *Sebelius,* 938 F. Supp. 2d 47, 63 (D.D.C. 2013) (upholding FDA rescission of medical device clearance), *rev'd on other grounds* 767 F. 3d 81 (D.C. Cir. 2014). In the presence of applicant malfeasance, more than six years has been held to be reasonable. *Ranbaxy Labs., Ltd.* v. *Burwell,* 82 F. Supp. 3d 159, 196 (D.D.C. 2015) (upholding FDA rescission of tentative approval of abbreviated new drug applications).

F. Comments on Subpart E—Miscellaneous Provisions and FDA Responses

1. Record Retention (§ 1107.58)

Proposed § 1107.58 described record retention requirements. The proposed provision would require that records supporting an SE order be maintained for a period of not less than 4 years from the date of an SE order. After considering comments on this proposed section, we are finalizing the section without change. We describe the comments to this section and our responses in the following paragraphs.

(Comment 80) A few comments state that by requiring manufacturers to trace their products back to the original predicate product (§ 1107.19(h)), a record retention requirement of 4 years has no effect since they would have to maintain records in ''perpetuity'' if the manufacturer wanted to use the original predicate tobacco product at a later date.

(Response 80) Section 1107.58 states that each applicant that receives an order under § 1107.46 authorizing the marketing of a new tobacco product must maintain all records required by this subpart and records that support the SE Report for a substantial equivalence order. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. All records must be retained for a period of not less than 4 years from the date of the order even if such product is discontinued. If an applicant believes that they will want to rely on the data in the future, they may choose to retain records longer than this time period. For example, manufacturers who elect to use a predicate that is a product that has been previously found SE may need to be able to produce records relating to the original predicate tobacco product where FDA is unable to make the finding required by section 910(a)(2)(A)(i)(I) of the FD&C Act based on the information in its files.

2. Confidentiality (§ 1107.60)

Proposed § 1107.60 described how FDA would determine the public availability of any part of an SE Report and other content related to such an SE Report under this proposed section and part 20 of this chapter. After considering comments on this proposed section, we are finalizing the section without change. We describe the comments to this section and our responses in the following paragraphs.

(Comment 81) One comment objects to the level of confidentiality afforded to SE Reports noting that this has ''prevented the public from having any significant information about FDA's review of such applications or the standards FDA is applying.'' The comment states that to obtain information about SE Reports, Freedom of Information Act (FOIA) requests must be submitted and the Agency's responses to those FOIA requests are too slow. This comment also notes that because FDA does not disclose the existence of SE Reports the public cannot participate in the consideration of such reports. Another comment disagrees with limiting disclosure of information to only the summary review or the final cycle primary discipline reviews for SE Reports found NSE (without the need for FOIA requests). This comment urges FDA to release reviewer notes from each cycle of review to the manufacturer (or applicant), as well as information related to the measures FDA takes to ensure consistency among reviewers.

(Response 81) We decline to make any changes to the codified provisions. Although we agree with the goals of transparency, the confidentiality provisions in this section align with the requirements of FOIA, other statutory provisions governing disclosure of pending SE Reports and the information contained in such SE Reports, and 21 CFR part 20. As FDA explained in the proposed rule, the intent to market a tobacco product that is not currently marketed is often considered confidential commercial information. Consistent with this rule, FDA will continue to make available to the public information related to tobacco product premarket review and marketing orders at *https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-marketing-orders*.

3. Electronic Submissions (§ 1107.62)

Proposed § 1107.62 describes the requirement for the electronic submission of an SE Report, unless the applicant requested and FDA granted a waiver request. After considering comments on this proposed section, we are finalizing this section with one minor change that the applicant include their email address to help ensure we have complete contact information. We note that we intend to periodically issue specifications and guidance pertaining to electronic submission format and organization to provide updated information related to electronic submission, *e.g.,* as technology evolves. We describe the comments to this section and our responses in the following paragraphs.

(Comment 82) One comment believes submitting the SE Report electronically should be optional and the applicant should be permitted to submit paper reports without requesting a waiver.

(Response 82) As stated in § 1107.62, FDA requires the SE Report and supporting information to be submitted electronically, unless the applicant requested and FDA granted a waiver request. In addition, § 1107.18 requires applicants to submit the SE Report using the forms that FDA provides (*i.e.,* Forms FDA 3964 and 3965) (FDA forms may be found at *https://www.fda.gov/about-fda/reports-manuals-forms/forms*). This approach is consistent with § 1105.10, which states that FDA generally intends to refuse to accept for review an SE Report if required forms are not included with the SE Report. Also, requiring electronic submission is consistent with the requirements for other FDA regulated products, *e.g.,* new drug applications (NDAs) and investigational new drug applications (INDs). FDA provides tools, such as eSubmitter, to facilitate the creation of an electronic submission. This is available for voluntary use by sponsors, manufacturers, and importers to create a variety of submission types within the drug, device, radiological health, tobacco, animal drug and animal food regulated industries.

Without the mandatory information from the forms and electronic submission, the processing and review of each submission would be slower and more burdensome. The use of a form also helps avoid the submission of incomplete information, which can hinder decision-making and prolong the review process. Electronic data and electronic submission enable automation in the review process, which in turn increases data quality by eliminating human error from manual data entry.

G. Comments on Other Issues for Consideration and FDA Response

FDA requested comment on whether some modifications to tobacco products that result in a new tobacco product, beyond those eligible for an exemption from substantial equivalence, might be handled through a ''categorical'' approach to substantial equivalence. For example, under such an approach, FDA could establish categories of modifications, and if a modification is within a category, the applicant could then submit a streamlined SE Report that identifies the modification and demonstrates substantial equivalence. We solicited comment on concerns or benefits of this type of approach, along with information on the types of modifications or categories that might be handled in this way, or should not be handled this way.

(Comment 83) Several comments support consideration of categories of modifications that could be subject to streamlined SE reviews or excluded from review, and provided specific examples. For example, one comment presents suggestions for categories of modifications for which no SE Report should be required, such as changes based on operation of law (*e.g.,* change made to comply with a product standard); supplier/commodity changes, modifications to ensure tobacco product consistency (*e.g.,* blending changes and

similar changes to maintain consistency); packaging changes, including changes to CCS; product quantity changes.

(Response 83) After considering these comments, FDA has determined that further consideration is needed on whether and, if so, what, categories should be created for a ''categorical'' approach to substantial equivalence, particularly once FDA has gained more experience and is able to identify potential categories. We note that some of the changes included as suggestions for exclusion may not require a premarket submission, *i.e.,* a change in supplier that does not result in a new product (there is no modification to the product as a result in the change in supplier).

(Comment 84) Some comments note that there are categories of minor changes which would not raise different questions of public health. One such comment includes several modifications that the commenter states does not raise different questions of public health. The comment notes that modifications that: (1) Reduce HPHC yield; (2) change quantity; (3) change product design; (4) change from loose to portioned tobacco; (5) change the packaging or container; (6) reduce ingredients; (7) change an ingredient supplier; (8) change a manufacturing process; or (9) respond to other FDA requirements should not require SE Reports because they do not raise different questions of public health.

(Response 84) We disagree that changes that result in a modification of the tobacco product should not require premarket authorization. The FD&C Act generally requires that before a new tobacco product may be introduced into interstate commerce for commercial distribution in the United States, the new tobacco product must undergo premarket review by FDA. However, depending on the modification, an applicant could proceed through the same characteristics SE pathway (which does not require a showing that any changes do not cause the product to raise different questions of public health) or the SE exemption pathway. In addition, as with some of the previous examples, some of the changes highlighted in this comment may not result in a new tobacco product, and therefore would not require premarket review (*e.g.,* changes to packaging that are not part of a container closure system, a change in supplier that does not result in a modification of the tobacco product, or a change in manufacturing process that does not affect the characteristics of the tobacco product).

(Comment 85) Similarly, a comment requests FDA to remove ''aesthetic'' changes, supplier changes, changes performed to ensure consistency of the product, and packaging changes from those modifications that would require applicants to submit an SE submission. This comment expresses concern that the rule as proposed would require a manufacturer to submit a report on a change that it may not even know took place.

(Response 85) An application is only required if the change renders a product a new tobacco product. ''Aesthetic'' changes that alter the name or labeling, changes to packaging that are not part of a container closure system, or other modifications that do not impact the characteristics of a tobacco product do not require submission of an SE Report. However, any modifications that create a new tobacco product must receive authorization through the submission of an application (*e.g.,* PMTA, SE Report, or Exemption Request). Otherwise, if the new tobacco product enters into interstate commerce for commercial distribution, it would be adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act and subject to enforcement action.

(Comment 86) One comment opposes the creation of categories of products eligible for a streamlined substantial equivalence process stating that the FD&C Act contemplates product-by-product review. This comment refers to FDA's experience with SE reviews and notes that the majority of SE Reports do not result in SE orders and that this shows ''that manufacturers, if not required to produce specific evidence in support of substantial equivalence, will make claims of substantial equivalence that cannot be supported.'' Other comments request further clarification on the issue. The comments request that if FDA were to adopt a categorical approach, FDA publish the list of categorical modifications appropriate under the approach.

(Response 86) Given the wide range of suggested categories and other feedback on this topic, FDA agrees with the comments that indicate further consideration is needed on whether and, if so, what, categories should be created. FDA intends to continue to consider this issue and how we might best proceed in providing additional clarity and recommendations on the premarket approach that may work best for any ''category'' of change.

VI. Effective Date

As stated in the proposed rule, this final rule will become effective 30 days after the final rule publishes in the **Federal Register**. FDA responds to the comments on the effective date in the following paragraphs.

(Comment 87) More than one comment requests that FDA delay or stagger the effective date of the final regulation or the submission dates for premarket applications.

(Response 87) We decline to change the effective date for the rule, or add compliance dates at this time. We note that premarket requirements already apply to new tobacco products as described in the statute and the deeming final rule (sections 905 and 910 of the FD&C Act and 81 FR 28974, May 10, 2016, see *https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10685.pdf*, codified at 21 CFR 1101.) This rule supports those existing requirements by, among other things, providing content and format requirements related to SE Reports for new tobacco products that will help applicants prepare SE Reports and enable FDA to make SE determinations for new tobacco products.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have determined that the compliance costs are less than 0.2 percent of revenues, we certify that the rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after

adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

This analysis uses the state of the world where manufacturers routinely submit SE Reports as the baseline. This final rule will impose compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, keep records, and fill out a form for SE Reports. We estimate that the present value of industry compliance costs ranges from $0.4 million to $3.4 million, with a primary estimate of $1.9 million at a 3 percent discount rate, and from $0.4 million to $2.9 million, with a primary estimate of $1.6 million at a 7 percent discount rate over 10 years. Annualized industry compliance costs over 10 years range from $0.05 million to $0.39 million, with a primary estimate of $0.22 million at a 3 percent discount rate and from $0.06 million to $0.42 million, with a primary estimate of $0.23 million at a 7 percent discount rate. The costs to industry range from around $200 to around $1,400 per affected entity per year, with a primary estimate of around $800 per entity per year.

The incremental benefits of this final rule are potential time-savings to industry and cost-savings to FDA. The final rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product. Certifying may save applicants time in preparing their SE Reports. We anticipate shorter review times for SE Reports as a result of this final rule. In addition, based on our experience with prior SE Reports, we believe this final rule will lead to higher quality SE Reports, saving us time in review and requiring fewer staff to review SE Reports, which will result in cost-savings. We estimate that the present value of government cost-savings ranges from $15.1 million to $150.6 million, with a primary estimate of $50.2 million at a 3 percent discount rate, and from $12.4 million to $124 million, with a primary estimate of $41.3 million at a 7 percent discount rate over 10 years. Annualized government cost-savings over 10 years range from $1.8 million to $17.7 million, with a primary estimate of $5.9 million at both 3 and 7 percent discount rates. The FDA cost-savings per report ranges from around $17,700 to around $58,800, with our best estimate at around $29,400.

The qualitative benefits of this final rule include additional clarity to industry about the requirements for the content and format of SE Reports. The final rule establishes the general procedures we intend to follow in reviewing and communicating with applicants. In addition, this final rule will make the SE pathway more predictable.

Table 1 summarizes the benefits and costs of the final rule.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

Category	Low estimate (million)	Primary estimate (million)	High estimate (million)	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$1.8	$5.9	$17.7	2018	7	10	Cost-savings to government.
	1.8	5.9	17.7	2018	3	10	Cost-savings to government.
Annualized Quantified				2018	7	10	
				2018	3	10	
Qualitative							Greater certainty for SE applicants.
Costs:							
Annualized Monetized $millions/year	0.06	0.23	0.42	2018	7	10	
	0.05	0.22	0.39	2018	3	10	
Annualized Quantified				2018	7	10	
				2018	3	10	
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year				2018	7	10	
				2018	3	10	
	From:			To:			
Other Annualized Monetized $millions/year				2018	7	10	
				2018	3	10	
	From:			To:			
Effects:							
State, Local or Tribal Government: No effect.							
Small Business: No effect..							
Wages: No effect..							
Growth: No effect..							

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 86) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

VIII. Analysis of Environmental Impact

The Agency has determined under § 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No extraordinary circumstances exist to indicate that the specific action may significantly affect the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject

to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Substantial Equivalence Reports for Tobacco Products.

Description: Tobacco Products, Substantial Equivalence Reports, Requirements for Submitting Information Needed to Determine Substantial Equivalence and Maintaining Records to Support a Substantial Equivalence Report.

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the **Federal Register** of April 2, 2019. In response to this rule FDA received the following PRA related comments:

(Comment 88) Some comments state that FDA underestimated the burden associated with collecting the information and suggest the proposed collection of information would have better utility and value if FDA went by product category. Specifically, the comments take issue with estimates of 683 SE reports filed and state that FDA failed to consider foreign manufacturers filing when the Agency used the registration and listing data to estimate the associated burden with the requirements. The comments also state that FDA has underestimated the burden of the proposed collection of information on FDA and does not reflect the level of agency resources needed to review the thousands of SE reports.

(Response 88) We disagree. The rule reflects estimates of the burden for the submission and review of SE Reports beginning when the rule becomes effective, which will be 30 days after the final rule publishes. These estimates reflect what we expect will be the level of submissions and burden at that time, based on our experience with SE Reports since the inception of the program. We disagree that we did not account for foreign firms. For SE purposes foreign firms are handled the same way as domestic firms. Although foreign firms are currently not required to register and list, they must still provide a U.S. agent to export a tobacco product.

(Comment 89) Several comments stated that our estimate of 87 to 300 hours to prepare and submit an SE Report is too low and that this must not account for the burden associated with HPHC testing. Several comments suggest that, based on the commenters' experience, it will take approximately 900–1,000 hours to prepare an SE Report for one product, and other comments estimate that it may take 15–28 months to prepare an SE Report depending on the scientific testing required. One comment asserts that this estimate is too low because the Agency is assuming a single submission, when the commenter's experience is that multiple submissions may be made with an SE Report including the original report. In addition, the comment states that this estimate does not include the time associated with amending the SE Report or an environmental assessment. The comment states that FDA may need multiple years to review and process SE Reports for tobacco products subject to the deeming final rule (''deemed tobacco products''), such as cigars, and that FDA will likely make multiple requests to applicants for additional information. One comment states that SE Reports require extensive data that could take thousands of hours per application to prepare and submit.

(Response 89) Because the estimates are based on our experience with SE Reports, we are maintaining the estimates as proposed. The SE program was originally approved by OMB in 2010. Since then, FDA has reassessed the program burden each time the collection was up for extension and other related programmatic changes in between. Additionally, we have further analysis on our reporting and recordkeeping requirements that was provided in the preamble to the proposed rule and the proposed regulatory impact analysis. We note that the final rule provides more clarity on both design parameters for cigars, pipes, and other deemed tobacco products, and also when scientific testing may be needed. This information will assist applicants in understanding the content and format of an SE report which will accelerate the process of submitting a report.

(Comment 90) A comment states that our estimated burden of ''bundled'' SE Reports is significantly lower than our estimate for a single product. The comments believe that this is wrong because the bundled applications cover multiple products and should therefore be greater than the burden associated with preparing a report for a single product.

(Response 90) We agree that the total time to submit a bundled SE Report is greater than the time to submit a report for a single product. Our estimates for ''bundled'' SE Reports were the time associated with submitting for each additional product in the bundle. Therefore, the total cost for submitting a bundle of 3 products would be the full SE burden for the first product, plus two times the burden to submit a bundled report. We have clarified this in the final analysis.

(Comment 91) Several commenters provided estimates for the hours needed for preparing and submitting SE Reports of between 900 hours and 28 months. Based on these hours, the commenters estimate that the cost per SE Report could be between $250,000 and $2,000,000, although they state there may be some economies of scale in submitting multiple reports.

(Response 91) We believe some commenters have confused cost estimates from the regulatory impact analysis (RIA) and burden hours from the PRA. Although these concepts are similar and account for some corresponding items, they ultimately serve different purposes and separate functions. The PRA estimates burden in hours on an annual basis generally for three years; while the regulatory impact analysis uses these estimated burden hours on an annual basis, along with an estimate of wage per hour, to estimate a cost in terms of dollars over a long-term horizon. See comment 4 of the RIA and comment 1 in the appendix of the RIA for a further discussion regarding costs and see comments 2 and 3 of the RIA for discussion on burden hours.

(Comment 92) A comment states that they believe our estimated burden for an environmental assessment is too high as a proportion of the time to prepare and submit an SE Report. They state that our estimate of 52 to 80 hours for an EA is potentially more than our estimated burden for an SE Report at 35 to 220 hours. Other comments suggest that the burden associated with EAs is too low.

(Response 92) FDA has estimated 80 hours for an environmental assessment for the SE program for many years. Based on experience with SE Reports,

interactions with the industry, and information related to other regulated products we do not have evidence suggesting a different estimate and note that the range given for EAs is intended to reflect the variation that might exist depending on the specific tobacco product.

(Comment 93) Several comments believe that FDA has substantially underestimated the number of SE Reports it will receive annually. The comments state that FDA should expect tens of thousands of SE Reports—much higher than the proposed rule estimate of 683 standalone SE Reports and 456 bundled SE Reports each year. Additionally, the commenter also notes that it expects to submit well over 100 reports per year as opposed to the FDA estimate of one application per year.

(Response 93) FDA believes our PRA estimates are accurate as we have had years of experience with the SE pathway. The SE program was originally approved by OMB in 2010. Since then FDA has reassessed the program burden each time the collection was up for extension and other related programmatic changes in between. Additionally, we have further analysis that was provided in the preamble to the proposed rule and the proposed regulatory impact analysis. As referenced in the proposed rule, many of our estimates were based on submissions being bundled. As is currently the practice, applicants may continue to bundle groups of SE Reports submitted under § 1107.18 that have the same proposed modifications (*e.g.,* a change in ingredient supplier that results in a new tobacco product). Co-packaging two or more tobacco products may result in a new tobacco product. When groups of full or product quantity change SE Reports have identical content, they may be submitted together (bundled); when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report. Additionally, manufacturers may bundle groups of SE Reports for their new products in the same product category and subcategory where the proposed modifications are the same; when a group of similar SE Reports are bundled, the reporting burden for the initial SE Report is expected to take the same amount of time as a stand-alone SE Report. However, the reporting burden for subsequent bundled SE Reports is expected to be lower than the initial SE Report.

Section 1107.18, paragraphs (b) and (c) include requirements that the applicant use the forms that FDA provides when submitting an SE Report. Following our consideration of the comments related to the forms, we are finalizing these requirements without change. We describe the comments to these sections and our responses next.

(Comment 94) At least one comment states that use of the FDA forms should be optional rather than mandatory.

(Response 94) We disagree. As explained in the proposed rule, the requirements in this rule, including use of these forms, are intended to provide clarity to applicants with respect to what they should submit in an SE Report and to help ensure that an SE Report provides information necessary for FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007. Additionally, use of a standardized form allows FDA to receive information in a way that allows for faster processing and uploading of the SE Report and its contents, thereby increasing efficiency of the review process.

(Comment 95) Another comment notes that although FDA appears to recognize that the evidence required in an SE Report depends on whether new tobacco product has ''same'' characteristics as the predicate product or if the new tobacco product has ''different'' characteristics than the predicate product, this distinction is not reflected in either the draft of Form FDA 3965 or the rule itself.

(Response 95) We disagree. The form and the rule are structured to clarify both the common elements (''same'' characteristics) and distinct elements (''different'' characteristics) of SE Reports for both new tobacco products with the ''same'' characteristics as the predicate product and for new tobacco products with ''different'' characteristics than the predicate product. This includes reference to and discussion of these elements in the forms and throughout the rule. Applicants should indicate that their report is a ''same characteristics'' report where no data is necessary to demonstrate that the new tobacco product is substantially equivalent to its predicate. The form has been revised to include a section where the applicant would distinguish whether they are submitting a ''same characteristics'' SE Report, or a ''different characteristics'' SE Report. For a ''same characteristics'' SE Report, an applicant must describe the modification and certify that is the only change between the new and predicate tobacco product.

(Comment 96) One comment believes FDA has underestimated the time needed to complete the forms and did not explain how it arrived at these estimates.

(Response 96) FDA conducted a thorough analysis of the current paperwork burden associated with the SE program and other similar forms and applied the most accurate burden to the forms; however, upon consideration of this comment and certain updates made to the form based on comments received and product categorization changes FDA is revising the burden associated with entering the data into the form (which includes searching existing data sources and gathering and maintaining the data needed) to be 45 minutes per individual product (rather than 30 minutes per product) on Form FDA 3965. For Form FDA 3964, FDA is revising the burden for this form to 10 minutes (from 5 minutes). This form serves several purposes from changing a point of contact (minimal burden) to providing additional substantive information for the purpose of the review of the SE Report (more burdensome). FDA notes that the comment did not provide a recommendation for the alternative estimates FDA might consider.

Description of Respondents: Manufacturers of tobacco products who submit SE Reports.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

This establishes requirements for the content and format of SE Reports (§§ 1107.18 and 1107.19). Most of the requirements mirror current practices and recommendations related to the submission of SE Reports, including information related to part 25 (environmental considerations), but the rule provides both applicants and FDA more certainty regarding the content and format for the SE Reports. A health information summary or statement would continue to be required (section 910(a)(4) of the FD&C Act) and the health summary or response to a request would be required to be in the format of a redacted SE Report, along with any additional health information about the new tobacco product, including any information, research, or data about adverse health effects, that the applicant has or knows about and that is not contained in the SE Report.

As is currently the practice, the rule continues to permit amendments for SE Reports submitted under § 1107.18, *e.g.,* to address deficiencies (§ 1107.20). Also, in accordance with current practice, the rule continues to permit withdrawals (§ 1107.22) of pending SE Reports. The rule also describes requirements for

when the ownership of an SE Report changes to ensure that FDA has information related to the current applicant (§ 1107.24).

The rule establishes a recordkeeping requirement, under which applicants are required to maintain records supporting the SE Report for an authorized new tobacco product for 4 years from the date of an order finding substantial equivalence, even if such product is discontinued (§ 1107.58).

The rule requires that respondents submit an SE Report in an electronic format, unless a waiver from this requirement is requested by the applicant and granted by FDA (§ 1107.62). FDA created two new forms for submission; Form FDA 3964, Tobacco Amendment and General Correspondence; and Form FDA 3965, Tobacco Substantial Equivalence Report Submission.

FDA estimates the burden as the following:

TABLE 2—EXISTING BURDEN FOR OMB CONTROL NUMBER 0910–0673, ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Full SE 905(j)(1)(A)(i) and 910(a)	683	1	683	300	204,900
Full SE 905(j)(1)(A)(i) and 910(a) Bundled	456	1	456	90	41,040
Product Quantity Change SE Report	239	1	239	87	20,793
Product Quantity Change Bundled SE Report	192	1	192	62	11,904
Total					278,637

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This chart represents the currently OMB approved burden for the SE program.

TABLE 3—NEW BURDEN PER THE FINAL RULE, ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; FDA form; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3965—Tobacco Substantial Equivalence Report Submission.	1,570	1	1,570	.75 (45 minutes)	1,178
FDA 3964—Tobacco Amendment and General Correspondence.	628	1	628	.16 (10 minutes)	100
Waiver from Electronic submission 1107.62(b)	240	1	240	.25 (15 minutes)	60
Totals					1,338

TABLE 4—FINAL REPORTING TABLE 2 + 3 REPORTING BURDEN, ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; FDA form; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
SE Report—1107.18	683	1	683	300	204,900
Bundled SE—1107.18	456	1	456	90	41,040
SE Report where applicant provides certification for identical characteristics—1107.18(g) and 1107.18(*l*)(2).	239	1	239	87	20,793
SE Report where applicant provides certification for some identical characteristics (bundled)—1107.18(g) and 1107.18(*l*)(2).	192	1	192	62	11,904
FDA 3965—Tobacco Substantial Equivalence Report Submission.	1,570	1	1,570	.75 (45 minutes)	1,178
FDA 3964—Tobacco Amendment and General Correspondence Report.	628	1	628	.16 (10 minutes)	100
Waiver from Electronic submission—1107.62(b)	240	1	240	.25 (15 minutes)	60
Totals					279,975

TABLE 5—NEW RECORDKEEPING BURDEN PER THE FINAL RULE, ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping SE Report under 1107.18–1107.58	471	1	471	5	2,355

FDA's estimates are based on experience with SE Reports, registration and listing data, interactions with the industry, and information related to other regulated products. Utilizing registration and listing data for deemed

tobacco products, the estimated annual number of SE Reports is expected to be 1,570. The expected number of reports has not changed since the proposed rule. As discussed earlier in this rule, FDA is not finalizing the proposed SE rule with respect to ''premium'' cigars. As such, the estimate of the number of reports expected is likely an overestimate as it includes ''premium'' cigars, which are excluded from the scope of this final rule.

When groups of full SE Reports or SE Reports that each contain a certification that some characteristics have identical content, they may be bundled; when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report.

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA expectations regarding the tobacco industry's use of the substantial equivalence pathway to market their products. Table 2 describes the annual reporting burden for compliance with the requirements to demonstrate substantial equivalence under the FD&C Act. We do not expect a large burden increase for this program, as, without the rule, manufacturers would routinely submit SE Reports for new tobacco products, and the Agency believes most respondents are currently practicing most of the requirements. FDA will revise this collection with the new burden.

Table 3 describes the annual reporting burden as a result of the requirements in §§ 1107.18 and 1107.19, implementing the substantial equivalence requirements of sections 905(j)(1)(A)(i) and 910(a) of the FD&C Act. This rule requires manufacturers to submit SE Reports electronically (§ 1107.62). We estimate that it would initially take about 45 minutes per product to fill out the Form FDA 3965. However, for amendments we estimate that filling out the Form FDA 3964 will take 10 minutes as applicants can copy and paste from the first submission. Section 1107.62(b) also allows for waivers from the electronic format requirement. FDA estimates that 240 respondents or 15 percent of SE Reports (1,570) will submit a waiver.

Based on updated information, FDA estimates that it will receive 683 full initial SE Reports for a new tobacco product each year under § 1107.18 that take a manufacturer approximately 300 hours to prepare. Additionally, manufacturers may bundle groups of SE Reports for their new products in the same product category and subcategory where the proposed modifications are the same; when a group of similar SE Reports are bundled, the reporting burden for the initial SE Report is expected to take the same amount of time as a stand-alone SE Report. However, the reporting burden for subsequent bundled SE Reports is expected to be lower than the initial SE Report. We expect to receive 456 bundled SE Reports under § 1107.18 (other than the initial SE Report in the bundle) at approximately 90 hours per response for a total of 41,040 hours.

In the absence of more specific information concerning SE Reports where applicants provide a certification for some identical characteristics under §§ 1107.18(g) and 1107.18(*l*)(2), FDA estimates receiving 239 such SE Reports at 87 hours per response for a total of 20,973 hours. We also estimate receiving 192 bundled SE Reports where applicants provide a certification for some identical characteristics under §§ 1107.18(g) and 1107.18(*l*)(2) (other than the initial SE Report in the bundle) at 62 hours per response for a total of 11,904 hours. Although we believe that the number of SE Reports that include a certification will increase because the rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product, in the absence of specific information on how many more applicants might choose to certify, we are maintaining our previous estimates at this time.

FDA has based these estimates on the full analysis of economic impacts and experience with the recently-revised existing information collection (OMB Control Number 0910–0673) that applies to tobacco products. In addition, anyone submitting an SE Report is required to submit an environmental assessment prepared in accordance with § 25.40 under § 1107.18(k). The burden for environmental reports has been included in the burden per response for each type of SE Report.

Based on FDA's experience with EAs for currently regulated tobacco products, we expect industry to spend 80 hours preparing an environmental assessment for a full SE Report under § 1107.18.

Generally, an applicant may withdraw its SE Report after submission (§ 1107.22), change the ownership of its SE Report (§ 1107.24), and amend its SE Report (§ 1107.20). Currently, FDA has an OMB approved information collection for SE. The information required to grant these applications is already being collected under the OMB approval, so we do not expect a change in burden to these sections.

FDA estimates that 30 percent of SE Reports or 471 respondents will maintain required records related to their SE Reports at 5 hours per record for a total of 2,355 recordkeeping hours. FDA has revised the estimated burden for recordkeeping per hour from 2.5 hours per record to 5 hours. As discussed in the RIA, the first SE Report in a chain must use a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, as a predicate product for the SE Report. Therefore, we believe that manufacturers will have records on those ''original'' predicate tobacco products from their initial SE Reports. Based on this assumption, this requirement could lead to manufacturers keeping records for a longer time. The final regulatory impact analysis estimates zero to 10 hours per entity each year for recordkeeping, and the PRA estimate has assumed a mid-point of that estimate.

FDA estimates that the burden for new requirements will increase this collection by 3,693 hours (1,338 reporting + 2,355 recordkeeping). The burden for the submission of substantial equivalence information is estimated to total 282,330 hours (279,975 reporting and 2,355 recordkeeping). This rule also refers to previously approved collections of information found in FDA regulations.

Section 1107.40 references meetings that may be held with applicants who want to meet with FDA to discuss scientific and other issues. Additional information about how to request meetings with FDA's CTP can be found in FDA's guidance entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products.'' The collections of information in the guidance referenced have been approved under OMB control number 0910–0731. In addition to the premarket application under section 910(b) and a report under 905(j)(1)(A)(i) of the FD&C Act, certain new tobacco products may use the exemption premarket pathway (see § 1107.1). The collections of information found in § 1107.1 have been approved under OMB control number 0910–0684.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 916(a)(2) of the FD&C Act is an express preemption provision. Section 916(a)(2) provides that ''no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to . . . premarket review.'' Thus, the final rule creates requirements that fall within the scope of section 916(a)(2) of the FD&C Act.

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

XII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required. We received one comment related to tribal consultation and we respond to this comment in the following paragraphs.

(Comment 97) A comment disagrees with the Agency's tentative determination that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The comment notes that FDA's decisions regarding substantial equivalence have had profound effects on the tribe's ability to raise revenue for government services and have required significant expenditures for compliance costs over the last 3 years.

The comment also states the tribe's representatives were unable to participate in an All Tribes' Call on the proposed rule due to late notice of the call. The tribe notes that, although FDA provided them with another opportunity for a call on the proposed rule, late notice of the All Tribes' Call may have caused other tribes to miss the opportunity for consultation and recommends a second All Tribes' Call with at least 30 days' notice, or an in-person consultation with a phone-in option, prior to completing the next phase of rulemaking.

(Response 97) The impact and costs of the proposed rule on tribal manufacturers were considered as part of the Preliminary Regulatory Impact Statement. FDA agrees that collaboration and consultation with Federally recognized tribal governments, per the FDA Tribal Consultation Policy and Executive Order 13175, is important. FDA engages with tribal stakeholders, including tribal government leaders, tribal health leaders, and public health professionals, about the implementation and enforcement of the Tobacco Control Act and related regulations by various methods (*e.g.,* ''Dear Tribal Leader'' letters, All Tribes' Calls, formal and informal consultations as well as face-to-face meetings). We also encourage tribes to stay informed about developments related to tobacco products through our website (*https://www.fda.gov/TobaccoProducts*).

There were several opportunities for tribes to engage with FDA about the proposed rule, including the impact and costs of the proposed rule on tribal manufacturers, which was considered as part of the Preliminary Regulatory Impact Statement (*https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*). In a ''Dear Tribal Leader'' letter dated April 4, 2019, FDA initiated consultation with federally recognized Indian tribes on the proposed rule and invited tribes to participate in an All Tribes' Call. The purpose of the call was to provide an overview of the proposed rule, answer questions, and hear tribal comments on the proposed rule. We provided contact information in the letter and during the call to help ensure that there was a mechanism to address any further questions. To help ensure accessibility to the call, we recorded the call and made that recording available on FDA's website for 30-days following the call, and we added a transcript of the call to the docket for the rulemaking. We also encouraged tribes to submit written comments on the proposed rule and supporting documents such as the Preliminary Regulatory Impact Statement. We note that no other tribe has requested additional consultation on the proposed rule.

XIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov*. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 1107

Administrative practice and procedure, Smoke, Smoking, Tobacco, Tobacco products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations will be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. In § 16.1(b)(2) add in numerical sequence an entry for ''§ 1107.50'' to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 1107.50, relating to rescission of an order finding a tobacco product substantially equivalent.

* * * * *

PART 1107—EXEMPTIONS AND SUBSTANTIAL EQUIVALENCE REPORTS

■ 3. The authority citation for part 1107 is revised to read as follows:

Authority: 21 U.S.C. 371, 374, 387b, 387c, 387e(j), 387i, and 387j.

■ 4. The heading of part 1107 is revised to read as set forth above.

■ 5. Add subparts B through E to read as follows:

Subpart B—General

Sec.

Subpart C—Substantial Equivalence Reports

Subpart D—FDA Review

Subpart E—Miscellaneous

Subpart B—General

§ 1107.10 Scope.

(a) Subparts B through E of this part apply to a substantial equivalence report (or an SE Report) for a new tobacco product, other than ''premium'' cigars as defined in § 1107.12, that has:

(1) Characteristics different from a predicate tobacco product and for which information is submitted to demonstrate it is not appropriate to regulate the product under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health or

(2) The same characteristics as a predicate tobacco product.

(b) These subparts set forth procedures and requirements for the submission to FDA of an SE Report under sections 905 and 910 of the Federal, Food, Drug, and Cosmetic Act; the basic criteria for establishing substantial equivalence; and the general procedures FDA will follow when evaluating submissions.

§ 1107.12 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that the term does not include tobacco or a pesticide chemical residue in or on raw tobacco, or a pesticide chemical.

Applicant means any manufacturer of tobacco products who is subject to chapter IX of the Federal Food, Drug, and Cosmetic Act that submits a premarket application to receive marketing authorization for a new tobacco product.

Brand means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes.

Characteristic means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

Commercial distribution means any distribution of a tobacco product, whether domestic or imported, to consumers or to any person, but does not include interplant transfers of a tobacco product between establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for personal consumption or resale. ''Commercial distribution'' does not include the handing or transfer of a tobacco product from one consumer to another for personal consumption.

Commercially marketed means selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Composition means the materials in a tobacco product, including ingredients, additives, and biological organisms. The term includes the manner in which the materials, for example, ingredients, additives, and biological organisms, are arranged and integrated to produce a tobacco product.

Constituent means any chemical or chemical compound in a tobacco product that is or potentially is inhaled, ingested, or absorbed into the body, any chemical or chemical compound in an emission (*e.g.,* smoke, aerosol, droplets) from a tobacco product, that either transfers from any component or part of the tobacco product to the emission or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

Container closure system means any packaging materials that are a component or part of a tobacco product.

Design means the form and structure concerning, and the manner in which, components or parts, ingredients, software, and materials are integrated to produce a tobacco product.

Distributor means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Finished tobacco product means a tobacco product, including all components and parts, sealed in final packaging (*e.g.,* filters or filter tubes sold to consumers separately or as part of kits) or in the final form in which it is intended to be sold to consumers.

Harmful or potentially harmful constituent (HPHC) means any chemical or chemical compound in a tobacco product or tobacco smoke or emission that:

(1) Is or potentially is inhaled, ingested, or absorbed into the body, including as an aerosol or any other emission; and

(2) Causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products.

Health information statement means a statement, made under section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, that the health information related to a new tobacco product will be made available upon request by any person.

Health information summary means a summary, submitted under section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, of any health information related to a new tobacco product.

Heating source means the source of energy used to burn or heat the tobacco product.

Ingredient means tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing.

Material means an assembly of ingredients. Materials are assembled to form a tobacco product or components or parts of tobacco products.

New tobacco product means:

(1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(2) Any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Other features means any distinguishing qualities of a tobacco product similar to those specifically enumerated in section 910(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. Such other features include harmful and potentially harmful constituents and any other product characteristics that relate to the chemical, biological, and physical properties of the tobacco product.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Predicate tobacco product means a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act.

Premium cigars means a type of cigar that:

(1) Is wrapped in whole tobacco leaf;

(2) Contains a 100 percent leaf tobacco binder;

(3) Contains at least 50 percent (of the filler by weight) long filler tobacco (*i.e.,* whole tobacco leaves that run the length of the cigar);

(4) Is handmade or hand rolled (*i.e.,* no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling);

(5) Has no filter, nontobacco tip, or nontobacco mouthpiece;

(6) Does not have a characterizing flavor other than tobacco;

(7) Contains only tobacco, water, and vegetable gum with no other ingredients or additives; and

(8) Weighs more than 6 pounds per 1,000 units.

Submission tracking number or *STN* means the number that FDA assigns to submissions that are received from a manufacturer of tobacco products, such as SE Reports and voluntary requests for determinations that a tobacco product was commercially marketed in the United States as of February 15, 2007.

Substantial equivalence or *substantially equivalent* means, with respect to a new tobacco product being compared to a predicate tobacco product, that FDA by order has found that the new tobacco product:

(1) Has the same characteristics as the predicate tobacco product; or

(2) Has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to require premarket review under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health.

Substantial equivalence report or *SE Report* means a submission under section 905(j)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act that includes the basis for the applicant's determination that a new tobacco product is substantially equivalent to a predicate tobacco product. This term includes the initial substantial equivalence report and all subsequent amendments.

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the Federal Food, Drug, and Cosmetic Act is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g)).

Tobacco product manufacturer means any person, including a repacker or relabeler, who:

(1) Manufactures, fabricates, assembles, processes, or labels a tobacco product, or

(2) Imports a finished tobacco product for sale or distribution in the United States.

Subpart C—Substantial Equivalence Reports

§ 1107.16 Submission of a substantial equivalence report.

An applicant may submit an SE Report intended to demonstrate that a new tobacco product is substantially equivalent to a predicate tobacco product. The applicant must submit the SE Report at least 90 calendar days prior to the date the applicant intends to introduce or deliver for introduction a new tobacco product into interstate commerce for commercial distribution. The applicant cannot begin commercial distribution of the new tobacco product until FDA has provided the applicant an order stating that the Agency has determined that the new tobacco product is substantially equivalent to a predicate tobacco product, unless the new tobacco product has received authorization to be marketed through another premarket pathway.

§ 1107.18 Required content and format of an SE Report.

(a) *Overview.* The SE Report must provide information uniquely identifying the new tobacco product and the predicate tobacco product, and compare the new tobacco product to either a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that FDA previously found to be substantially equivalent. The SE Report must provide sufficient information as described in this section to enable FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007. If FDA cites deficiencies and requests information to support a statement in the SE Report, the applicant must provide that information for review to continue, or FDA may issue an order under § 1107.48. FDA generally intends to refuse to accept an SE Report for review if it does not comply with § 1105.10 and this section. The SE Report must contain the following information:

(1) General information (as described in paragraph (c) of this section);

(2) Summary (as described in paragraph (d) of this section);

(3) New tobacco product description (as described in paragraph (e) of this section);

(4) Predicate tobacco product description (as described in paragraph (f) of this section), including a statement that the predicate tobacco product has not been removed from the market at the initiative of FDA and has not been determined by judicial order to be adulterated or misbranded, and the submission tracking number of the SE order finding the predicate product SE, or the submission tracking number of, or information to support, that the predicate tobacco product was commercially marketed (other than for test marketing) in the United States as of February 15, 2007;

(5) Comparison information (as described in paragraph (g) of this section);

(6) Comparative testing information (as described in paragraph (h) of this section);

(7) Statement of compliance with applicable tobacco product standards (as described in paragraph (i) of this section);

(8) Health information summary or statement that such information will be made available upon request (as described in paragraph (j) of this section);

(9) Compliance with part 25 of this chapter (as described in paragraph (k) of this section); and

(10) Certification statement (as described in paragraph (*l*) of this section).

(b) *Format.* The applicant must submit the SE Report using the form(s) that FDA provides. The SE Report must contain a comprehensive index and table of contents, be well-organized and legible, and be written in English. As described in § 1107.62, the applicant must submit the SE Report and all information supporting the SE Report in an electronic format that FDA can process, read, review, and archive, unless FDA has provided a waiver under § 1107.62(b).

(c) *General information.* The SE Report must include the following information, using the form FDA provides:

(1) The date the SE Report is submitted;

(2) Type of submission (*e.g.,* the SE Report or amendment to a report);

(3) FDA STN, if previously assigned;

(4) Any other relevant FDA STN, such as a voluntary request for a determination that a tobacco product was commercially marketed in the United States as of February 15, 2007, or SE Report previously found substantially equivalent (if applicable),

and cross-references to meetings with FDA regarding the new tobacco product;

(5) Applicant name, address, and contact information (including email address);

(6) Authorized representative or U.S. agent (for a foreign applicant), including the name, address, and contact information (including email address);

(7) For both the new and predicate tobacco products, the following information to uniquely identify the products:

(i) Manufacturer;

(ii) Product name, including the brand and sub brand (or other commercial name used in commercial distribution); and

(iii) Product category, product subcategory, and product properties (if the product does not have a listed product property, *e.g.,* ventilation or characterizing flavor, the report must state ''none'' for that property) as provided in the following table:

TABLE 1 TO § 1107.18(c)(7)(iii)

Tobacco product category	Tobacco product subcategory	Product properties
(A) Cigarettes	(*1*) Filtered	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89.1 millimeters (mm), 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing Flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Non-filtered	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89.1 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Characterizing Flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Other	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89.1 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing Flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
(B) Roll-Your-Own Tobacco Products.	(*1*) Roll-Your-Own Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20.1 grams (g), 16 ounces (oz.)). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Rolling Paper	—Package type (*e.g.,* box, booklet). —Product quantity (*e.g.,* 50 sheets, 200 papers). —Length (*e.g.,* 79.1 mm, 100 mm, 110.2 mm). —Width (*e.g.,* 28.1 mm, 33 mm, 45.2 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Filtered Cigarette Tube	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 tubes, 200 tubes). —Length (*e.g.,* 89.1 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Non-Filtered Cigarette Tube	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 tubes, 200 tubes). —Length (*e.g.,* 89.1 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Filter	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 filters, 200 filters). —Length (*e.g.,* 8 mm, 12.1 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Paper Tip	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 200 tips, 275 tips). —Length (*e.g.,* 12 mm, 15.1 mm).

TABLE 1 TO § 1107.18(c)(7)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Width (*e.g.,* 27.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*7*) Other	—Package type (*e.g.,* bag, box, booklet). —Product quantity (*e.g.,* 200 tips, 100 filters, 200 tubes). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product.
(C) Smokeless Tobacco Products	(*1*) Loose Moist Snuff	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 2.1 oz.). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable, *e.g.,* fine cut, long cut, straight cut).
	(*2*) Portioned Moist Snuff	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 pouches, 20 pieces). —Portion mass (*e.g.,* 1.5 g/pouch, 1 g/piece). —Portion length (*e.g.,* 15 mm, 20.1 mm). —Portion width (*e.g.,* 10 mm, 15.1 mm). —Portion thickness (*e.g.,* 5 mm, 7.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Loose Snus	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 2.1 oz.). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Portioned Snus	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 pouches, 20 pieces). —Portion mass (*e.g.,* 1.5 g/pouch, 1 g/piece). —Portion length (*e.g.,* 15 mm, 20.1 mm). —Portion width (*e.g.,* 10 mm, 15.1 mm). —Portion thickness (*e.g.,* 5 mm, 7.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Loose Dry Snuff	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 2.1 oz.). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Dissolvable	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 sticks, 20 pieces). —Portion mass (*e.g.,* 1.5 g/strip, 1 g/piece). —Portion length (*e.g.,* 10 mm, 15.1 mm). —Portion width (*e.g.,* 5 mm, 8.1 mm). —Portion thickness (*e.g.,* 3 mm, 4.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*7*) Loose Chewing Tobacco	—Package type (*e.g.,* bag, pouch, wrapped). —Product quantity (*e.g.,* 20 g, 3.1 oz.). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*8*) Portioned Chewing Tobacco	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 10 bits). —Portion mass (*e.g.,* 2.1 g/bit). —Portion length (*e.g.,* 8 mm, 10.1 mm). —Portion width (*e.g.,* 6 mm, 8.1 mm).

TABLE 1 TO § 1107.18(c)(7)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Portion thickness (*e.g.,* 5.1 mm, 7 mm).
		—Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen).
		—Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*9*) Other	—Package type (*e.g.,* box, bag, can).
		—Product quantity (*e.g.,* 20.1 g, 22.5 g, 3 oz.).
		—Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen, tobacco).
		—Additional properties needed to uniquely identify the tobacco product.
(D) Electronic Nicotine Delivery Systems (ENDS) (Vapes).	(*1*) Open E-Liquid	—Package type (*e.g.,* bottle, box, pod).
		—Product quantity (*e.g.,* 1 bottle, 5 bottles).
		—E-liquid volume (*e.g.,* 0.5 milliliters (ml)), 2 ml, 5.1 ml).
		—Nicotine concentration (*e.g.,* 0 mg/ml), 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/bottle).
		—Propylene Glycol (PG)/Vegetable Glycerin (VG) ratio (*e.g.,* not applicable (N/A), 0/100, 50/50, 100/0).
		—Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen).
		—Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Closed E-Liquid	—Package type (*e.g.,* cartridge, pod).
		—Product quantity (*e.g.,* 1 cartridge, 5 cartridges).
		—E-liquid volume (*e.g.,* 0.5 ml, 2 ml, 5.1 ml).
		—Nicotine concentration (*e.g.,* 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/bottle).
		—PG/VG ratio (*e.g.,* N/A, 0/100, 50/50, 100/0).
		—Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen).
		—Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Closed E-Cigarette	—Package type (*e.g.,* box, none, plastic clamshell).
		—Product quantity (*e.g.,* 1 e-cigarette, 5 e-cigarettes).
		—Length (*e.g.,* 100 mm, 120 mm)
		—Diameter (*e.g.,* 6 mm, 8 mm).
		—Wattage (*e.g.,* 100 watts (W), 200 W).
		—Battery capacity (*e.g.,* 100 milliampere hours (mAh), 200 mAh).
		—E-liquid volume (*e.g.,* 0.5 ml, 2 ml, 5.1 ml).
		—Nicotine concentration (*e.g.,* 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/e-cigarette).
		—PG/VG ratio (*e.g.,* N/A, 0/100, 50/50, 100/0).
		—Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen).
		—Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Open E-Cigarette	—Package type (*e.g.,* box, none, plastic clamshell).
		—Product quantity (*e.g.,* 1 e-cigarette, 5 e-cigarettes).
		—Length (*e.g.,* 100 mm, 120 mm)
		—Diameter (*e.g.,* 6 mm, 8 mm).
		—Wattage (*e.g.,* 100 W, 200 W).
		—Battery capacity (*e.g.,* 100 mAh, 200 mAh).
		—E-liquid volume (*e.g.,* 0.5 ml, 2 ml, 5.1 ml).
		—Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen).
		—Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) ENDS Component	—Package type (*e.g.,* box, none, plastic clamshell).
		—Product quantity (*e.g.,* 1 coil).
		—Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen, tobacco).
		—Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Other	—Package type (*e.g.,* box, none, plastic clamshell).
		—Product quantity (*e.g.,* 1 e-cigarette, 5 bottles).
		—Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen, tobacco).
		—Additional properties needed to uniquely identify the tobacco product.
(E) Cigars	(*1*) Filtered, Sheet-Wrapped	—Package type (*e.g.,* hard pack, soft pack, clam shell).
		—Product quantity (*e.g.,* 20 filtered cigars, 25 filtered cigars).

TABLE 1 TO § 1107.18(c)(7)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Length (*e.g.,* 89.1 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 0%, 10%, 25%). —Characterizing flavor (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Unfiltered, Sheet-Wrapped	—Package type (*e.g.,* box, film sleeve). —Product quantity (*e.g.,* 1 cigar, 5 cigarillos). —Length (*e.g.,* 100.1 mm, 140 mm). —Diameter (*e.g.,* 8 mm, 10.1 mm). —Tip (*e.g.,* none, wood tips, plastic tips). —Characterizing flavor (*e.g.,* none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Unfiltered, Leaf-Wrapped	—Package type (*e.g.,* box, film, sleeve, none). —Product quantity (*e.g.,* 1 cigar, 5 cigars). —Length (*e.g.,* 150.1 mm, 200 mm). h;Diameter (*e.g.,* 8 mm, 10.1 mm). —Wrapper material (*e.g.,* burley tobacco leaf, Connecticut shade grown tobacco leaf). —Characterizing flavor (*e.g.,* none, whiskey). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Cigar Component	—Package type (*e.g.,* box, booklet). —Product quantity (*e.g.,* 10 wrappers, 20 leaves). —Characterizing flavor (*e.g.,* none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Cigar Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 16.1 oz.). —Characterizing flavor (*e.g.,* none, tobacco, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Other	—Package type (*e.g.,* box, booklet). —Product quantity (*e.g.,* 1 cigar, 5 cigars, 20 leaves, 16 g). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product.
(F) Pipe Tobacco Products	(*1*) Pipe	—Package type (*e.g.,* box, none). —Product quantity (*e.g.,* 1 pipe). —Length (*e.g.,* 200 mm, 300.1 mm). —Diameter (*e.g.,* 25.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cavendish, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Pipe Tobacco Filler	—Package type (*e.g.,* box, none). —Product quantity (*e.g.,* 20 g, 16.1 oz.). —Tobacco cut style (*e.g.,* standard cut, such as shag cut, bugler cut, loose cut, etc., or a pressed cut, such as flake, cube cut, roll cake, etc. or a mixture). —Characterizing flavor(s) (*e.g.,* none, menthol, cavendish, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Pipe Component	—Package type (*e.g.,* box, bag, none). —Product quantity (*e.g.,* 1 bowl, 1 stem, 100 filters). —Characterizing flavor(s) (*e.g.,* none, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Other	—Package type (*e.g.,* box, bag, none). —Product quantity (*e.g.,* 1 pipe, 1 bowl, 1 stem, 100 filters). —Characterizing flavor(s) (*e.g.,* none, cherry). —Additional properties needed to uniquely identify the tobacco product.
(G) Waterpipe Tobacco Products ...	(*1*) Waterpipe	—Package type (*e.g.,* box, none). —Product quantity (*e.g.,* 1 waterpipe). —Height (*e.g.,* 200 mm, 500.1 mm). —Width (*e.g.,* 100.1 mm, 300 mm). —Diameter (*e.g.,* 100.1 mm, 300 mm). —No. of hoses (*e.g.,* 1, 2, 4). —Characterizing flavor(s) (*e.g.,* none). —Additional properties needed to uniquely identify the tobacco product (if applicable).

TABLE 1 TO § 1107.18(c)(7)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	(*2*) Waterpipe Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 16.1 oz.). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Waterpipe Heat Source	—Package type (*e.g.,* box, film sleeve, bag, none). —Product quantity (*e.g.,* 150 g, 680 g). —Portion count (*e.g.,* 20 fingers, 10 discs, 1 base). —Portion mass (*e.g.,* 15 g/finger, 10 g/brick). —Portion length (*e.g.,* 40 mm, 100 mm). —Portion width (*e.g.,* 10 mm, 40 mm). —Portion thickness (*e.g.,* 10 mm, 40 mm). —Source of energy (*e.g.,* charcoal, battery, electrical). —Characterizing flavor(s) (*e.g.,* none, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Waterpipe Component	—Package type (*e.g.,* box, bag, none). —Product quantity (*e.g.,* 1 base, 1 bowl, 1 hose, 10 mouthpieces). —Characterizing flavor(s) (*e.g.,* none, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Other	—Package type (*e.g.,* box, bag, none). —Product quantity (*e.g.,* 1 base, 1 bowl, 1 hose, 10 mouthpieces). —Characterizing flavor(s) (*e.g.,* none, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
(H) Heated Tobacco Products (HTP).	(*1*) Closed HTP	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 device, 1 HTP). —Length (*e.g.,* 100 mm, 120 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Wattage (*e.g.,* 100 W, 200 W). —Battery capacity (*e.g.,* 100 mAh, 200 mAh). —Characterizing flavor(s) (*e.g.,* none). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Open HTP	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 device, 1 HTP). —Length (*e.g.,* 100 mm, 120 mm) —Diameter (*e.g.,* 6 mm, 8.1 mm). —Wattage (*e.g.,* 100 W, 200 W). —Battery capacity (*e.g.,* 100 mAh, 200 mAh). —Characterizing flavor(s) (*e.g.,* none). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) HTP Consumable	—Package type (*e.g.,* hard pack, soft pack, plastic clamshell). —Product quantity (*e.g.,* 20 sticks, 25 cartridges). —Length (*e.g.,* 60 mm, 82 mm.) —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) HTP Component	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 mouthpiece, 1 spacer). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Other	—Package type (*e.g.,* box, bag, plastic clamshell, none). —Product quantity (*e.g.,* 1 base, 5 capsules). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
Other	Other	—Package type (*e.g.,* box, bag, plastic clamshell, none). —Product quantity (*e.g.,* 1 base, 5 capsules). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).

(8) Address and the FDA Establishment Identifier number(s) of the establishments involved in the manufacture and/or importation of the new and predicate tobacco products.

(d) *Summary.* The SE Report must include a summary at the beginning of the SE Report that includes the following:

(1) A concise description of the characteristics of the new tobacco product;

(2) A statement as to whether the applicant believes the new tobacco product has the same characteristics as the predicate tobacco product or has different characteristics but any differences in characteristics do not cause the new tobacco product to raise different questions of public health; and

(3) A concise description of the similarities and differences between the new tobacco product and the predicate tobacco product with respect to their characteristics (materials, ingredients, design, composition, heating source, or other features).

(e) *New tobacco product description.* The applicant must identify one new tobacco product in the SE Report for comparison to one predicate tobacco product. The SE Report must describe the new tobacco product in sufficient detail to enable FDA to evaluate its characteristics. This part of the SE Report must include:

(1) A narrative description of the new tobacco product and detailed drawings or schematics of the new tobacco product, including its container closure system, illustrating all components or parts of the product. For a portioned tobacco product, the SE Report must also include a diagram illustrating all components or parts of the individual unit of use;

(2) A description and the function of each component or part of the new tobacco product, and an explanation of how each component or part is integrated into the design of the new tobacco product; and

(3) A concise overview of the process used to manufacture the new tobacco product. If the manufacturing process for the new tobacco product does not affect the characteristics of the new tobacco product beyond what is described elsewhere in the SE Report, an applicant must state that to satisfy this provision.

(f) *Description of predicate tobacco product.* (1) The applicant must identify a predicate tobacco product that is either a tobacco product commercially marketed (other than for test marketing) as of February 15, 2007, or a tobacco product that FDA previously found to be substantially equivalent.

(2) A tobacco product to which a new tobacco product is compared must:

(i) Have been either:

(A) Commercially marketed (other than for test marketing) in the United States as of February 15, 2007, as shown by either specific information sufficient to support this in the SE Report, including a statement that ''I, (insert name and position title of responsible official), confirm that the predicate tobacco product associated with this submission, (insert name of predicate tobacco product), was commercially marketed (other than for test marketing) in the United States as of February 15, 2007,'' and, if applicable, reference to an STN for a previous determination by FDA that the predicate product was commercially marketed (other than for test marketing) in the United States as of February 15, 2007; or

(B) Previously determined to be substantially equivalent by FDA;

(ii) Be an individual product and not a composite of multiple products;

(iii) Not be the subject of a rescission action by FDA, as described in § 1107.50; and

(iv) Not have been removed from the market at the initiative of FDA and not have been determined by judicial order to be adulterated or misbranded.

(g) *Comparison information.* The SE Report must include a comparison of the characteristics of the new tobacco product and the predicate tobacco product. If the new tobacco product has limited changes to a characteristic(s) when compared to the predicate tobacco product, and all other characteristics are identical (*e.g.,* a change to product quantity), the applicant must provide comparison information related to any characteristic(s) that have changed, but may certify that the other characteristics are identical under paragraph (l)(2) of this section. The applicant must maintain records supporting the certification consistent with § 1107.58.

(h) *Comparative testing information.* Other than for characteristics that are identical, and for which the applicant has certified that the characteristics are identical under paragraph (l)(2) of this section, the SE Report must provide comparative testing information that has been demonstrated to be fully validated on the characteristics of the new and predicate tobacco products except where the applicant adequately justifies that such comparative testing information is not necessary to demonstrate that the new product:

(1) Has the same characteristics as the predicate or

(2) Does not raise different questions of public health.

(i) *Statement of compliance with applicable tobacco product standards.* The SE Report must either:

(1) List and describe the action(s) taken by the applicant to comply with applicable requirements under section 907 of the Federal Food, Drug, and Cosmetic Act; or

(2) State there are no applicable requirements under section 907 of the Federal Food, Drug, and Cosmetic Act.

(j) *Health information summary or statement regarding availability of such information.* The SE Report must include either a health information summary or a statement that such information will be made available upon request, as provided in section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, in accordance with the following:

(1) *Health information summary.* If including a health information summary with the SE Report, the applicant must provide a copy of the full SE Report that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63 of this chapter; and either

(i) Provide accurate, complete, and not false or misleading, additional health information, including information, research, or data about adverse health effects, that the applicant has or knows about concerning the new tobacco product that is not contained in the SE Report; or

(ii) Provide the following statement, if true, about the new tobacco product: ''Applicant does not have or know of any additional health information, including information, research or data regarding adverse health effects, about the new tobacco product that is the subject of this SE Report.''

(2) *Statement regarding availability of health information.* If the applicant chooses to make the health information available upon request, the SE Report must include the following statement, with the appropriate applicant information inserted as indicated by parenthetical text, signed by an authorized representative of the applicant, made on a separate page of the SE Report, and clearly identified as ''910(a)(4) health information statement'': ''I certify that, in my capacity as (*the position held in company by person required to submit the SE Report, preferably the responsible official of the applicant*) of (*company name*), I will make available, upon request, the information identified in 21 CFR 1107.18(j)(3) within 30 calendar days of a request.''

(3) *Content of health information.* The health information the applicant agrees

to make available in paragraph (j)(2) of this section must be a copy of the full SE Report, excluding all research subject identifiers, trade secrets, and confidential commercial information, as defined in §§ 20.61 and 20.63 of this chapter; and either:

(i) Accurate, complete, and not false or misleading, additional health information, including information, research, or data about adverse health effects, that the applicant has or knows about concerning the new tobacco product and that is not contained in the SE Report; or

(ii) The following statement, if true, about the new tobacco product: ''(*Company name*) does not have or know of any additional health information, including information, research or data regarding adverse health effects about the new tobacco product that is the subject of the provided SE Report.''

(4) *Requests for information.* All requests for information under paragraph (j)(2) of this section must be made in writing to the authorized representative of the applicant, whose contact information will be posted on the FDA website listing substantial equivalence determinations. The applicant must provide FDA any updated information if the contact information changes.

(5) *No modified risk violations.* To the extent information is included in the health information summary or health information provided upon request under paragraphs (j)(1) and (2) of this section that is not required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act or this paragraph (j), that information must not contain a statement that would cause the tobacco product to be in violation of section 911 of the Federal Food, Drug, and Cosmetic Act upon the introduction or delivery for introduction of the proposed new product into interstate commerce.

(k) *Compliance with part 25 of this chapter.* (1) The SE Report must include an environmental assessment prepared in accordance with § 25.40 of this chapter, or a valid claim of categorical exclusion. If the applicant believes that the action qualifies for an available categorical exclusion, the applicant must state under § 25.15(a) and (d) of this chapter that the action requested qualifies for a categorical exclusion, citing the particular exclusion that is claimed, and that to the applicant's knowledge, no extraordinary circumstances exist under § 25.21.

(2) The environmental assessment must include a statement explaining whether the new tobacco product is intended to replace the predicate tobacco product after the new tobacco product receives market authorization, is intended to be a line extension of the predicate tobacco product, is intended to be introduced as an additional product by the same manufacturer, or if the new tobacco product will be introduced as an additional product but by a different manufacturer.

(l) *Certification statement.* (1) The SE Report must contain the following certification, with the appropriate information inserted (as indicated by parenthetical text), and be signed by an authorized representative of the applicant: ''I (*name of responsible official*) on behalf of (*applicant*), hereby certify that (*applicant*) will maintain all records to substantiate the accuracy of this SE Report for the period of time required in 21 CFR 1107.58 and ensure that such records remain readily available to the FDA upon request. I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.''

(2) The SE Report must include the following certification, as well as a justification for the certification, if an applicant chooses to certify that certain characteristics are identical in lieu of providing data for each characteristic of the new and predicate tobacco products. This certification must include the appropriate information inserted (as indicated by parenthetical text) and be signed by an authorized representative of the applicant: ''I, (*name of responsible official*), on behalf of (*name of company*), certify that (*new tobacco product name*) has the following modification(s) as compared to (*name of predicate tobacco product*): (*describe modification(s), e.g., change in product quantity or change in container closure system*). Aside from these modifications, the characteristics of (new tobacco product name) and (name of predicate tobacco product) are identical. I certify that (*name of company*) understands this means there is no other modification to the materials, ingredients, design features, heating source, or any other feature. I also certify that (*name of company*) will maintain records to support the comparison information in 21 CFR 1107.19 that substantiate the accuracy of this statement for the period of time required in 21 CFR 1107.58, and ensure that such records remain readily available to FDA upon request.''

§ 1107.19 Comparison information.

The SE Report must include a comparison of the characteristics of the new tobacco product to the predicate tobacco product. Where test data is submitted, the testing information must include the test protocols, quantitative acceptance criteria, and test results (including means and variances, data sets, and a summary of the results). Comparison testing must be conducted on a sufficient sample size and on test samples that reflect the finished tobacco product composition and design. The SE report must state whether the same test methods were used for the new tobacco product and the predicate product, and if the methods differed, an explanation as to how the results of the different test methods can be compared. The SE report must identify national and international standards used to test the new and predicate tobacco products and explain any deviations from the standard, or state that no standards were used for the testing. The SE report must include the following:

(a) *Comparison of product design.* The SE Report must include a description of the product designs of the new and predicate tobacco products and an identification of any differences. The SE Report must include, in a tabular format, a side-by-side comparison of each design parameter of the new and predicate tobacco products. The target specification and upper and lower range limits must be provided for each design parameter. Test data (including test protocols, quantitative acceptance criteria, data sets (*i.e.,* measured values), and a summary of the results) must be provided for the new and predicate tobacco products when the target specification or range limits of the new tobacco product differ from the predicate tobacco product. For tobacco cut size or particle size, when target specifications and range limits are not available, the following alternative information may be submitted in place of this information: A description of the tobacco cutting process (including a complete description of the milling, cutting, and sifting process; the control parameters of the miller or cutter; and any sift specifications) or the measured particle size distribution for the new and predicate tobacco products.

(1) *Cigarettes.* For cigarettes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 1 TO § 1107.19(a)(1)

Provide Target Specification With Upper and Lower Range Limits for:
- —Cigarette length (mm).
- —Cigarette circumference or diameter (mm).
- —Tobacco filler mass (mg).
- —Tobacco rod density (g/cm^3).
- —Tobacco moisture or oven volatiles (%).
- —Tobacco cut size (mm or cuts per inch (CPI)).
- —Filter ventilation (%).
- —Tipping paper length (mm).
- —Cigarette paper base paper porosity (CORESTA unit (CU)) or permeability.
- —Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
- —Cigarette paper band width (mm).
- —Cigarette paper band space (mm).
- —Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (*e.g.,* denier per filament (DPF), total denier (g/9000m), and filter density (g/cm^3))).
- —Filter length (mm).
- —Filter pressure drop (mm H_2O).

TABLE 2 TO § 1107.19(a)(1)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
- —Tobacco filler mass (mg).
- —Tobacco moisture (%) or oven volatiles (%).
- —Filter ventilation (%).
- —Tobacco cut size (mm or CPI).
- —Cigarette paper base paper porosity (CU).
- —Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)).
- —Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))).
- —Filter pressure drop (mm H_2O).

(2) *Smokeless Tobacco.* For portioned and non-portioned smokeless tobacco products, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 3 TO § 1107.19(a)(2)

Provide Target Specification With Upper and Lower Range Limits for:
- Portioned Smokeless Tobacco Products:
  - —Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron).
  - —Tobacco moisture (%).
  - —Portion length (mm).
  - —Portion width (mm).
  - —Portion mass (mg).
  - —Pouch material thickness (mm) (if applicable).
  - —Pouch material porosity or permeability (CU or L/m^2/s) (if applicable).
  - —Pouch material basis weight (g/m^2). (if applicable).
  - —Nicotine dissolution rate (%/min) (if applicable).
- Non-portioned Smokeless Tobacco Products:
  - —Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron).
  - —Tobacco moisture (%).

TABLE 4 TO § 1107.19(a)(2)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
- Portioned Smokeless Tobacco Products:
  - —Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron).
  - —Tobacco moisture (%).
  - —Portion mass (mg).
  - —Pouch material porosity or permeability (CU or L/m^2/s).
  - —Pouch material basis weight (g/m^2).
  - —Nicotine dissolution rate (%/min) (if applicable).
- Non-portioned Smokeless Tobacco Products:
  - —Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron).
  - —Tobacco moisture (%).

(3) *Roll-your-own tobacco, rolling papers.* For roll-your-own tobacco rolling papers, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 5 TO § 1107.19(a)(3)

Provide Target Specifications With Upper and Lower Range Limits for:
—Paper length (mm).
—Paper width (mm).
—Mass per paper (mg).
—Cigarette paper base paper basis weight (g/m^2).
—Cigarette paper base paper porosity or permeability (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigarette paper band width (mm) (if applicable).
—Cigarette paper band space (mm) (if applicable).

TABLE 6 TO § 1107.19(a)(3)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Mass per paper (mg).
—Cigarette paper base paper basis weight (g/m^2).
—Cigarette paper base paper porosity or permeability (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).

(4) *Roll-your-own tobacco, non-filtered tubes.* For roll-your-own tobacco non-filtered tubes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 7 TO § 1107.19(a)(4)

Provide Target Specifications With Upper and Lower Range Limits for:
—Tube length (mm).
—Tube circumference or diameter (mm).
—Tube mass (mg).
—Cigarette paper base paper basis weight (g/m^2).
—Cigarette paper base paper porosity (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigarette paper band width (mm) (if applicable).
—Cigarette paper band space (mm) (if applicable).

TABLE 8 TO § 1107.19(a)(4)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Tube mass (mg).
—Cigarette paper base paper basis weight (g/m^2).
—Cigarette paper base paper porosity (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)).

(5) *Roll-your-own tobacco, filtered tubes.* For roll-your-own tobacco filtered tubes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 9 TO § 1107.19(a)(5)

Provide Target Specifications With Upper and Lower Range Limits for:
—Tube length (mm).
—Tube circumference or diameter (mm).
—Tube mass (mg).
—Tipping paper length (mm).
—Filter ventilation (%).
—Cigarette paper base paper basis weight (g/m^2).
—Cigarette paper base paper porosity or permeability (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigarette paper band width (mm) (if applicable).
—Cigarette paper band space (mm) (if applicable).
—Filter length (mm).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))).
—Filter pressure drop (mm H_2O).

TABLE 10 TO § 1107.19(a)(5)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Tube mass (mg).

TABLE 10 TO § 1107.19(a)(5)—Continued

—Filter ventilation (%).
—Cigarette paper base paper basis weight (g/m^2).
—Cigarette paper base paper porosity or permeability (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))).
—Filter pressure drop (mm H_2O).

(6) *Roll-your-own tobacco.* For roll-your-own tobacco, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 11 TO § 1107.19(a)(6)

Provide Target Specifications With Upper and Lower Range Limits for:
—Tobacco cut size (mm or CPI).
—Tobacco moisture (%) or oven volatiles (%).

TABLE 12 TO § 1107.19(a)(6)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Tobacco cut size (mm or CPI).
—Tobacco moisture (%) or oven volatiles (%).

(7) *Filtered, sheet-wrapped cigars.* For filtered, sheet-wrapped cigars, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 13 TO § 1107.19(a)(7)

Provide Target Specifications With Upper and Lower Range Limits for:
—Cigar mass (mg).
—Cigar wrapper basis weight (g/m^2).
—Cigar binder length (mm).
—Cigar binder width (mm).
—Cigar binder basis weight (g/m^2).
—Cigar length (mm).
—Cigar overall diameter (mm).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).
—Cigar wrapper porosity or permeability (CU).
—Cigar wrapper length (mm).
—Cigar wrapper width (mm).
—Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar wrapper band width (mm) (if applicable).
—Cigar wrapper band space (mm) (if applicable).
—Tipping paper length (mm).
—Cigar binder porosity or permeability (CU).
—Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar binder band width (mm) (if applicable).
—Cigar binder band space (mm) (if applicable).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigar filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density(g/cm^3))).
—Filter pressure drop (mm H_2O).
—Filter length (mm).
—Filter diameter (mm).
—Filter ventilation (%).

TABLE 14 TO § 1107.19(a)(7)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Cigar mass (mg).
—Puff count.
—Cigar wrapper basis weight (g/m^2).

TABLE 14 TO § 1107.19(a)(7)—Continued

—Cigar wrapper porosity or permeability (CU).
—Cigar binder porosity or permeability (CU).
—Cigar binder basis weight (g/m^2).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco cut size (CPI or mm).
—Tobacco moisture or oven volatiles (%).
—Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar binder band width (mm) (if applicable).
—Cigar binder band space (mm) (if applicable).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).
—Filter ventilation (%).
—Filter pressure drop (mm H_2O).

(8) *Unfiltered, sheet-wrapped cigars.* For unfiltered, sheet-wrapped cigars, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 15 TO § 1107.19(a)(8)

Provide Target Specifications With Upper and Lower Range Limits for:
—Cigar length (mm).
—Cigar mass (mg).
—Cigar overall diameter (mm).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).
—Cigar wrapper porosity or permeability (CU).
—Cigar wrapper length (mm).
—Cigar wrapper width (mm).
—Cigar wrapper basis weight (g/m^2).
—Cigar binder porosity or permeability (CU).
—Cigar binder width (mm) (if applicable).
—Cigar binder basis weight (g/m^2).
—Cigar tip mass (mg) (if applicable).
—Tip length (mm) (if applicable).
—Tip inner diameter (mm) (if applicable).
—Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar binder band width (mm) (if applicable).
—Cigar binder band space (mm) (if applicable).
—Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar wrapper band width (mm) (if applicable).
—Cigar wrapper band space (mm) (if applicable).

TABLE 16 TO § 1107.19(a)(8)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Puff count.
—Cigar mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco cut size (CPI or mm).
—Tobacco moisture or oven volatiles (%).
—Tobacco filler mass (mg).
—Cigar wrapper basis weight (g/m^2).
—Cigar wrapper porosity or permeability (CU).
—Cigar binder width (mm) (if applicable).
—Cigar binder basis weight (g/m^2).
—Cigar binder porosity or permeability (CU).
—Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar tip mass (mg) (if applicable).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).

(9) *Unfiltered, leaf-wrapped cigars.* For unfiltered, leaf-wrapped cigars, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 17 TO § 1107.19(a)(9)

Provide Target Specifications With Upper and Lower Range Limits for:
—Cigar length (mm).
—Cigar mass (mg).
—Overall diameter (mm).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).
—Cigar wrapper length (mm).
—Cigar wrapper width (mm).
—Cigar wrapper basis weight (g/m^2).
—Cigar binder width (mm).
—Cigar binder basis weight (g/m^2).

TABLE 18 TO § 1107.19(a)(9)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Puff count.
—Cigar mass (mg).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco cut size (CPI or mm).
—Cigar wrapper basis weight (g/m^2).
—Cigar binder basis weight (g/m^2).
—Tobacco moisture or oven volatiles (%).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).

(10) *Cigar filler.* For cigar filler, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 19 TO § 1107.19(a)(10)

Provide Target Specifications With Upper and Lower Range Limits for:
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).

TABLE 20 TO § 1107.19(a)(10)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).

(11) *Cigar component.* For cigar components, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 21 TO § 1107.19(a)(11)

Provide Target Specifications With Upper and Lower Range Limits for:
—Cigar wrapper length (mm).
—Cigar wrapper width (mm).
—Cigar wrapper porosity (CU).
—Cigar wrapper basis weight (g/m^2).

TABLE 22 TO § 1107.19(a)(11)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Cigar wrapper length (mm).

TABLE 22 TO § 1107.19(a)(11)—Continued

—Cigar wrapper width (mm).
—Cigar wrapper basis weight (g/m^2).

(12) *Pipes.* For pipes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 23 TO § 1107.19(a)(12)

Provide Target Specifications With Upper and Lower Range Limits for:
—Bowl chamber outer diameter (mm).
—Bowl chamber inner diameter (mm).
—Draught hole diameter (mm).
—Draught hole location.
—Draught hole shape.
—Bowl chamber hole shape.
—Bowl chamber volume (cm^3).
—Stem length (mm).
—Stem diameter (mm).
—Shank length (mm).
—Shank diameter (mm).
—Draught hole area (mm^2).
—Pressure drop through air valve (mm H_2O).
—Air flow through air valve (cc/min).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))).
—Filter pressure drop (mm H_2O).
—Filter length (mm).

TABLE 24 TO § 1107.19(a)(12)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Bowl chamber volume (cm^3).
—Air flow through air valve (cc/min).
—Filter length (mm).
—Filter pressure drop (mm H_2O).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))).

(13) *Pipe filler.* For pipe filler, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 25 TO § 1107.19(a)(13)

Provide Target Specifications With Upper and Lower Range Limits for:
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).

TABLE 26 TO § 1107.19(a)(13)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).

(14) *Waterpipes.* For waterpipes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 27 TO § 1107.19(a)(14)

Provide Target Specifications With Upper and Lower Range Limits for:
—Hose length (mm).
—Hose internal diameter (mm).
—Hose materials.
—Stem length (mm).
—Stem internal diameter (mm).
—Base diameter (mm).

TABLE 27 TO § 1107.19(a)(14)—Continued

—Base volume (cm^3).
—Base shape.
—Pressure drop (mm H_2O).
—Water filter efficiency (%).
—Hose air permeability (CU).
—Head height (mm).
—Head top diameter (mm).
—Head bottom diameter (mm).
—No. of holes.
—Head volume (mm^3).
—Heating source type.
—Head materials.

TABLE 28 TO § 1107.19(a)(14)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Hose length (mm).
—Hose internal diameter (mm).
—Stem length (mm).
—Stem internal diameter (mm).
—Base diameter (mm).
—Base volume (cm^3).
—Pressure drop (mm H_2O).
—Water filter efficiency (%).
—Head height (mm).
—Head top diameter (mm).
—Head bottom diameter (mm).
—Head volume (mm^3).

(15) *Waterpipe, heating source.* For waterpipe heating sources, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 29 TO § 1107.19(a)(15)

Provide Target Specifications With Upper and Lower Range Limits for:
—Heating element mass (mg).
—Heating element density (g/cm^3).
—Heating element resistance (ohms) (if applicable).
—No. of heating elements.
—Heating element configuration.
—Heating element diameter (gauge).
—Battery current rating (mA) (if applicable).
—Battery capacity (mAh) (if applicable).
—Battery voltage operating range (volts) (if applicable).
—Battery current operating range (amps) (if applicable).
—Power delivery unit (PDU) voltage operating range (volts) (if applicable).
—PDU current operating range (amps) (if applicable).
—PDU wattage operating range (watts) (if applicable).
—PDU temperature cut-off (°C) (if applicable).

TABLE 30 TO § 1107.19(a)(15)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Heating element temperature range (°C) (if applicable).
—Heating element mass (mg).
—Heating element density (g/cm^3).
—Heating element resistance (ohms) (if applicable).
—Heating element diameter (gauge).
—Battery current rating (mA) (if applicable).
—Battery capacity (mAh) (if applicable).
—Battery voltage operating range (volts) (if applicable).
—Battery current operating range (amps) (if applicable).
—Power delivery unit (PDU) voltage operating range (volts) (if applicable).
—PDU current operating range (amps) (if applicable).
—PDU wattage operating range (watts) (if applicable).
—PDU temperature cut-off (°C) (if applicable).

(16) *Waterpipe component, head.* For waterpipe heads, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 31 TO § 1107.19(a)(16)

Provide Target Specifications With Upper and Lower Range Limits for:
—Head height (mm).
—Head top diameter (mm).
—Head bottom diameter (mm).
—No. of holes.
—Head volume (mm^3).
—Head materials.

TABLE 32 TO § 1107.19(a)(16)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Head height (mm).
—Head top diameter (mm).
—Head bottom diameter (mm).
—Head volume (mm^3).

(17) *Waterpipe component, foil.* For waterpipe foil, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 33 TO § 1107.19(a)(17)

Provide Target Specifications With Upper and Lower Range Limits for:
—Length (mm) (for square or rectangular shape foil).
—Width (mm) (for square or rectangular shape foil).
—Diameter (mm) (for circular shape foil).
—Foil thickness (mm).
—No. of holes.
—Diameter of the holes (mm).

TABLE 34 TO § 1107.19(a)(17)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Length (mm) (for square or rectangular shape foil).
—Width (mm) (for square or rectangular shape foil).
—Diameter (mm) (for circular shape foil).
—Foil thickness (mm).
—Diameter of the holes (mm).

(18) *Waterpipe filler.* For waterpipe filler, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 35 TO § 1107.19(a)(18)

Provide Target Specifications With Upper and Lower Range Limits for:
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).

TABLE 36 TO § 1107.19(a)(18)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).

(19) *Electronic Nicotine Delivery System (ENDS).* For ENDS (vapes), the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 37 TO § 1107.19(a)(19)

Provide Target Specifications With Upper and Lower Range Limits for:
—Draw resistance (mm H_2O).
—Puff count (for full tank/cartridge).
—Atomizer tank/cartridge volume (mL).
—No. of heating elements (*e.g.,* coil).
—Heating element diameter (gauge).
—Heating element length (mm).
—Heating element resistance (Ohms).
—Heating element temperature range (°C).
—Heating element configuration (target only).
—Battery voltage operating range (V).
—Battery current operating range (mA).
—Battery capacity (mAh).
—Battery nominal voltage (V).
—Battery current rating (mA).
—Battery charging temperature limits (°C).
—Battery discharge temperature limits (°C).
—Battery end of discharge voltage (V).
—Battery maximum charging current (mA).
—Battery maximum discharging current (mA).
—Battery upper limits charging voltage (V).
—Power Delivery Unit (PDU) voltage operating range (V).
—PDU current operating range (mA).
—PDU wattage operating range (watts).
—PDU temperature cut-off (°C) (if applicable).
—PDU current cut-off (mA) (if applicable).
—Airflow rate (L/min) (if applicable).
—Ventilation (%).
—Inhaled aerosol temperature (°C).

TABLE 38 TO § 1107.19(a)(19)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Draw resistance (mm H_2O).
—Puff count (for full tank/cartridge).
—Atomizer tank/cartridge volume (mL).
—Heating element diameter (gauge).
—Heating element resistance (Ohms).
—Heating element temperature range (°C).
—Battery voltage operating range (V).
—Battery current operating range (mA).
—PDU voltage operating range (V).
—PDU current operating range (mA).
—PDU wattage operating range (watts).
—PDU current cut-off (mA) (if applicable).
—Inhaled aerosol temperature (°C).
—PDU temperature cut-off (°C) (if applicable).
—Battery capacity (mAh).
—Battery nominal voltage (V).
—Battery current rating (mA).
—Heating element length (mm).
—Battery charging temperature limits (°C).
—Battery discharge temperature limits (°C).
—Battery maximum charging current (mA).
—Battery maximum discharging current (mA).
—Battery upper limits charging voltage (V).
—Airflow rate (L/min) (if applicable).
—Ventilation (%).

(20) *E-liquids.* For e-liquids, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 39 TO § 1107.19(a)(20)

Provide Target Specifications With Upper and Lower Range Limits for:
—E-liquid viscosity (at 20°C).
—E-liquid volume (ml).
—Particle number concentration (#/cm^3).
—Count median diameter (nm).

TABLE 39 TO § 1107.19(a)(20)—Continued

—$PM_{2.5}$ (μg/m^3).

TABLE 40 TO § 1107.19(a)(20)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—E-liquid viscosity (at 20°C).
—E-liquid volume (ml).
—Particle number concentration (#/cm^3).
—Count median diameter (nm).
—$PM_{2.5}$ (μg/m^3).

(21) *Heated Tobacco Products (HTP).* For HTPs, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 41 TO § 1107.19(a)(21)

Provide Target Specifications With Upper and Lower Range Limits for:
—Overall Device:
—Mass (mg).
—Length (mm).
—Width (mm).
—Height (mm).
—Diameter (mm).
—Draw resistance (mm H_2O).
—Puff count (for full tank/cartridge).
—Puff volume (mL).
—Product volume (mL).
—Airflow rate (L/min) (if applicable).
—Ventilation (%).
—Operational temperature (°C).
—Temperature sensor (if applicable).
—Material wrapper length (mm) (if applicable).
—Material wrapper width (mm) (if applicable).
—Material wrapper basis weight (g/m^2) (if applicable).
—Material porosity or permeability (CU) (if applicable).
—Heating element:
—Heating element source/type/approach (electrical, carbon, aerosol, etc.).
—Heating element temperature range (°C).
—Heating element operational temperature (°C).
—Heating element maximum temperature (boost temperature) (°C).
—Heating element material.
—Heating element configuration.
—Heating element length (mm).
—Heating element mass (mg).
—Heating element location.
—No. of heating elements (*e.g.,* coil).
—Heating element diameter (gauge) (if applicable).
—Heating element resistance (Ohms) (if applicable).
—Tobacco/E-liquid:
—Tobacco mass (mg) (if applicable).
—Tobacco density (g/cm^3) (if applicable).
—Tobacco moisture or oven volatiles (%) (if applicable).
—Tobacco cut size (CPI or mm) (if applicable).
—E-liquid volume (mL) (if applicable).
—E-liquid viscosity (at 20°C) (if applicable).
—Battery (if applicable):
—Battery capacity (mAh).
—Battery voltage operating range (V) or wattage (W).
—Battery current charging range (amps).
—Battery nominal voltage (V).
—Battery current rating (mA).
—Battery charging temperature limits (°C).
—Battery discharge temperature limits (°C).
—Battery end of discharge voltage (V).
—Battery maximum charging current (mA).
—Battery maximum discharging current (mA).
—Battery upper limits charging voltage (V).
—Power Delivery Unit (PDU) voltage operating range (V).
—PDU current operating range (mA).
—PDU wattage operating range (watts).

TABLE 41 TO § 1107.19(a)(21)—Continued

—PDU temperature cut-off (°C) (if applicable).
—PDU current cut-off (mA) (if applicable).
—Aerosol:
—Inhaled aerosol temperature (°C).
—Aerosol particle number concentration (#/cm^3).
—Count median diameter (nm).
—$PM_{2.5}$ (μg/m^3).
—Filter (if applicable):
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density(g/cm^3))).
—Filter pressure drop (mm H_2O).
—Filter length (mm).
—Filter diameter (mm).
—Filter ventilation (%).

TABLE 42 TO § 1107.19(a)(21)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Overall device:
—Draw resistance (mm H_2O).
—Puff count (for full tank/cartridge) (dimensionless).
—Product volume (mL).
—Airflow rate (L/min) (if applicable).
—Ventilation (%).
—Operational temperature (°C).
—Temperature sensor (if applicable).
—Material wrapper length (mm) (if applicable).
—Material wrapper width (mm) (if applicable).
—Material wrapper basis weight (g/m^2) (if applicable).
—Material porosity or permeability (CU) (if applicable).
—Heating element:
—Heating element diameter (gauge) (if applicable).
—Heating element resistance (Ohms) (if applicable).
—Heating element temperature range (°C).
—E-liquid:
—E-liquid viscosity (at 20°C) (if applicable).
—E-liquid volume (ml) (if applicable).
—Tobacco:
—Tobacco moisture or oven volatiles (%) (if applicable).
—Tobacco cut size (CPI or mm) (if applicable).
—Tobacco density (g/cm^3) (if applicable).
—Battery:
—Battery voltage operating range (V) or wattage (W).
—Battery current operating range (mA).
—PDU voltage operating range (V).
—PDU current operating range (mA).
—PDU wattage operating range (watts).
—PDU current cut-off (mA) (if applicable).
—PDU temperature cut-off (°C) (if applicable).
—Battery capacity (mAh).
—Battery nominal voltage (V).
—Battery current rating (mA).
—Battery charging temperature limits (°C).
—Battery discharge temperature limits (°C).
—Battery maximum charging current (mA).
—Battery maximum discharging current (mA).
—Battery upper limits charging voltage (V).
—Aerosol:
—Inhaled aerosol temperature (°C).
—Aerosol particle number concentration (#/cm^3).
—Count median diameter (nm).
—$PM_{2.5}$ (μg/m^3).
—Filter (if applicable):
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density(g/cm^3))).
—Filter ventilation (%).
—Filter pressure drop (mm H_2O).

(b) *Comparison of heating sources.* The SE Report must include a description of the heating source for the new and predicate tobacco products and identify any differences, or state that there is no heating source.

(c) *Comparison of product composition.* The SE Report must include descriptions of the product composition of the new and predicate tobacco products and identify any differences. The SE Report must include, in a tabular format, a side-by-side comparison of the materials and ingredients for each component or part of the new and predicate tobacco products. For each material and ingredient quantity, the target specifications and range of acceptable values, actual measured value (where applicable), and range of measured values (where applicable) reported as mass per component or part, must be provided.

(1) *Materials.* For each material in the products include:

(i) The material name and common name(s), if applicable;

(ii) The component or part of the tobacco product where the material is located;

(iii) The subcomponent or subpart where the material is located, if applicable;

(iv) The function of the material;

(v) The quantities (including ranges or means, acceptance limits) of the material(s) in each new tobacco product and predicate tobacco product (with any specification variation, if applicable);

(vi) The specification(s) (including quality/grades, suppliers) used for the new tobacco product and predicate tobacco product (with any specification variations, if applicable); and

(vii) Any other material properties necessary to characterize the new and predicate tobacco products.

(2) *Ingredients other than tobacco.* For each ingredient other than tobacco in each material or component or part of the product include:

(i) The International Union of Pure and Applied Chemistry (IUPAC) chemical name and common name, if applicable;

(ii) The Chemical Abstracts Service (CAS) number(s) or FDA Unique Ingredient Identifier (UNII);

(iii) The function of the ingredient;

(iv) The quantity with the unit of measure (including ranges or means, acceptance limits) of the ingredient in the new tobacco product and predicate tobacco product reported as mass per gram of tobacco for non-portioned tobacco products and as mass per portion for portioned tobacco products (with any specification variation, if applicable);

(v) The specification(s) (including purity or grade and supplier);

(vi) For complex purchased ingredients, each single chemical substance reported separately; and

(vii) Any other ingredient information necessary to characterize the new and predicate tobacco products.

(3) *Tobacco ingredients.* For tobacco include:

(i) The type (*e.g.,* Bright, Burley, reconstituted);

(ii) The curing method (*e.g.,* flue cured, dark air cured);

(iii) The quantity of each type with the unit of measure (including ranges or means, acceptance limits) of tobacco in the new tobacco product and predicate tobacco product reported as mass per gram of tobacco for non-portioned tobacco products and as mass per portion for portioned tobacco products;

(iv) A description of any genetic engineering of the tobacco; and

(v) Any other information necessary to characterize the new and predicate tobacco products.

(vi) If the new tobacco product does not contain tobacco, then include a statement that the new tobacco product does not contain tobacco.

(4) *Container closure system.* A description of the container closure system for the new and predicate tobacco products, including a side-by-side quantitative comparison of the components and materials and annotated illustrations.

(d) *Comparison of other features.* The SE Report must include descriptions of any other features of the new and predicate tobacco products, such as those described in paragraphs (d)(1) and (2) of this section, and identify any differences. If a specific feature specified in paragraphs (d)(1) and (2) of this section is not applicable to the product design, this must be stated clearly. If FDA requests a scientific justification explaining why a feature is not applicable, the applicant must provide the justification to FDA. The comparison of other features must include information on:

(1) *Constituents.* HPHCs and other constituents, as appropriate, to demonstrate that:

(i) The new tobacco product has the same characteristics as the predicate tobacco product, or

(ii) Any differences in characteristics between the new and predicate product do not cause the new tobacco product to raise different questions of public health, including:

(A) The constituent names in alphabetical order;

(B) The common name(s);

(C) The Chemical Abstract Services number(s);

(D) The mean quantity and variance with unit of measure;

(E) The number of samples and measurement replicates for each sample;

(F) The analytical methods used, associated reference(s), and full validation reports for each analytical method;

(G) The testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(H) Length of time between dates of manufacture and date(s) of testing;

(I) Storage conditions of the tobacco product before it was tested;

(J) Reference product datasets (if applicable);

(K) Full test data (including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria and complete data sets) for all testing performed. Test data for combusted or inhaled tobacco products must reflect testing conducted using both intense and non-intense smoking or aerosol-generating regimens, where established; and

(L) Complete descriptions of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable.

(2) *Any other features.* A description and comparison of any other features of the new tobacco product and the predicate tobacco product.

(e) *Comparison of tobacco processing.* The SE Report must include information on the tobacco processes in paragraphs (e)(1) and (2) of this section for the new and predicate tobacco products, if applicable, and identify any differences.

(1) *Fermentation process.* For smokeless tobacco products and tobacco products that contain fermented tobacco (including naturally fermented tobacco), the SE Report must contain the following information regarding the fermentation process of the new and predicate tobacco products and identify any differences:

(i) Description of the fermentation process;

(ii) Composition of the inoculum (starter culture) with genus and species name(s) and concentration(s) (if applicable);

(iii) Any step(s) taken to reduce microbes already present during processing (*e.g.,* cleaning of contact surfaces);

(iv) Specifications and test data for pH, temperature, and moisture content or water activity;

(v) Frequency of aeration or turning (if applicable);

(vi) Duration of fermentation;

(vii) Added ingredients;

(viii) Method used to stabilize or stop fermentation ((*e.g.,* heat treatment), if

applicable), including parameters of the method (*e.g.,* length of treatment, temperature) and method validation data; and

(ix) Storage conditions of the fermented tobacco prior to further processing or packaging and duration of storage (if applicable).

(2) *Heat treatment process.* For tobacco products that are heat treated, the SE Report must contain the following information regarding the heat treatment process of the new and predicate tobacco products and identify any differences:

(i) Description of the heat treatment process;

(ii) Type of heat treatment;

(iii) Conditions of heat treatment, including time, temperature, and moisture; and

(iv) Method validation data, including microbial loads (including bacteria, spores, yeast and fungi) and tobacco-specific nitrosamines (TSNAs) before and after heat treatment.

(f) *Shelf life and stability information.* With the exception of SE Reports for roll-your-own tobacco products and cigarettes that are not HTPs, SE Reports for all tobacco products must contain information on the stability of the new and predicate tobacco products over the shelf life, including the following information:

(1) The length of the shelf life, a description of how shelf life is determined, and a description of how shelf life is indicated on the tobacco product, if applicable. If a tobacco product does not have a defined shelf life, state as such;

(2) Any known or expected impacts of the differences between the new and predicate products on the product stability. If no impact is known or expected, state that;

(3) Stability data assessed at the beginning (zero time), middle, and end of the expected shelf life. If a tobacco product does not have a defined shelf life, provide stability data over a specified amount of time and a justification for why that time period is appropriate. Stability testing must be performed for the microbial and chemical endpoints as follows:

(i) Microbial content data including total aerobic microbial count and total yeast and mold count;

(ii) Water activity; and

(iii) Tobacco-specific nitrosamine yields (total, N-nitrosonornicotine (NNN), and 4-methylnitrosamino)-1-(3-pydridyl)-1-butanone) (NNK)).

(4) Stability testing details for each microbial and chemical endpoint, including:

(i) The mean quantity and variance with unit of measure;

(ii) The number of samples and measurement replicates for each sample;

(iii) The methods used, associated reference(s), and full validation reports for each method (as applicable);

(iv) The testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(v) Length of time between dates of tobacco product manufacture and date(s) of testing;

(vi) Storage conditions of the tobacco products before they were tested;

(vii) A statement that the testing was performed on a tobacco product in the same container closure system in which the tobacco product is intended to be marketed; and

(viii) Full test data (including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria, complete data sets, and a summary of the results) for all stability testing performed.

(g) *Applicant's basis for substantial equivalence determination.* The applicant must state that the new tobacco product has either:

(1) The same characteristics as the predicate tobacco product and the basis for this determination, or

(2) Different characteristics than the predicate tobacco product. Where an applicant states that its new tobacco product has different characteristics than the predicate tobacco product, the applicant must also include an explanation as to why a difference in any of the following characteristics do not cause the new product to raise different questions of public health: Product design (paragraph (a) of this section); heating source (paragraph (b) of this section); materials and ingredients (paragraph (c) of this section); and other features (paragraph (d) of this section). In addition, to demonstrate that a new tobacco product is substantially equivalent, an applicant must also explain why any differences in the manufacturing process between the new tobacco product and the predicate tobacco product would not change the characteristics of the new tobacco product such that the new tobacco product could raise different questions of public health (§ 1107.18(e)). Similarly, for smokeless tobacco products and tobacco products that contain fermented tobacco, an applicant must explain why any difference in stability between the new tobacco product and the predicate tobacco product does not cause the new tobacco product to raise different questions of public health (paragraph (f) of this section).

(h) *Comparison to original predicate tobacco product.* If the applicant is comparing the new tobacco product to a predicate tobacco product that FDA has previously found to be substantially equivalent, FDA may request that the applicant include information related to the original predicate tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, even if that original predicate tobacco product is back several predicate tobacco products. FDA will request this information when necessary to ensure that any order the Agency issues finding the new tobacco product substantially equivalent complies with section 910(a)(2)(A)(i)(I) of the Federal Food, Drug, and Cosmetic Act. FDA may need to review the first SE Report that received a finding of substantial equivalence using the original predicate tobacco product as a predicate tobacco product in order to make this finding.

§ 1107.20 Amendments.

(a) Except as provided in paragraphs (b) and (c) of this section, the applicant may submit an amendment to an SE Report in accordance with subpart C of this part. If an applicant chose to submit a health information summary with its SE Report under § 1107.18(j)(1), the applicant must submit with the amendment a redacted copy of the amendment that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63 of this chapter.

(b) An applicant may not amend an SE Report to change the predicate tobacco product.

(c) An applicant may not amend an SE Report after FDA has closed the SE Report under § 1107.44 or it has been withdrawn under § 1107.22.

(d) In general, amendments will be reviewed in the next review cycle as described in § 1107.42.

§ 1107.22 Withdrawal by applicant.

(a) An applicant may at any time make a written request to withdraw an SE Report for which FDA has not issued an order. The withdrawal request must state:

(1) Whether the withdrawal is due to a health or safety concern related to the tobacco product;

(2) The submission tracking number; and

(3) The name of the new tobacco product that is the subject of the SE Report.

(b) An SE Report will be considered withdrawn when FDA issues a notice stating the SE Report has been withdrawn.

(c) The SE Report is an Agency record, even if withdrawn. FDA will retain the withdrawn SE Report under Federal Agency records schedules. The availability of the withdrawn SE Report will be subject to FDA's public information regulations in part 20 of this chapter.

§ 1107.24 Change in ownership of an SE Report.

An applicant may transfer ownership of its SE Report. On or before the time of transfer, the new and former applicants are required to submit information to FDA as follows:

(a) The former applicant must sign and submit a notice to FDA that states that all of the former applicant's rights and responsibilities relating to the SE Report have been transferred to the new applicant. This notice must identify the name and address of the new applicant and the SE Report transferred.

(b) The new applicant must sign and submit a notice to FDA containing the following:

(1) The new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the SE Report;

(2) The date that the change in ownership is effective;

(3) Either a statement that the new applicant has a complete copy of the SE Report and order (if applicable), including amendments and records that are required to be kept under § 1107.58, or a request for a copy of the SE Report from FDA's files by submitting a request in accordance with part 20 of this chapter. In accordance with the Freedom of Information Act, FDA will provide a copy of the SE Report to the new applicant under the fee schedule in FDA's public information regulations in § 20.45 of this chapter; and

(4) A certification that no modifications have been made to the new tobacco product since the SE Report was submitted to FDA.

Subpart D—FDA Review

§ 1107.40 Communications between FDA and applicants.

(a) *General principles.* During the course of reviewing an SE Report, FDA may communicate with applicants about relevant matters, including scientific, medical, and procedural issues that arise during the review process. These communications may take the form of telephone conversations, letters, or emails, and will be documented in the SE Report in accordance with § 10.65 of this chapter.

(b) *Meeting.* Meetings between FDA and applicants may be held to discuss scientific and other issues. Requests for meetings will be directed to the Office of Science, Center for Tobacco Products, and FDA will make every attempt to grant requests for meetings that involve important issues.

(c) *Acceptance of an SE Report for review.* After receiving an SE Report under § 1107.18, FDA will either refuse to accept the SE Report for review or issue an acceptance for review letter.

(d) *Notification of deficiencies in an SE Report submitted under § 1107.18.* FDA will make reasonable efforts to communicate to applicants the procedural, administrative, or scientific deficiencies found in an SE Report and any additional information and data needed for the Agency's review. The applicant must also provide additional comparison information under § 1107.19 if requested by FDA.

(e) *Withdrawal of SE Report.* An SE Report will be considered withdrawn when FDA issues a notice stating that the SE Report has been withdrawn.

§ 1107.42 Review cycles.

(a) *Initial review cycle.* FDA intends to review the SE Report and either communicate with the applicant as described in § 1107.40 or take an action under § 1107.44 within 90 calendar days of FDA's receipt of the SE Report, or within 90 calendar days of determining that the predicate was found to be commercially marketed (other than for test marketing) in the United States as of February 15, 2007 (if applicable), whichever is later. This 90-day period is called the ''initial review cycle.''

(b) *Additional review cycles.* If FDA issues a deficiency notification under § 1107.40(d) during the initial review cycle, FDA will stop reviewing the SE Report until it receives a response from the applicant or the timeframe specified in the notification of deficiencies for response has elapsed. If the applicant fails to respond within the time period provided in the notification of deficiency, FDA will issue an order denying marketing authorization under the criteria set forth in § 1107.48. If the applicant's response to the notification of deficiencies provides the information FDA requested, but FDA identifies additional deficiencies, FDA may issue an additional deficiency notification. Each response will begin a new 90-day review cycle.

(c) *Inadequate response.* If the applicant's response to FDA's deficiency notification(s) does not provide the information FDA requested, or the applicant provides information but the SE Report is still deficient, FDA generally intends to issue an order denying market authorization under the criteria set forth in § 1107.48. At any time before FDA issues an order, an applicant may make a written request to withdraw an SE Report under § 1107.22.

§ 1107.44 FDA action on an SE Report.

After receipt of an SE Report, FDA will:

(a) Refuse to accept the SE Report for review if it does not comply with § 1107.18 and § 1105.10 of this chapter;

(b) Request additional information as provided in § 1107.40(d);

(c) Issue a letter administratively closing the SE Report if it is not possible to make a determination on an SE Report;

(d) Issue a letter canceling the SE Report if FDA finds the SE Report was created in error;

(e) Issue an order as described in § 1107.46 finding the new tobacco product to be substantially equivalent and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act; or

(f) Issue an order as described in § 1107.48 denying marketing authorization because the new tobacco product is:

(1) Not substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States on February 15, 2007, or

(2) Not in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act.

§ 1107.46 Issuance of an order finding a new tobacco product substantially equivalent.

If FDA finds that the information submitted in the SE Report establishes that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed (other than for test marketing) in the United States on February 15, 2007, and finds that the new tobacco product is in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, FDA will send the applicant an order authorizing marketing of the new tobacco product. A marketing authorization order becomes effective on the date the order is issued.

§ 1107.48 Issuance of an order denying marketing authorization.

(a) *General.* FDA will issue an order that the new tobacco product cannot be marketed if FDA finds that:

(1) The information submitted in the SE Report does not establish that the new tobacco product is substantially

equivalent to a predicate tobacco product that was commercially marketed (other than for test marketing) in the United States on February 15, 2007; or

(2) The new tobacco product is not in compliance with the Federal Food, Drug, and Cosmetic Act.

(b) *Basis for order.* The order will describe the basis for denying marketing authorization.

§ 1107.50 Rescission of order.

(a) *Grounds for rescinding a substantially equivalent order.* FDA may rescind a substantially equivalent order allowing a new tobacco product to be marketed if FDA determines that:

(1) The tobacco product for which the order has been issued:

(i) Does not have the same characteristics as the predicate tobacco product; or

(ii) Has different characteristics and there is insufficient information demonstrating that it is not appropriate to require a premarket tobacco product application under section 910(b) of the Federal Food, Drug, and Cosmetic Act because the product does not raise different questions of public health; or

(2) The SE Report (including any submitted amendments) contains an untrue statement of material fact; or

(3) Concerning an SE Report that compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent,

(i) The predicate tobacco product relied on in the SE Report has been found ineligible because its SE Report (including any amendments) contains an untrue statement of material fact; or

(ii) A predicate tobacco product on which any of the previous substantial equivalence determinations was based, going back to the original predicate tobacco product, has been found ineligible because its SE Report (including any amendments) contains an untrue statement of material fact; or

(4) FDA or the applicant has removed from the market, due to a health or safety concern related to the tobacco product:

(i) The predicate tobacco product on which the substantial equivalence determination is based; or

(ii) A predicate tobacco product on which any of the previous substantial equivalence determinations is based, going back to the original predicate tobacco product, if the substantial equivalence SE Report compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent.

(b) *Opportunity for a hearing.* (1) Except as provided in paragraphs (b)(2) and (3) of this section, FDA will rescind an order only after notice and opportunity for a hearing under part 16 of this chapter.

(2) FDA may rescind a substantially equivalent order prior to notice and opportunity for a hearing under part 16 of this chapter if it finds that there is a reasonable probability that continued marketing of the tobacco product presents a serious risk to public health. In that case, FDA will provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

(3) FDA may rescind a substantially equivalent order without notice and opportunity for a hearing under part 16 of this chapter if the applicant has notified the Agency of a mistake in the application, FDA has determined that the mistake is part of the underlying scientific determination of the order which makes the order invalid, and the applicant has agreed that FDA can rescind the order without providing notice and opportunity for a hearing under part 16 of this chapter.

Subpart E—Miscellaneous

§ 1107.58 Record retention.

Each applicant that receives an order under § 1107.46 authorizing the marketing of a new tobacco product must maintain all records required by this subpart and that support the SE Report for a substantial equivalence order. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. All records must be retained for a period of not less than 4 years from the date of the order even if such product is discontinued.

§ 1107.60 Confidentiality.

(a) *General.* FDA will determine the public availability of any part of an SE Report and other content related to such an SE Report under this section and part 20 of this chapter.

(b) *Confidentiality of data and information prior to an order.* Prior to issuing an order under this section:

(1) FDA will not publicly disclose the existence of an SE Report unless:

(i) The tobacco product has been introduced or delivered for introduction into interstate commerce for commercial distribution; or

(ii) The applicant has publicly disclosed or acknowledged the existence of the SE Report (as such disclosure is defined in § 20.81 of this chapter), or has authorized FDA in writing to publicly disclose or acknowledge, that the applicant has submitted the SE Report to FDA.

(2) FDA will not disclose the existence of or contents of an FDA communication with an applicant regarding its SE Report except to the extent that the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence of or contents of that particular FDA communication.

(3) FDA will not disclose information contained in an SE Report unless the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information. If the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information contained in an SE Report, FDA may disclose that particular information.

(c) *Disclosure of data and information after issuance of an order under § 1107.46.* After FDA issues an order under § 1107.46 finding a new tobacco product substantially equivalent, it will make the following information related to the SE Report and order available for public disclosure upon request or at FDA's own initiative, including information from amendments to the SE Report and FDA's reviews of the SE Report:

(1) All data previously disclosed to the public, as such disclosure is defined in § 20.81 of this chapter;

(2) Any protocol for a test or study, except to the extent it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter;

(3) Information and data submitted to demonstrate that the new tobacco product does not raise different questions of public health, except to the extent it is shown to fall within the exemptions established in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy;

(4) Correspondence between FDA and the applicant, including any requests FDA made for additional information and responses to such requests, and all written summaries of oral discussions between FDA and the applicant, except to the extent it is shown to fall within the exemptions in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy; and

(5) In accordance with § 25.51 of this chapter, the environmental assessment or, if applicable, the claim of categorical exclusion from the requirement to

submit an environmental assessment under part 25 of this chapter.

(d) *Disclosure of data and information after issuance of an order under § 1107.48.* After FDA issues an order under § 1107.48 (denying marketing authorization), FDA may make certain information related to the SE Report and the order available for public disclosure upon request or at FDA's own initiative except to the extent the information is otherwise exempt from disclosure under part 20 of this chapter. Information FDA may disclose includes the tobacco product category (*e.g.,* cigarette), tobacco product subcategory (*e.g.,* filtered), package size, and the basis for the order denying marketing authorization.

(e) *Health information summary or statement.* Health information required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, if submitted as part of the SE Report (which includes any amendments), will be disclosed within 30 calendar days of issuing a substantially equivalent order. If the applicant has instead submitted a 910(a)(4) statement as provided in § 1107.18(j)(2), FDA will make publicly available on FDA's website the responsible official to whom a request for health information may be made.

§ 1107.62 Electronic submission.

(a) *Electronic format requirement.* Applicants submitting any documents to the Agency under this part must provide all required information to FDA using the Agency's electronic system, except as provided in paragraph (b) of this section. The SE Report and all supporting information must be in an electronic format that FDA can process, read, review, and archive.

(b) *Waivers from electronic format requirement.* An applicant may submit a written request that is legible and written in English, to the Center for Tobacco Products asking that FDA waive the requirement for electronic format and content. Waivers will be granted if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants can send the written request to the address included on our website (*www.fda.gov/tobaccoproducts*). The request must include the following information:

(1) The name and address of the applicant, list of individuals authorized for the applicant to serve as the contact person, and contact information including an email address. If the applicant has submitted an SE Report previously, the regulatory correspondence must also include any identifying information for the previous submission.

(2) A statement that creation and/or submission of information in electronic format is not reasonable for the person requesting the waiver, and an explanation of why creation and/or submission in electronic format is not reasonable. This statement must be signed by the applicant or by an employee of the applicant who is authorized to make the declaration on behalf of the applicant.

(c) *Paper submission.* An applicant who has obtained a waiver from filing electronically must send a written SE Report through the Document Control Center to the address provided in the FDA documentation granting the waiver.

Dated: September 21, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2021–21009 Filed 10–4–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1107 and 1114

[Docket No. FDA–2019–N–2854]

RIN 0910–AH44

Premarket Tobacco Product Applications and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, us, or we) is issuing a final rule that sets forth requirements for premarket tobacco product applications (PMTAs) and requires manufacturers to maintain records establishing that their tobacco products are legally marketed. The rule will help ensure that PMTAs contain sufficient information for FDA to determine whether a marketing granted order should be issued for a new tobacco product. The rule codifies the general procedures FDA will follow when evaluating PMTAs and creates postmarket reporting requirements for applicants that receive marketing granted orders. The rule also requires tobacco product manufacturers to keep records establishing that their tobacco products are legally marketed, such as documents showing that a tobacco product is not required to undergo premarket review or has received premarket authorization.

DATES: This rule is effective November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Office of Regulations, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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Executive Summary

A. Purpose of the Regulatory Action

FDA is issuing this final rule to improve the efficiency of the submission and review of PMTAs. We are finalizing this rule after reviewing comments to the proposed rule (84 FR 50566, September 25, 2019) (hereinafter referred to as the proposed rule) and are basing this rule on the experience the Agency has gained by reviewing several types of premarket applications submitted by industry, including substantial equivalence (SE) reports, requests for exemptions from the SE requirements, modified risk tobacco product applications (MRTPAs), and PMTAs. As described in the proposed rule, FDA has received thousands of premarket applications that range widely in the level of detail they contain. This rule describes and sets forth requirements related to the content and format of PMTAs and will provide applicants with a better understanding of the information a PMTA must contain. The rule requires an applicant to submit detailed information regarding the physical aspects of its new tobacco product and full reports of information regarding investigations that may show the health risks of the new tobacco product and whether it presents the same or different risks compared to other tobacco products. FDA is requiring the submission of these health risk investigations to ensure it understands the full scope of what is known about the potential health risks of a new tobacco product.

The rule also addresses issues such as the procedures by which FDA reviews a PMTA, retention of records related to a PMTA, confidentiality of application information, electronic submission of the PMTA and amendments, and postmarket reporting requirements. FDA will announce the withdrawal of its September 2011 draft guidance entitled ''Applications for Premarket Review of New Tobacco Products'' in the **Federal Register**. Additionally, FDA will update the guidance for industry entitled ''Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems'' (the ENDS PMTA Guidance) [1] to ensure the product-specific recommendations on preparing and submitting PMTAs for ENDS are consistent with the requirements of this rule.

Additionally, the rule creates requirements for the maintenance of records demonstrating the legal marketing status of Pre-Existing Tobacco Products (*i.e.,* tobacco products, including those products in test markets) that were commercially marketed in the United States as of February 15, 2007) and products that are exempt from the requirements of demonstrating substantial equivalence. These recordkeeping requirements will allow FDA to more efficiently determine the legal marketing status of a tobacco product.

B. Legal Authority

This rule is being issued under FDA's authority to require premarket review of new tobacco products under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387j), FDA's authority to require records and reports under section 909(a) of the FD&C Act (21 U.S.C. 387i(a)), FDA's authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387b and 387c), as well as FDA's rulemaking and inspection authorities under sections 701(a) and 704 of the FD&C Act (21 U.S.C. 371(a) and 374).

C. Summary of Major Provisions

This rule describes and sets forth content and format requirements for PMTAs and includes FDA's interpretations of various provisions in section 910 of the FD&C Act. Under the rule, a PMTA must contain information necessary for FDA to determine whether it should issue a marketing granted order for a new tobacco product under section 910(c)(1)(A) of the FD&C Act. Specifically, the PMTA must enable FDA to find whether: (1) There is a showing that permitting the marketing of the new tobacco product would be appropriate for the protection of the public health; (2) the methods used in, or the facilities and controls used for, the manufacture, processing, or packing of the product conform to the requirements of section 906(e) of the FD&C Act (21 U.S.C. 387f(e)); (3) the product labeling is not false or misleading in any particular; and (4) the product complies with any applicable product standard in effect under section 907 of the FD&C Act (21 U.S.C. 387g) or there is adequate information to justify a deviation from such standard. The rule will also allow applicants to submit a supplemental PMTA or a resubmission, which will improve the efficiency of submitting and reviewing an application in certain instances. A supplemental PMTA can be submitted in situations where an applicant is seeking authorization for a new tobacco product that is a modified version of a tobacco product for which they have already received a marketing granted order. A resubmission can be submitted to address application deficiencies following the issuance of a marketing denial order.

In addition, the rule explains how an applicant can amend or withdraw a PMTA and how an applicant may transfer ownership of a PMTA to a new owner. The rule also addresses FDA communications with applicants and identifies the actions that FDA may take after receipt of a PMTA. Where an applicant receives a marketing granted order, the rule requires the submission of postmarket reports, addresses when FDA may withdraw a marketing granted order, and explains how long an applicant will be required to maintain the records related to the PMTA and postmarket reports. The rule also sets forth FDA's disclosure procedures regarding PMTAs and requires the electronic submission of PMTAs, unless the applicant requests and obtains a waiver. Additionally, the rule requires tobacco product manufacturers to maintain records related to the legal marketing of Pre-Existing Tobacco Products and products that are exempt from the requirements of demonstrating substantial equivalence.

D. Costs and Benefits

The final rule will require manufacturers of Pre-Existing Tobacco Products and manufacturers of products that are exempt from the requirements of demonstrating SE to maintain records to demonstrate that they can legally market their products. For products that receive a PMTA marketing granted

[1] Available at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

order, the final rule will require certain postmarket reporting, including periodic reporting and adverse experience reporting. The final rule will also implement and set forth requirements for the content and format of PMTAs and the general procedures we intend to follow in reviewing and communicating with applicants.

The final rule will make the review of PMTAs more efficient. As a result, the final rule will create cost savings for FDA related to the review of some PMTAs. The final rule will also create cost savings for FDA and for PMTA applicants by reducing the number of PMTAs submitted. We estimate that annualized benefits over 20 years will equal $2.04 million at a 7 percent discount rate, with a low estimate of $1.36 million and a high estimate of $2.85 million. We estimate that annualized benefits over 20 years will equal $2.08 million at a 3 percent discount rate, with a low estimate of $1.43 million and a high estimate of $2.84 million.

This is the first regulation to address the costs of PMTA requirements for new, originally regulated tobacco products. While we already included the costs to submit and review PMTAs for deemed tobacco products [2] in the final regulatory impact analysis (RIA) for the deeming final rule, no RIA includes the costs to submit and review PMTAs for originally regulated tobacco products. Therefore, we include the costs to prepare and review PMTAs for these tobacco products in this analysis.

The final rule will increase the cost for applicants to prepare a PMTA. As a result, the final rule will generate incremental costs related to the preparation of PMTAs for ENDS products. Firms will incur costs to maintain and submit postmarket reports and we will incur costs to review these reports. Finally, firms will incur costs to read and understand the rule and costs to maintain records for some Pre-Existing Tobacco Products. We estimate that annualized costs over 20 years will equal $4.73 million at a 7 percent discount rate, with a low estimate of $2.63 million and a high estimate of $7.45 million. We estimate that annualized costs over 20 years will equal $4.86 million at a 3 percent discount rate, with a low estimate of $2.50 million and a high estimate of $7.95 million.

TABLE OF ABBREVIATIONS/COMMONLY USED ACRONYMS

Abbreviation acronym	What it means
APPH	Appropriate for the protection of public health
CAS	Chemical Abstracts Service
CCI	Confidential commercial information
CCS	Container Closure System
CGMP	Current good manufacturing practices
CORESTA	Cooperation Centre for Scientific Research Relative to Tobacco
CTP	Center for Tobacco Products
DPF	Denier per filament
EA	Environmental assessment
ENDS	Electronic nicotine delivery systems
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FEI	Facility Establishment Identifier
FOIA	Freedom of Information Act
GLP	Good laboratory practice
HACCP	Hazard analysis and critical control point
HCI	Health Canada Intense
HHS	Department of Health and Human Services
HPHC	Harmful or potentially harmful constituent
HTP	Heated tobacco products
IUPAC	International Union of Pure and Applied Chemistry
ICH	International Council for Harmonization
IRB	Institutional Review Board
ISO	International Organization for Standardization
MDSS	Manufacturing Data Sheet Specification
mL	Milliliters
mm	Minimum and maximum diameter
MRTP	Modified risk tobacco product
MRTPA	Modified risk tobacco product application
NCI	National Cancer Institute
NEPA	National Environmental Policy Act of 1969
NNK	4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone
NNN	N-nitrosonornicotine
NTRM	Nontobacco related material
NYTS	National Youth Tobacco Survey
OMB	Office of Management and Budget
OTDN	Oral tobacco-derived nicotine
OV	Oven volatiles
PDU	Power delivery unit
PK	Pharmacokinetic
PM	Particulate matter
PMTA	Premarket tobacco product application
RIA	Regulatory Impact Analysis
RTA	Refuse to accept
RTF	Refuse to file
RYO	Roll-your-own
SAS	Statistical Analysis Software
SE	Substantial equivalence
Secretary	Secretary of Health and Human Services
SES	Socioeconomic status
STN	Submission tracking number
TAMC	Total aerobic microbial count
TPMF	Tobacco product master file
TSNA	Tobacco specific nitrosamine
TYMC	Total yeast and mold count
TPSAC	Tobacco Products Scientific Advisory Committee
UNII	Unique ingredients identifier
a_w	Water activity

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) provides FDA with the authority to regulate tobacco products under the FD&C Act. The FD&C Act, as amended by the Tobacco Control Act, generally requires that a new tobacco product undergo premarket review by FDA before it may be introduced or delivered for introduction into interstate commerce. Section 910(a)(1) of the FD&C Act defines a ''new tobacco product'' as: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (21 U.S.C. 387j(a)(1)).

The FD&C Act establishes three premarket review pathways for a new tobacco product:

- Submission of a PMTA under section 910(b);
- submission of a report intended to demonstrate that the new tobacco product is substantially equivalent to a predicate tobacco product under section 905(j)(1)(A) (21 U.S.C. 387e(j)(1)(A)) (SE Report); [3] and
- submission of a request for an exemption under section 905(j)(3) (implemented at 21 CFR 1107.1) (exemption request).

Generally, if a new tobacco product is marketed without either a marketing granted order (for PMTAs), a

[2] Note that for the purposes of this final rule, ''deemed tobacco products'' are those tobacco products subject to Chapter IX of the FD&C Act as a result of regulations enacted by FDA (Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 FR 28974, May 10, 2016 (''deeming final rule'')). These products include cigars, pipe tobacco, waterpipe tobacco, electronic nicotine delivery systems (ENDS), and other novel tobacco products.

[3] Additionally, section 910(a)(2)(B) of the FD&C Act also allows for the continued marketing of new tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, for which a manufacturer submitted an SE Report prior to March 23, 2011 (''provisional tobacco products''), unless FDA issues an order that the tobacco product is not substantially equivalent.

substantially equivalent order (for SE reports), or a finding of exemption from SE (for exemption requests), it is adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act and subject to enforcement action.

Since 2010, FDA has received a large volume of premarket applications for tobacco products, thousands of which have been PMTAs. Of these PMTAs, FDA has completed its full substantive review and acted on several sets of bundled PMTAs, which are single submissions containing PMTAs for a number of similar or related tobacco products. To assist manufacturers in preparing PMTAs, FDA has issued guidance, conducted webinars, met with manufacturers, hosted public meetings regarding premarket submissions, and posted the technical project lead reviews (which describe the reviews completed on specific PMTAs) and marketing granted orders issued to date. FDA has also completed review and issued decisions on hundreds of exemption requests, thousands of SE reports, and thousands of voluntarily submitted requests for Pre-Existing Tobacco Product status review, which has provided FDA with information and experience to use when implementing the PMTA program and establishing recordkeeping requirements.

FDA issued the proposed rule on September 25, 2019, to set forth proposed requirements related to the PMTA premarket pathway and outline the information needed for FDA to determine whether it will issue a marketing granted order under the pathway. FDA received about 1,000 comments to the docket for the proposed rule, including comments from individuals, academia, healthcare professionals, consumer advocacy groups, industry, public health groups, and trade associations. We summarize and respond to these comments in section III of this rule. After considering these comments, FDA developed this final rule, which includes changes made in response to the comments.

II. Legal Authority

As described in the following paragraphs, FDA is describing and setting forth requirements for the content, format, submission, and review of PMTAs, as well as other requirements related to PMTAs, including recordkeeping requirements, and postmarket reporting. FDA is also creating recordkeeping requirements regarding the legal marketing of Pre-Existing Tobacco Products and products that are exempt from the requirements of demonstrating substantial equivalence. In accordance with section 5 of the Tobacco Control Act, FDA intends that the requirements that are established by this rule be severable and that the invalidation of any provision of this rule would not affect the validity of any other part of this rule.

Section 910(a)(2) of the FD&C Act requires that a new tobacco product be the subject of a marketing granted order unless FDA has issued an order finding it to be substantially equivalent to a predicate product, or exempt from the requirements of demonstrating substantial equivalence.[4] A manufacturer may choose to submit a PMTA under section 910(b) of the FD&C Act to satisfy the requirements of premarket review. Section 910(b)(1) describes the required contents of a PMTA and, in addition to the items specified in section 910(b)(1)(A) through (F), allows FDA to require applicants to submit other information relevant to the subject matter of the application under section 910(b)(1)(G). Section 910(c)(2) of the FD&C Act requires FDA to issue an order denying a PMTA if it finds that the applicant has not made a showing that permitting the marketing of the new tobacco product would be appropriate for the protection of the public health; the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of the product do not conform to the requirements of section 906(e) of the FD&C Act; the proposed labeling is false or misleading in any particular; or the product has not been shown to meet the requirements of a product standard in effect and there is a lack of adequate information to justify a deviation from the standard, if applicable.

Section 909(a) of the FD&C Act authorizes FDA to issue regulations requiring tobacco product manufacturers or importers to maintain records, make reports, and provide information as may be reasonably required to assure that their tobacco products are not adulterated or misbranded and to otherwise protect public health. Section 910(f) of the FD&C Act allows FDA to require that applicants who receive marketing granted orders establish and maintain records, and submit reports to enable FDA to determine, or facilitate a determination of, whether there are or may be grounds for withdrawing or temporarily suspending an order.

Section 910(d)(1) of the FD&C Act grants FDA authority to issue an order withdrawing a marketing granted order if FDA finds:

- That the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;
- that the application contained or was accompanied by an untrue statement of a material fact;
- that the applicant:
  - Has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909 of the FD&C Act;
  - has refused to permit access to, or copying or verification of, such records as required by section 704 of the FD&C Act; or
  - has not complied with the requirements of section 905 of the FD&C Act;
- on the basis of new information before the Secretary of Health and Human Services (the Secretary) with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) of the FD&C Act and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;
- on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or
- on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907 of the FD&C Act, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard, if applicable.

Under section 902(6) of the FD&C Act, a tobacco product is adulterated if it is required to have premarket review and does not have an order in effect under

[4] See section I for a discussion of provisional tobacco products and their relation to the premarket review requirements.

section 910(c)(1)(A)(i), or if it is in violation of an order under section 910(c)(1)(A) of the FD&C Act. Under section 903(a)(6) of the FD&C Act, a tobacco product is misbranded if a notice or other information respecting it was not provided as required by section 905(j) of the FD&C Act. In addition, a tobacco product is misbranded if there is a failure or refusal to furnish any material or information required under section 909 (section 903(a)(10)(B) of the FD&C Act). Section 701(a) of the FD&C Act also gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act and section 704 of the FD&C Act provides FDA with general inspection authority.

III. General Description of Comments on the Proposed Rule

FDA received over 1,000 comments on the proposed rule. The comments came from individuals, academia, healthcare professionals, consumer advocacy groups, industry, public health groups, and trade associations. In addition to the comments specific to this rulemaking that we address in sections IV through XVIII, we received many general comments expressing support or opposition to the rule. Some of these comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response. Other comments addressed topics outside the scope of this rulemaking, such as requests for product standards under section 907 of the FD&C Act, recommendations regarding the compliance date for manufacturers of deemed tobacco products to submit premarket applications, statements that ENDS and pipes should not be regulated as tobacco products, and that pipes should not be subject to the requirements of premarket review.

We describe and respond to comments in the description of the final rule in sections IV through XVIII. To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, will appear before each comment, and the word ''Response,'' in parentheses, will appear before each response. We have numbered the comments to make it easier to distinguish between comments; the numbers are for organizational purposes only and do not reflect the order in which we received the comments or any value associated with the comment. We have combined similar comments, or comments on similar topics that can be addressed by a single response, under one numbered comment.

IV. Description of the Final Regulations for, and Comments and FDA's Responses Regarding, the Maintenance of Records Demonstrating That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (Part 1100, Subpart C)

The rule adds subpart C regarding records to part 1100 of subchapter K of Title 21. Other than the comments and changes described in this section regarding the proposed definition of the term ''grandfathered tobacco product,'' (now referred to as a ''Pre-Existing Tobacco Product''), FDA received no comments regarding proposed part 1100 and FDA is finalizing the requirements as proposed without additional changes.

A. Purpose and Scope (§ 1100.200)

Subpart C of part 1100 establishes requirements for the maintenance of records by tobacco product manufacturers who introduce a Pre-Existing Tobacco Product, or deliver it for introduction, into interstate commerce. These requirements are created under the authority of section 909 of the FD&C Act, which authorizes FDA to require tobacco product manufacturers to establish and maintain records to assure that a tobacco product is not adulterated or misbranded and to otherwise protect public health. Under section 902(6)(A), a tobacco product is adulterated if it is required by section 910(a) of the FD&C Act to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i). In addition, under section 903(a)(6) of the FD&C Act, a tobacco product is misbranded if a notice or other information respecting it was not provided as required by section 905(j) of the FD&C Act. The records that are required under this subpart demonstrate that a tobacco product is a Pre-Existing Tobacco Product and, therefore, not required by section 910(a) to have premarket review and not adulterated or misbranded if marketed without an FDA order. FDA is basing these requirements on its experience gained by performing thousands of Pre-Existing Tobacco Product status reviews conducted during its review of SE reports and at manufacturers' voluntary requests. These requirements are needed because currently manufacturers do not always maintain sufficient documentation to demonstrate that their tobacco product is a Pre-Existing Tobacco Product. The records that are required under this rule will allow FDA to more quickly and efficiently determine whether a tobacco product is a Pre-Existing Tobacco Product.

B. Definitions (§ 1100.202)

Section 1100.202 sets forth the meaning of terms as they apply to part 1100:

1. Tobacco Product

The rule defines the term ''tobacco product'' consistent with section 201(rr)(1) of the FD&C Act (21 U.S.C. 321(rr)(1))

2. Tobacco Product Manufacturer

The rule defines the term ''tobacco product manufacturer'' consistent with section 900(20) of the FD&C Act (21 U.S.C. 387(20)). FDA interprets the phrase ''manufactures, fabricates, assembles, processes, or labels'' in the definition as including, but not being limited to: (1) Repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package; (2) reconstituting tobacco leaves; or (3) applying any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist. For the purposes of the definition, ''finished tobacco product'' means a tobacco product, including all components and parts, sealed in final packaging (*e.g.,* filters or filter tubes sold to consumers separately or as part of kits) or in the final form in which it is intended to be sold to consumers.

3. Commercially Marketed

In the proposed rule, FDA proposed to define ''commercially marketed'' as ''selling or offering a tobacco product for sale to consumers in all or in parts of the United States.''

(Comment 1) Several comments discussed specific changes to the proposed definition of the term ''commercially marketed.'' One comment stated that the proposed definition of commercially marketed departs from the plain meaning of the statutory language and FDA's historical approach to evaluating whether a product is a Pre-Existing Tobacco Product. Specifically, comments raised concerns that inclusion of ''in all or in parts of the United States'' seems to depart from the plain meaning of the statutory phrase ''commercially marketed in the United States'' and requires that firms demonstrate that a product was offered nationwide, in multiple regions, or even across State lines. The comments also argue that, for example, the statutory definition of ''new tobacco product'' does not state or imply that a product offered for sale within a particular State cannot qualify as ''commercially marketed in the United States.'' The comments state that FDA should define ''commercially marketed'' as ''offered for sale in the

United States to any individual or entity by advertising or by any other manner used to communicate that the tobacco product is available for purchase.'' Another comment expressed similar concerns, stating that the definition seems to require the selling or marketing of products directly to consumers as well as offering it for sale nationwide.

(Response 1) After reviewing the comments related to commercially marketed, we have added a definition of this term to the final rule, which reflects the input we received. Given the wide variety of input we have received on this term as well as the dictionary definition, we do not believe that the term ''commercially marketed'' has a plain meaning. Instead, we have added a definition stating that ''commercially marketed'' means selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States. This definition clarifies that tobacco products that are not sold or offered for sale in order to reach consumers within the United States, such as tobacco products sold solely for export, fall outside of the definition of commercial marketing. Examples of products that may not be covered by the definition of commercially marketed include investigational tobacco products and free samples. Examples of documentation of commercial marketing may include the following items listed in § 1100.204(a): dated bills of lading, dated freight bills, dated waybills, dated invoices, dated purchase orders, dated advertisements, dated catalog pages, dated promotional material, dated trade publications, dated manufacturing documents, inventory lists, or any other document demonstrating that the product was commercially marketed in the United States as of February 15, 2007.

(Comment 2) One comment requested clarification as to whether limited edition products would be considered test marketed products or commercially marketed products.

(Response 2) ''Limited edition'' products are considered commercially marketed if they were sold or offered for sale in the United States to consumers or to any person for the eventual purchase by consumers in the United States—regardless of whether they were solely sold or offered for sale in a test market. Therefore, if a ''limited edition'' product was commercially marketed—even if only in a test market—as of February 15, 2007, it would be a Pre-Existing Tobacco Product. We note that considering test marketed products to be commercially marketed is a change in FDA's interpretation of section 910(a)(1)(A) of the FD&C Act, which is discussed further in the response to comment 3. However, a product that was solely in a test market as of February 15, 2007, cannot serve as a predicate product under section 905(j) of the FD&C Act. Test marketed products may include, for example, products that were sold or offered for sale to determine the commercial viability of a product through the collection of consumer reaction data.

4. Pre-Existing Tobacco Product

In the proposed rule, we proposed to define the term ''grandfathered tobacco product'' as ''a tobacco product that was commercially marketed in the United States as of February 15, 2007'' and does not include a tobacco product exclusively in test markets as of that date. A grandfathered tobacco product is not subject to the premarket requirements of section 910 of the FD&C Act.'' In the final rule, we have changed this term from ''grandfathered tobacco product'' to ''Pre-Existing Tobacco Product'' because it more appropriately describes these products by using the more precise ''Pre-Existing'' in place of ''grandfathered.'' FDA received many comments regarding the definition of ''Pre-Existing Tobacco Product,'' [5] which are discussed as follows.

(Comment 3) Multiple comments discussed the proposed definition of the term ''commercially marketed'' as well as the definition of the term ''test marketing'' set forth in the preamble of the proposed rule as used in, or to inform, the definitions of ''Pre-Existing Tobacco Product'' and ''new tobacco product'' in the proposed rule. Some comments argued that Congress was intentional in its use of test markets in the definition of new tobacco product and, as such, a product in test market as of February 15, 2007 (if not subsequently modified within the meaning of section 910(a)(1)(B)), of the FD&C Act is not a new tobacco product and is not subject to premarket review. These comments also stated that because section 905(j)(1)(A)(i) of the FD&C Act explicitly excludes test marketed products from the commercially marketed products that may serve as valid predicate products, it demonstrates that the term ''commercially marketed'' encompasses products that are test marketed (*i.e.,* if test marketed products did not constitute commercially marketed products, there would have been no need for Congress to exclude them from the types of commercially marketed products that may qualify for use as predicate products under the substantial equivalence premarket pathway). Some comments requested FDA include the definitions as they were defined in the proposed rule, including as they relate to the definition of the term ''new tobacco product'' in proposed part 1114 (21 CFR part 1114). Other comments stated that the proposed definitions should not be included in the final rule because they are unnecessary, confusing, conflicting, and not useful. Specifically, some comments argued that FDA did not provide a workable or rational basis to distinguish ''test marketing'' from ''commercially marketed'' and the proposed definitions do not reflect industry realities.

(Response 3) Following our consideration of these comments, we have revised the definitions related to ''Pre-Existing Tobacco Product'' to remove language related to ''exclusively'' test marketed.

Upon reviewing comments received, we reassessed our interpretation of section 910(a)(1)(A) of the FD&C Act, and we agree with the comment indicating that a tobacco product test marketed in the United States as of February 15, 2007, is not a new tobacco product. Section 910(a)(1)(A) defines a ''new tobacco product'' to include ''any tobacco product (including those in test markets) that was not commercially marketed in the United States as of February 15, 2007.'' The parenthetical ''including those in test markets'' in section 910(a)(1)(A) of the FD&C Act modifies the phrase directly before it—''any tobacco product''—and is intended to clarify that tobacco products commercially marketed in test markets in the United States as of February 15, 2007, should be treated the same way as any other tobacco product that was commercially marketed as of February 15, 2007, *i.e.,* they are not ''new tobacco products.'' We also agree that section 905 of the FD&C Act provides additional context that supports this interpretation. Section 905(j)(1)(A)(i) of the FD&C Act describes products that can serve as valid predicate tobacco products: A tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that the Secretary by delegation to FDA has previously determined, pursuant to section 910(a)(3), is substantially equivalent. Here, Congress' inclusion of the parenthetical ''(other than for test marketing)'' supports a reading of the term ''commercially marketed'' as

[5] Although comments were submitted regarding the term ''grandfathered tobacco product,'' we describe them using the new term, ''Pre-Existing Tobacco Product,'' throughout this document for clarity.

including products that were test marketed; otherwise, there would not be the need to specifically carve out test marketed products from the commercially marketed products that can serve as valid predicate products.

In addition, in the preamble to the proposed rule, we explained that FDA was considering whether to add the following definition of test marketing: ''test marketing'' means distributing or offering for sale (which may be shown by advertisements, etc.) a tobacco product in the United States for the purpose of determining consumer response or other consumer reaction to the tobacco product, with or without the user knowing it is a test product, in which any of the following criteria apply: (1) Offered in a limited number of regions; (2) offered for a limited time; or (3) offered to a chosen set of the population or specific demographic group (84 FR 50566 at 50571).

We agree with the commenter that further discussion of the term, test marketing, is needed to more accurately capture the scope of this term; accordingly, we are not including a definition of test marketing in the final rule.

After reviewing these comments and for the purposes of consistency, FDA is finalizing the definition of ''Pre-Existing Tobacco Product'' with changes to better align with the statute, first, by adding ''(including those products in test markets)'', and, second, by removing ''and does not include a tobacco product exclusively in test markets as of that date.'' Specifically, FDA defines a ''Pre-Existing Tobacco Product'' to mean a tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007. The definition of ''Pre-Existing Tobacco Product'' in this rule reflects FDA's interpretation that ''as of'' means ''on'', which has been included as part of previously issued regulations and guidance.[6] For more information on this topic, see the response to comment 5 explaining FDA's interpretation that ''as of'' means ''on.'' A Pre-Existing Tobacco Product is not subject to the premarket review requirements of section 910 of the FD&C Act.

C. Recordkeeping Requirements (§ 1100.204)

1. Required Records

Consistent with the authority to require recordkeeping under section 909 of the FD&C Act, § 1100.204(a) requires any tobacco product manufacturer that introduces a Pre-Existing Tobacco Product, or delivers it for introduction, into interstate commerce to maintain records and information necessary to adequately demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. This requirement will ensure, among other things, that records are available to FDA during an inspection. The rule does not require tobacco product manufacturers to maintain records for all of the types of information listed in § 1100.204(a); rather, the list provides examples of the types of records that may be used to demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007.

2. Record Maintenance

Section 1100.204(b) requires that all records maintained under this part be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. This section also requires documents that have been translated from another language into English to be accompanied by: (1) The original language version of the document; (2) a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate; and (3) a brief statement of the qualifications of the person who made the translation (*e.g.,* education and experience). This information will help FDA ensure that the English language translations of documents are complete and accurately reflect the content of the original documents.

3. Record Retention

Section 1100.204(c) requires that the records and documents demonstrating that the tobacco product was commercially marketed as of February 15, 2007, be retained for a period of at least 4 years from the date that either FDA makes a Pre-Existing Tobacco Product determination or the tobacco product manufacturer permanently ceases the introduction or delivery for introduction into interstate commerce of the tobacco product, whichever occurs sooner. FDA has selected 4 years to help ensure that the records will be available for at least one biennial FDA inspection under sections 704 and 905(g) of the FD&C Act. FDA's biennial inspections under section 905(g) of the FD&C Act are required to occur at least once in every 2-year period after a manufacturer registers an establishment with FDA, which could result in inspections occurring nearly 4 years apart. Retaining records for 4 years after a manufacturer permanently ceases introduction or delivery for introduction into interstate commerce of the tobacco product will allow FDA to verify the Pre-Existing Tobacco Product status of the product during the time period in which it is offered for sale to consumers. Manufacturers that only temporarily cease the introduction or delivery for introduction into interstate commerce of the tobacco product must retain the records to allow FDA to verify the Pre-Existing Tobacco Product status of the product when they resume marketing the product. Additionally, manufacturers might want to retain records for longer than 4 years to help establish their product is a Pre-Existing Tobacco Product and may be eligible as a predicate product in an SE Report if it was commercially marketed (other than for test marketing) in the United States as of February 15, 2007.

V. Description of the Final Regulations for, and the Comments and FDA's Responses Regarding, the Maintenance of Records Relating to Exemptions From the Requirements of Demonstrating Substantial Equivalence (§ 1107.3)

The rule adds § 1107.3 to part 1107 of subchapter K of Title 21. Other than the comments and changes described in this section regarding the proposed definition of the term ''grandfathered tobacco product'' (now referred to as a ''Pre-Existing Tobacco Product''), FDA received no comments regarding proposed § 1107.3, FDA is finalizing the requirements as proposed with one other change; we have removed the proposed requirement to maintain product labeling a part of § 1107.3 because it is not necessary to support an abbreviated report.

Section 1107.3 establishes recordkeeping requirements related to tobacco products that are exempt from the requirements of demonstrating SE under section 910(a)(2)(A)(ii) of the FD&C Act. Consistent with the authority to require recordkeeping under section 909 of the FD&C Act, § 1107.3 requires applicants that submitted an abbreviated report under section 905(j)(1)(A)(ii) of the FD&C Act, and received a letter from FDA

[6] See the final rule entitled ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (81 FR 28973 at 28978, May 10, 2016) and the guidance entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' (79 FR 58358, September 29, 2014). Available at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

acknowledging the receipt of an abbreviated report, to maintain all records necessary to support the exemption for at least 4 years from the date FDA issues an acknowledgement letter in response to an abbreviated report. The rule requires the applicant to maintain records that are legible, written in English, and available for inspection and copying by officers or employees designated by the Secretary. Applicants may want to retain the records for a longer period if, for example they intend to submit a subsequent exemption request for a modification to the tobacco product.

A. Definition

Section 1107.3(a) defines ''Pre-Existing Tobacco Product'' [7] as a tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007. FDA has considered the comments described in section IV and revised this term as described in the responses in that section. As described in section IV.B.4., FDA interprets the phrase ''as of February 15, 2007,'' as meaning that the tobacco product was commercially marketed in the United States ''on February 15, 2007.'' See the response to comment 5 explaining FDA's interpretation that ''as of'' means ''on.''

B. Record Maintenance

The rule requires applicants to maintain all documents that support their abbreviated report, which includes the documents listed in § 1107.3(b)(1). The rule does not require an applicant to create new or additional records; rather, it requires an applicant to maintain the records it has, obtains, or creates (including those created on its behalf, such as by a contract research organization) that support its abbreviated report. This includes documents that an applicant creates under other regulatory or statutory sections such as the submission of exemption requests under § 1107.1, PMTAs under part 1114, SE Reports under section 905(j) of the FD&C Act, and tobacco product manufacturing practice requirements issued under section 906(e) of the FD&C Act. The records an applicant is required to maintain include, but are not limited to:

- A copy of the abbreviated report and, if applicable, the exemption request and all amendments thereto;
- a copy of the acknowledgement letter issued in response to an abbreviated report and, if applicable, a copy of the exemption order issued by FDA;
- documents related to formulation of product, product specifications, packaging, and related items. Product formulation includes, for example, items such as the types of information described in § 1114.7(i) as described in section VIII.B.;
- documents showing that design specifications are consistently met. This could include, for example, information about testing procedures that are carried out before the product is released to market, such as the information described in § 1114.7(j) as described in section VIII.B.;
- documents related to product packing and storage conditions;
- analytical test method records, including:
  - Performance criteria;
  - validation or verification documentation; and
  - reports/results from these test methods; and
- source data and related summaries.

In addition to the documents specified in § 1107.3(b)(1), paragraphs (b)(2) through (b)(4) require tobacco product manufacturers to maintain records that support a determination that their exemption request meets the requirements of section 905(j)(3)(A)(i) of the FD&C Act that the modification to a product additive described in the exemption request was a minor modification made to a tobacco product that can be sold under the FD&C Act. This means that applicants need to maintain records demonstrating that the modification is being made to either a Pre-Existing Tobacco Product or a new tobacco product that has satisfied the premarket review requirements of section 910(a)(2) of the FD&C Act. For abbreviated reports based on a modification to a Pre-Existing Tobacco Product, § 1107.3(b)(2) requires applicants to maintain the documentation in § 1100.204 to demonstrate that the product that is being modified is legally marketed. For abbreviated reports based on a modification to a tobacco product that has previously received an exemption order in response to a request under § 1107.1 (and for which the applicant has submitted an abbreviated report under 905(j)(1)(A)(ii)), or a substantially equivalent order or a marketing granted order from FDA, § 1107.3(b)(3) requires applicants to maintain a copy of the exemption order, substantially equivalent order, or marketing granted order to demonstrate the product being modified is legally marketed. For abbreviated reports based on a modification to a tobacco product that is being marketed pursuant to section 910(a)(2)(B) of the FD&C Act for which FDA has not issued a substantially equivalent order, an applicant must maintain all communications to and from FDA relating to the pending SE Report, such as a letter acknowledging receipt of the report.

C. Record Quality

Section 1107.3(c) requires the records to be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. FDA also requires documents that have been translated from another language into English be accompanied by: (1) The original language version of the document, (2) a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and (3) a brief statement of the qualifications of the person who made the translation (*e.g.,* education and experience). This information helps FDA ensure that the English language translations of documents are complete and accurately reflect the content of the original documents.

D. Record Retention

Section 1107.3(d) requires the records described in § 1107.3(b) to be maintained for a period of not less than 4 years from the date on which FDA issues an acknowledgement letter in response to an abbreviated report. FDA has selected 4 years as a means to help ensure that the records are available for at least one biennial FDA inspection under sections 704 and 905(g) of the FD&C Act. FDA's biennial inspections under section 905(g) of the FD&C Act are required to occur at least once in every 2-year period after a manufacturer registers an establishment with FDA, which could result in inspections occurring nearly 4 years apart.

VI. Description of the Final Regulations for, and the Comments and FDA's Responses Regarding, Premarket Tobacco Product Applications (Part 1114)

The rule adds part 1114 to subchapter K of Title 21. The requirements set forth in this part apply to PMTAs for new tobacco products. Subpart A sets out the scope and definitions that apply to this part. Subpart B sets out the criteria for PMTA submission, content and format of PMTAs, application amendments, withdrawal of an application by an applicant, supplemental PMTAs, resubmissions, and change in ownership or contact information for a

[7] As described in section IV.B, we have changed the term ''grandfathered tobacco product'' to ''Pre-Existing Tobacco Product.''

PMTA. Subpart C describes FDA review and actions on applications, including provisions for withdrawal and temporary suspension of orders. Subpart D describes postmarket restrictions and reporting requirements. Subpart E sets miscellaneous requirements such as record retention, confidentiality, and electronic submission.

VII. General (Part 1114, Subpart A)

A. Scope (§ 1114.1)

Section 1114.1 describes the scope of part 1114 and its applicability to the submission and review of, and postmarket requirements related to, PMTAs. Section 1114.1 provides that part 1114 does not apply to MRTPAs, except instances where a single application is submitted to seek both a marketing granted order and a modified risk order instead of a separate PMTA and MRTPA. Under the rule, a single application seeking both a marketing granted order and a modified risk order under section 911(g) of the FD&C Act needs to meet the content and format requirements of both part 1114 and section 911 of the FD&C Act (21 U.S.C. 387k) (and any implementing regulations). This section also notes that references in the rule to regulatory sections of the Code of Federal Regulations (CFR) are to chapter I of Title 21, unless otherwise noted. Therefore, any CFR reference that begins with ''part,'' ''section,'' or the section symbol (§) should be read as if it were preceded by ''21 CFR'' (*e.g.,* § 1114.1 refers to 21 CFR 1114.1, part 58 refers to 21 CFR part 58), unless another source is cited (*e.g.,* the FD&C Act).

(Comment 4) Some comments requested that ''premium'' cigars be exempt from the PMTA premarket pathway or that a different premarket pathway be created for them. Several comments describe the difference between ''premium'' cigars and other products, such as cigarettes or ENDS, and argue that these differences make it more difficult for ''premium'' cigars to comply with PMTA requirements. These comments request that FDA exempt ''premium'' cigars from premarket requirements, create a different premarket pathway for ''premium'' cigars, or delay the effective date for submitting premarket applications.

(Response 4) FDA received a range of comments related to ''premium'' cigars. A recent court decision ''remand[ed] the [deeming final rule] to the FDA to consider developing a streamlined substantial equivalence process for premium cigars'' and ''enjoin[ed] the FDA from enforcing the premarket review requirements against premium cigars . . . until the agency has completed its review.'' [8] Under the terms of the court's order, a ''premium'' cigar is defined as a cigar that meets all of the following eight criteria:

- Is wrapped in whole tobacco leaf;
- contains a 100 percent leaf tobacco binder;
- contains at least 50 percent (of the filler by weight) long filler tobacco (*i.e.,* whole tobacco leaves that run the length of the cigar);
- is handmade or hand rolled; [9]
- has no filter, nontobacco tip, or nontobacco mouthpiece;
- does not have a characterizing flavor other than tobacco;
- contains only tobacco, water, and vegetable gum with no other ingredients or additives; and
- weighs more than 6 pounds per 1,000 units.

As directed by the court in the *Cigar Ass'n of Am.* decision, FDA is further considering the comments submitted to the deeming final rule docket that requested FDA create a streamlined SE process for ''premium'' cigars. Additionally, FDA notes that a Committee of the National Academies of Science, Engineering, and Medicine is conducting a study on such products. FDA intends to consider the findings of that Committee as well as any additional research specific to ''premium'' cigars (as defined in the preceding paragraph) and their health effects, patterns of use (such as frequency of use and usage patterns among underage persons), and other factors. Such information will inform the Agency's regulatory policy with respect to premarket review of ''premium'' cigars. Although the court opinion specifically discusses considering comments on the SE pathway, FDA's research efforts may also inform issues related to the review of applications for premium cigars under the PMTA pathway. Because these are ongoing efforts, at this time, FDA is not finalizing the proposed PMTA rule with respect to ''premium'' cigars. Rather, FDA will take appropriate action once it has further considered this matter, including the results from additional research. As such, the codified language has been revised to exclude ''premium'' cigars from the scope of this final rule, and the *Cigar Ass'n of Am.* court's definition of ''premium'' cigars has been added to section § 1114.3.

B. Definitions (§ 1114.3)

Section 1114.3 provides the meaning of terms as they apply to part 1114:

1. Additive

As defined in section 900(1) of the FD&C Act, ''additive'' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco, or a pesticide chemical residue in or on raw tobacco, or a pesticide chemical.

An additive can be a type of ingredient in a tobacco product; an example is methyl salicylate in smokeless tobacco, which can serve as an absorption enhancer and affect the characteristics of the tobacco product by changing the rate of absorption into the body. Tobacco is not an additive.

2. Brand

As defined in section 900(2) of the FD&C Act, ''brand'' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes.

3. Characteristics

As defined in section 910(a)(3)(B) of the FD&C Act, ''characteristics'' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product. The terms used in the definition of characteristic (materials, ingredients, design, etc.) are defined in § 1114.3.

4. Label

As defined in section 201(k) of the FD&C Act, ''label'' means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of the FD&C Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is

[8] *Cigar Ass'n of Am., et al.* v. *Food and Drug Admin., et al.,* Case No. 1:16–cv–01460 (APM), (D.D.C. August 19, 2020), Dkt. No. 214 (*Cigar Ass'n of Am.*).

[9] A product is ''handmade or hand rolled'' if no machinery was used apart from simple tools, such as a scissors to cut the tobacco prior to rolling.

easily legible through the outside container or wrapper.

5. Labeling

As defined in section 201(m) of the FD&C Act, ''labeling'' means all labels and other written, printed, or graphic matter: (1) Upon any article or any of its containers or wrappers or (2) accompanying such article.

6. New Tobacco Product

As defined in section 910(a)(1) of the FD&C Act, ''new tobacco product'' means: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

FDA received many comments regarding the proposed definition of ''new tobacco product,'' as discussed below.

(Comment 5) Multiple comments questioned FDA's interpretation of the phrase ''as of February 15, 2007'' as used in the definition of the terms ''Pre-Existing Tobacco Product'' and ''new tobacco product'' and stated that there is a lack of rationale for its interpretation. Comments argue that the plain meaning of the term ''as of'' support the interpretation that ''as of'' means ''on or before'' rather than ''on''. As such, a tobacco product must qualify as a Pre-Existing Tobacco Product if it was commercially marketed in the United States at any time on or before February 15, 2007.

(Response 5) As previously stated, FDA's longstanding interpretation is that the statutory phrase ''as of February 15, 2007,'' means that the tobacco product was commercially marketed in the United States ''on February 15, 2007'' (see the final guidance entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' (79 FR 58358, September 29, 2014)). Contrary to the comments, the term ''as of'' does not have a clear plain meaning. The dictionary definitions of ''as of'' include: ''on; at'' (Webster's II New Riverside University Dictionary, 1988); ''beginning on; on and after'' (Webster's Unabridged Dictionary Random House 1997); ''from, at, or until a given time'' (The American Heritage Dictionary of Idioms 2003); ''on, at, from—used to indicate a time or date at which something begins or ends'' (Merriam Webster's Online Dictionary). As evidenced from these varying definitions (*e.g.,* compare ''until'' with ''from''), the term is ambiguous. Even assuming ''as of'' could be interpreted as ''at any time prior to and not necessarily including on the particular date'' (in short referred to as the ''on or before'' interpretation), interpreting ''as of'' to mean ''on'' gives a firm line of demarcation that provides clarity. Additionally, reading ''as of'' to mean ''on or before'' would mean that obsolete, abandoned, or discontinued tobacco products could return to the market without any premarket review and could serve as predicates under the SE provision. It is reasonable to conclude that Congress did not intend to allow an immeasurable number of obsolete, abandoned, or discontinued products that were marketed before February 15, 2007, to return to the market without any premarket review or serve as predicates under the SE provision, but rather intended to confine this number to those products that were commercially marketed in the United States on February 15, 2007. Thus, we decline to adopt the interpretation the comments suggest.

Under section 910(a)(1) of the FD&C Act, and as reflected in the definition, new tobacco products include those that are new because they have been rendered new through any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (21 U.S.C. 387j(a)(1)(B)). For example, modifications to cigarette paper, container closure systems (*e.g.,* change from glass to plastic e-liquid vials or from plastic to tin container closures), product quantity, or tobacco cut size would result in a new tobacco product.

(Comment 6) One comment stated that the term ''co-packaging,'' which is included in the discussion of the definition of the term ''new tobacco product,'' is confusing and does not provide a basis for regulating co-packaged products as part of premarket review.

(Response 6) Manufacturers sometimes co-package tobacco products, and FDA seeks to clarify what effect co-packaging tobacco products may have on whether those products are required to undergo premarket review. If there has been a change to the packaging of co-packaged tobacco products that is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product, then it is a change to the container closure system and, therefore, is a new tobacco product. Under section 910(a)(1)(B) of the FD&C Act, new tobacco products include those that are new because they have been rendered new through any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. Therefore, if two or more products are co-packaged together within a container closure system, it results in a new tobacco product requiring premarket authorization. However, co-packaging two or more legally marketed tobacco products, where there are no changes, including no change to the container closure system(s), does not result in a new tobacco product.

In addition, for purposes of determining whether a tobacco product is new under section 910 of the FD&C Act, and therefore requires premarket authorization prior to marketing, a ''tobacco product'' encompasses the whole product (*e.g.,* a pack of cigarettes or a tin of loose tobacco), and is not limited to a single unit or portion of the whole product (*e.g.,* a single cigarette or a single snus pouch). See *Philip Morris USA Inc.* v. *U.S. Food & Drug Admin.,* 202 F. Supp. 3d 31, 55–57 (D.D.C. 2016). If a premarket application includes information on only a portion of a new tobacco product, FDA would have an incomplete understanding of the tobacco product (*e.g.,* FDA may not get information on the container closure system, which could impact the consumable product) and would not be able to determine, for example, potential impacts on initiation and cessation of tobacco.

7. Package or Packaging

As defined in section 900(13) of the FD&C Act, the term ''package,'' also referred to in the rule as ''packaging,'' means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers. A subset of package is the container closure system (also defined in this rule). For example, the carton holding multiple soft packs of cigarettes is considered the package, and each soft

pack with surrounding cellophane is considered the container closure system. Packaging that constitutes the container closure system is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product (*e.g.,* leaching substances that are then incorporated into a consumable tobacco product), but packaging that is not the container closure system is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product and is, therefore, not a component or part of a tobacco product.

8. Tobacco Product

As defined in section 201(rr) of the FD&C Act, the term ''tobacco product'' means any product that is made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that is a drug under section 201(g)(1), a device under section 201(h), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)).

9. Tobacco Product Manufacturer

As defined in section 900(20) of the FD&C Act, the term ''tobacco product manufacturer'' means any person, including any repacker or relabeler, who: (1) Manufactures, fabricates, assembles, processes, or labels a tobacco product or (2) imports a finished tobacco product for sale or distribution in the United States. FDA interprets ''manufactures, fabricates, assembles, processes, or labels'' as including, but not being limited to, (1) repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package; (2) reconstituting tobacco leaves; or (3) applying any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist. A definition for the term ''finished tobacco product'' is also included in the rule.

10. Accessory

FDA defines ''accessory'' as any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

- Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or
- is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product, but:
  - Solely controls moisture and/or temperature of a stored product or
  - solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

This matches the definition of accessory set forth in § 1100.3. Examples of accessories are ashtrays and spittoons because they do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product.

11. Adverse Experience

FDA defines ''adverse experience'' as any unfavorable physical or psychological effect in a person that is temporally associated with the use of or exposure to a tobacco product, whether or not the person uses the tobacco product, and whether or not the effect is considered to be related to the use of or exposure to the tobacco product. FDA received many comments regarding this definition, as discussed below.

(Comment 7) Multiple comments requested changes to the definition of what constitutes an adverse experience. One comment requested FDA amend the definition to explicitly include increased use by youth or young adults. Another comment stated that the definition of adverse experience is too broad and subjective, and should be revised to refer to a health-related event associated with the use of or exposure to (intended or incidental) a tobacco product.

(Response 7) FDA declines to change the definition of adverse experience because this widely understood definition is generally consistent with language used throughout the Agency and is designed to capture a broad swath of information related to health effects from FDA regulated products. Due to the fact that the experience may not relate to the individual user but could also affect the general public or bystander, it is FDA's intent that the definition remain broad to ensure we receive the potential wide variety of voluntary reports of adverse experiences involving tobacco products from investigators, consumers, healthcare professionals and concerned members of the public. Additionally, FDA declines to revise the definition to include use by youth and young adults because it constitutes a behavior, not a health effect related to an adverse experience. Increases in use by individuals under the minimum age of sale will be monitored through the review of periodic reports submitted under § 1114.41, among other means.

FDA notes that it is important to also include information regarding adverse experiences associated with use of or exposure to a product where the individual suffering the adverse experience did not use the product because it can help FDA determine health risks for nonusers, such as the effects of second-hand exposure or accidental exposure (*e.g.,* skin burns from accidental exposure to liquid nicotine, harmful effects resulting from a child drinking an e-liquid, respiratory difficulties from second-hand exposure to an e-cigarette). Additionally, reporting information regarding all adverse experiences that are temporally associated with the use of or exposure to the product will help the applicant avoid self-selection bias of what is reported to FDA and help identify harmful effects that are not obviously attributable to the product.

12. Applicant

FDA defines ''applicant'' as any person that submits a PMTA to receive a marketing granted order for a new tobacco product.

13. Commercially Marketed

In the proposed rule, FDA proposed to define ''commercially marketed'' as ''selling or offering a tobacco product for sale to consumers in all or in parts of the United States.'' After reviewing comments described in section IV, FDA has decided to finalize the definition of ''commercially marketed'' to mean selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States. Examples of products that may not be covered by the definition of commercially marketed include investigational tobacco products and free samples. Examples of documentation of commercial marketing may include dated bills of lading, dated freight bills, dated waybills, dated invoices, dated purchase orders, dated advertisements, dated catalog pages, dated promotional material, dated trade publications, dated manufacturing documents, inventory lists, or any other document demonstrating that the

product was commercially marketed in the United States as of February 15, 2007. See discussion in section IV.B.3.

14. Component or Part

FDA defines ''component or part'' as any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product. A container closure system (which is also defined in this section) is considered a component or part. With respect to these definitions, FDA notes that ''component'' and ''part'' are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this rule, FDA is using the terms ''component'' and ''part'' interchangeably and without emphasizing a distinction between the terms. FDA may clarify the distinctions between ''component'' and ''part'' in the future. This definition matches the definition in § 1100.3.

15. Composition

FDA defines ''composition'' as the materials in a tobacco product, including ingredients, additives, and biological organisms. The term includes the manner in which the materials, for example, ingredients, additives, and biological organisms, are arranged and integrated to produce a tobacco product. Composition refers primarily to the chemical and biological properties of a tobacco product, whereas design refers to the physical properties of a tobacco product. A biological organism refers to any living biological entity, such as an animal, plant, fungus, or bacterium.

16. Constituent

In this final rule, we have updated the definition of constituent on our own initiative to clarify the meaning. FDA defines ''constituent'' as any chemical or chemical compound in a tobacco product that is or potentially is inhaled, ingested, or absorbed into the body, any chemical or chemical compound in an emission (*e.g.,* smoke, aerosol, droplets) from a tobacco product, that either transfers from any component or part of the tobacco product to the emission or that is formed by the product, including through combustion or heating of tobacco, additives, or other components of the tobacco product.

17. Container Closure System

FDA defines ''container closure system'' as any packaging materials that are a component or part of a tobacco product. FDA received several comments regarding the proposed definition, as discussed below.

(Comment 8) A few comments suggested related revisions to both the definitions of the terms ''container closure system'' (CCS), ''packaging,'' and ''component or part,'' as well as what modifications to a CCS FDA considers to result in a new tobacco product. The comments requested that the definition of CCS be limited to only the product packaging that is designed or reasonably expected to alter the product characteristics after the time of manufacture. Comments stated that failure to make such a change would be inconsistent with the court's decision in *Philip Morris* v. *FDA,* 202 F. Supp. 3d 31, 51 (D.D.C. 2016). Citing this case, which in the course of distinguishing between a product and its labeling, referenced ''the physical attributes of the product itself, as distinct from its label or the package in which it is contained,'' the comments argue that the law's requirements for new tobacco products apply only when there are changes in ''the physical attributes of a tobacco product—not its labeling or packaging.'' *Id.* Likewise, the comments stated that modifications to the CCS should result in a new tobacco product only if modifications are intended or reasonably expected to alter the characteristics of the product. The comments maintained that if the packaging's purpose is merely to maintain or preserve the characteristics of the product, it should only be considered packaging, not a CCS.

(Response 8) As described in the rule, FDA defines ''component or part'' as any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Contrary to the commenter's assertion, packaging that constitutes the container closure system is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product (*e.g.,* leaching substances that are then incorporated into a tobacco product), and is thus a component or part of a tobacco product. This is consistent with the holding of *Philip Morris,* 202 F. Supp. at 51, as is its converse: Packaging that is not the container closure system and is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product is, therefore, not a component or part of a tobacco product. As such, packaging that is, for example, the packaging around a blister pack is not part of the PMTA review process if it is not intended or reasonably expected to alter or affect the performance, composition, constituents, or characteristics of the tobacco product within the blister pack. However, where a change in the container closure system could affect the chemistry of the product, FDA requires the applicant, where it submits a PMTA, to demonstrate that permitting marketing of the product with the change in the container closure system is appropriate for the protection of public health.

For example, packaging materials constitute a container closure system if substances within that packaging are intended or reasonably expected to affect product moisture, *e.g.,* when the manufacturer changes the package of a moist snuff from plastic to fiberboard, which can affect microbial stability and tobacco-specific nitrosamine (TSNA) formation during storage. Another example of this is when menthol or other ingredients are applied to the inner foil to become incorporated into the consumed product (Ref. 1). Packaging materials may also be intended or reasonably expected to affect the characteristics of a tobacco product by impacting the rate of leaching into, and ultimately, the amount of substances found in, the consumable tobacco product. In fact, it has been demonstrated that compounds in packaging materials may diffuse into snuff and affect its characteristics (Ref. 2). Thus, packaging material that affects the characteristics of a tobacco product by impacting the moisture level or shelf life of a tobacco product is a container closure system (*e.g.,* a plastic versus a metal container of smokeless tobacco). A difference in tobacco moisture is reasonably expected to affect microbial growth in the product, extraction efficiency, and total exposure to nicotine or the carcinogens *N*-nitrosonornicotine (NNN) or 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) (Ref. 3).

Considering a distinct subset of packaging (*i.e.,* container closure system) to be a component or part is consistent with the FD&C Act and furthers the fundamental purpose of the Tobacco Control Act to protect the public health. For example, section 900(1) of the FD&C Act defines an ''additive'' as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product

(including any substance intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical. Congress specifically included a broad definition of ''additive'' that encompasses not just substances that do in fact have such effects but also those that may reasonably be expected to have such effects. Similarly, if FDA were to adopt a narrow construction of ''tobacco product'' to exclude these materials, the Agency's ability to evaluate whether permitting the marketing of the new tobacco product was appropriate for the protection of public health (APPH) would be impeded, thereby leaving the Agency unable to fully execute its mission to protect the public health. The definition of ''package'' in section 900(13) of the FD&C Act does not dictate a contrary result and can be reasonably interpreted to mean that a distinct subset of packaging is also a component or part of a tobacco product.

18. Design

FDA defines ''design'' to mean the form and structure concerning, and the manner in which components or parts, ingredients, software, and materials are integrated to produce a tobacco product. This term refers to the physical properties of a tobacco product. Examples of design parameters include ventilation, paper porosity, filter efficiency, battery voltage and current operating range, and electrical heater coil resistance. FDA received one comment on this definition, as discussed below.

(Comment 9) One comment stated that the definition of the term ''design'' does not take into account the inherent variability that can occur in tobacco crops over the years. The comment stated that such variability may require manufacturers to alter, in a limited capacity, certain characteristics of the product, in order to minimize variability of constituent levels in its final aerosol. The comment concluded that the proposed definition was rather narrow and did not allow for the control of emission levels through design adjustments. The comment recommended that the definition be amended to allow applicants to adjust design features for the sole purpose of accommodating natural variability of tobacco plants, without requiring the submission of a new PMTA or a supplemental PMTA.

(Response 9) FDA declines to make changes as a result of this comment. At this time, FDA does not intend to enforce the requirement of premarket review in section 910 for tobacco blending changes required to address the natural variation of tobacco (*e.g.,* blending changes due to variation in growing conditions) to maintain a consistent product.[10] Where an applicant changes other characteristics of a tobacco product (*i.e.,* characteristics other than tobacco blend) to minimize variability of the product, FDA intends to enforce the premarket authorization requirements, and the PMTA must contain all appropriate information for the distinct new tobacco product that would result from such changes.

19. Finished Tobacco Product

FDA defines ''finished tobacco product'' to mean a tobacco product, including all components and parts, sealed in final packaging (*e.g.,* filters or filter tubes sold to consumers separately or as part of kits, or e-liquids sealed in final packaging sold to consumers either separately or as part of kits) or in the final form in which it is intended to be sold to consumers. FDA received one comment on this definition, as discussed below.

(Comment 10) One comment stated that the definition of the term ''finished tobacco product'' should conform to the definition previously used in the registration and listing guidance, which included the phrase ''intended for consumer use.''

(Response 10) FDA has edited the definition of the term ''finished tobacco product'' to include the phrase ''or in the final form in which it is intended to be sold to consumers'' to help clarify the meaning of the term ''finished.'' We believe that by including products sold in the final form in which it is intended to be sold to consumers, we are capturing a variety of products including those intended for consumer use as requested by the commenter.

20. Harmful or Potentially Harmful Constituent (HPHC)

FDA defines ''harmful or potentially harmful constituent'' as any chemical or chemical compound in a tobacco product or tobacco smoke or emission that: (1) Is or potentially is inhaled, ingested, or absorbed into the body, including as an aerosol or any other emission and (2) causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products. This definition aligns with the definition provided for in the guidance for industry entitled '''Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the FD&C Act.''

The established list of HPHCs can be found on FDA's website at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list* (77 FR 20034, April 3, 2012). FDA issued a notice in the **Federal Register** of August 5, 2019 (84 FR 38032), seeking public comment on the proposed addition of 19 constituents to the established list of HPHCs. FDA is proposing these additions to reflect the range of tobacco products now subject to FDA's tobacco product authorities, including deemed tobacco products such as ENDS. FDA will finalize the addition of these HPHCs to the established list, as appropriate, after reviewing public comment and generally intends to make any future updates to the established list of HPHCs through a similar notice and comment process.

FDA received one comment on this definition, as discussed below.

(Comment 11) One comment stated that FDA should either change the definition of the term ''harmful or potentially harmful constituent'' (HPHC) to include a list of all HPHCs for which testing results must be submitted in a PMTA or include a list of all such HPHCs elsewhere in the rule.

(Response 11) FDA declines to revise the definition of HPHC. In defining this term, FDA is describing criteria for what constitutes an HPHC and is not attempting to identify specific constituents. In contrast, section 904 of the FD&C Act requires FDA to establish, and periodically revise, a list of HPHCs. More importantly for PMTA content, as discussed in section VIII.B.9.a.v., an application would not be required to contain testing for all HPHCs; rather, it would be required to contain testing for constituents, including HPHCs, that are contained within and can be delivered by the type of product and contain a description of why the HPHCs that were tested are appropriate for the type of product.

FDA similarly declines to set forth a list of constituents that must be tested because it would be overly broad as it pertains to most tobacco products. It is FDA's understanding that manufacturers have information concerning what constituents might be

[10] For more information on FDA's enforcement of premarket review for tobacco blending changes, see the guidance entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions'' available at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

emitted from their specific tobacco products. FDA believes that allowing applicants to use this knowledge in selecting the appropriate constituents for testing would result in a more efficient process for preparing PMTAs than requiring manufacturers to test for each constituent in a broad list, including HPHCs that might not pertain to the applicant's specific product.

21. Heating Source

FDA defines ''heating source'' as the source of energy used to burn or heat the tobacco product. Examples of a heating source include a flame or a rechargeable battery.

22. Ingredient

FDA defines ''ingredient'' as tobacco, substances, compounds, or additives added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing. For example, an ingredient may be a single chemical substance, leaf tobacco, or the product of a reaction, such as a chemical reaction, in manufacturing. Examples of substances and compounds (ingredients) reasonably expected to be formed through a chemical reaction during tobacco product manufacturing include the following:

- The reaction of sugars with amines to form families of compounds with new carbon-nitrogen bonds, including Maillard reaction products and Amadori compounds;
- the reaction of sodium hydroxide with citric acid to form sodium citrate;
- the production of ethyl alcohol, a residual solvent, from ethyl acetate during production of tipping paper adhesive;
- products of thermolytic reactions, such as the production of carboxylic acids from sugar esters;
- products of enzymatically or nonenzymatically catalyzed reactions, such as the hydrolytic production of flavor or aroma precursors from nonvolatile glucosides; and
- products of acid-base reactions, such as removal of a proton from protonated nicotine to generate the basic form of nicotine (''free'' nicotine).

23. Line Data

FDA defines ''line data'' to mean an analyzable dataset of observations for each individual study participant, laboratory animal, or test replicate. Line data typically provides information that is more useful to FDA's review of an application than data in its more ''raw'' forms because it allows information about time, people, and places involved in investigations to be organized and reviewed quickly, and it facilitates tracking of different categories of cases. FDA is requiring an applicant to submit line data rather than source data (also referred to as raw data) to allow for a more efficient review process. As described in § 1114.45, applicants are required to retain all source data in the event that FDA needs to inspect the data as part of its application review.

24. Material

FDA defines ''material'' to mean an assembly of ingredients. Materials are assembled to form a tobacco product, or components or parts of tobacco product. For example, material includes the glue or paper pulp for a cigarette where the paper pulp includes multiple ingredients (*e.g.,* multiple types of tobacco, water, and flavors) assembled into the paper (or pulp depending on the water content). Another example of a material is a plastic composed of chemical substances that houses electrical components.

25. Marketing Granted Order

FDA defines ''marketing granted order'' to mean the order described in section 910(c)(1)(A)(i) of the FD&C Act that authorizes the new tobacco product to be introduced or delivered for introduction into interstate commerce.

26. Marketing Denial Order

FDA defines ''marketing denial order'' to mean the order described in section 910(c)(1)(A)(ii) of the FD&C Act that the product may not be introduced or delivered for introduction into interstate commerce.

27. Other Features

FDA defines ''other features'' to mean any distinguishing qualities of a tobacco product similar to those specifically enumerated in section 910(a)(3)(B) of the FD&C Act. The definition includes: (1) HPHCs (the definition of new tobacco product includes any modification to any constituents, including smoke constituents; section 910(a)(1)(B) of the FD&C Act) and (2) any other product characteristics that relate to the chemical, biological, or physical properties of the tobacco product. The term ''other features'' also encompasses other product characteristics that relate to the chemical, biological, and physical properties of the product that would not be included as a material, ingredient, design, composition, or heating source.

28. Premarket Tobacco Product Application or PMTA

FDA defines ''premarket tobacco product application'' or ''PMTA'' to mean the application described in section 910(b) of the FD&C Act. This term includes the initial premarket tobacco product application and all subsequent amendments.

29. ''Premium'' Cigar

As discussed in section VI.A., we are adding the *Cigar Ass'n of Am.* court's definition of ''premium'' cigars to § 1114.3. ''Premium'' cigars means a type of cigar that: (1) Is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains at least 50 percent (of the filler by weight) long filler tobacco (*i.e.,* whole tobacco leaves that run the length of the cigar); (4) is handmade or hand rolled (*i.e.,* no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); (5) has no filter, nontobacco tip, or nontobacco mouthpiece; (6) does not have a characterizing flavor other than tobacco; (7) contains only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weighs more than 6 pounds per 1,000 units.

30. Serious Adverse Experience

FDA defines ''serious adverse experience'' to mean an adverse experience that results in any of the following outcomes: (1) Death; (2) a life-threatening condition or illness; (3) inpatient hospitalization or prolongation of existing hospitalization; (4) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions (*e.g.,* seizures that do not result in hospitalization, burns that result in damage to a limb or nerve damage); (5) a congenital anomaly/birth defect; or (6) any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition. This could include, for example, carbon monoxide poisoning, which if left untreated, could result in long term and possibly delayed brain damage or heart damage.

FDA received one comment on this definition, as discussed below.

(Comment 12) One comment stated that the definition of the term ''serious adverse experience'' needs to be clarified, recommending that it be aligned with a similar definition used by FDA for drugs. Specifically, the comment requested that FDA further

define the term ''life-threatening condition or illness'' in paragraph (b) of the definition to mean, as it does in the drug context, any adverse experience that places the patient, in the view of the initial reporter, at immediate risk of death from the adverse experience as it occurred, *i.e.,* it does not include an adverse experience that, had it occurred in a more severe form, might have caused death. The comment also requested that FDA restrict the ''catch-all'' in paragraph (f) of the definition so that it focuses on ''important medical events,'' similar to the definition for drugs, rather than ''adverse experiences'' as the definition currently does.

(Response 12) FDA declines to revise the definition of serious adverse experience because it captures the events for which FDA would need prompt notification once a product is on the market. Through paragraph (b) of the definition of ''serious adverse experience,'' FDA is seeking information about adverse experiences carrying an immediate risk of death. In contrast, through paragraph (f) of the definition of ''serious adverse experience,'' FDA is interested in receiving prompt notification of a condition that could have delayed consequences, for example, one that that could cause death or severe organ damage if left untreated, or immediate death had it occurred in a more severe form so we can investigate whether the condition could occur in a more severe form and cause death in different individuals. We believe that having paragraph (f) focus on adverse experiences appropriately captures this scope. Applicants with questions regarding whether an adverse experience qualifies as a serious adverse experience are encouraged to promptly contact FDA.

31. Submission Tracking Number or STN

FDA defines ''submission tracking number'' or ''STN'' to mean the number that FDA assigns to submissions that are received from an applicant, such as a PMTA and a supplemental PMTA. FDA has added this definition to the final rule on its own initiative to help clarify requirements to specify submission tracking numbers.

32. Unexpected Adverse Experience

FDA defines ''unexpected adverse experience'' to mean an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with: (1) The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA (including the results of human subject investigations) and other relevant sources of information, such as the product labeling and postmarket reports; (2) the expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or (3) the results of nonclinical investigations.

FDA received one comment regarding this definition, as discussed below.

(Comment 13) One comment stated that the definition of unexpected adverse experience is unnecessarily complex and would likely lead to unduly burdensome reporting. The comment noted potential difficulties with assessing what constitutes a ''foreseeable'' risk and expressed a belief that the definition should be aligned with those found in other product groups that focus on unexpected adverse experiences being those that are not currently listed on product packaging and not previously observed.

(Response 13) FDA declines to revise the definition of unexpected adverse experience because it captures the events and information that should be disclosed. This information is important to FDA's ongoing monitoring of a tobacco product because it would alert the Agency to the potential scope and frequency for health risks that were not previously considered as part of application review and may inform a determination of whether the marketing granted order should be withdrawn or temporarily suspended. Foreseeable risks are harms that could reasonably be predicted based upon the content of the PMTA and other available sources of information and is largely based on mechanism of action or composition of the tobacco product.

33. Vulnerable populations

The proposed rule did not expressly discuss vulnerable populations. However, FDA received several comments regarding this issue, as discussed below.

(Comment 14) Multiple comments raised concerns related to the lack of reference to vulnerable populations in the proposed rule. One comment stated that the tobacco industry has a history of marketing its products to individuals with specific characteristics, including, but not limited to veterans, individuals with a low socioeconomic status (SES), and vulnerable populations. The comment requested that FDA require applicants to specify detailed demographic information in their marketing plans, including the targeting of its marketing by SES as part of a PMTA. Another comment stated that a definition of vulnerable populations should be included in the final rule. In addition, multiple comments requested FDA require PMTAs to contain a consideration of the effects of permitting the marketing of the new tobacco product on vulnerable or sensitive subpopulations (*e.g.,* individuals whose health has been compromised).

(Response 14) FDA agrees that consideration of vulnerable populations is an important part of determining whether permitting the marketing of a new tobacco product would be APPH. As discussed in section IX.D.1., FDA considers many factors when making its APPH determination, including the likelihood that existing users of tobacco products will stop using such products and the likelihood that nonusers of tobacco products will start using. This could include information regarding the marketing of a new tobacco product that may produce a positive effect for some subpopulations while producing differential effects for other subpopulations. For example, a non-combusted tobacco product that may help current adult smokers transition away from cigarettes may appeal to and lead to tobacco product initiation among youth and young adults who have never used tobacco products.

To ensure FDA understands the full health impact of the product, it is important for FDA to consider vulnerable populations and how the marketing of the new tobacco product can impact the likelihood that existing users of tobacco products will stop using such products and the likelihood that nonusers will start using the product. FDA has revised the rule to emphasize the importance of considering the effect of marketing a new tobacco product would have on vulnerable populations as well defined the term ''vulnerable populations'' in § 1114.3 to mean groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation. Relevant vulnerable populations will vary depending on the type of tobacco product and may change over time, and can include, but are not limited to, youth and young adults, those who are of low SES, certain racial or ethnic populations, underserved rural populations, people with co-morbid mental health conditions or substance use disorders, military or veteran populations, people who are pregnant or are trying to become pregnant, and sexual or gender minorities (Refs. 4–9).

Also note that section VIII.B.6.b. includes SES as an example demographic characteristic to clarify the range of potential characteristics that may be included in descriptions of marketing plans.

VIII. Premarket Tobacco Product Applications (Part 1114, Subpart B)

A. Application Submission (§ 1114.5)

As described in § 1114.5, if an applicant seeks a marketing granted order under the PMTA pathway for its new tobacco product, it would be required to submit a PMTA to FDA and receive a marketing granted order before the tobacco product may be introduced or delivered for introduction into interstate commerce. An applicant submitting a PMTA to FDA should include all information required to be in a PMTA as part of its initial submission, including all sections specified in § 1114.7(a), except for product samples which, if required, must be submitted after a PMTA is accepted for review as described in the discussion § 1114.7(e) in section VII.B.5. Submitting a complete application as part of an initial submission is important because, as explained in the discussion of § 1114.27 in section VIII.B, FDA may refuse to accept or file an incomplete application for review.

FDA received several comments regarding the scope of products required to submit a PMTA.

(Comment 15) Some comments request that certain tobacco products, such as ENDS and oral tobacco derived nicotine, be exempt from the PMTA premarket pathway or that a different premarket pathway be created for them. The comments described certain products as significantly less harmful than other products, which they contended justifies either an exemption from the requirements of the PMTA pathway or a creation of a streamlined pathway under which products can be authorized based upon a few approaches, such as the submission of significantly less information that would be required under this rule. Other comments requested a similar streamlined pathway for small businesses due to the cost of preparing a PMTA.

(Response 15) As described in detail throughout this rule, the information required by part 1114 is necessary to ensure FDA has sufficient information to consider, as required by section 910(c) of the FD&C Act, the potential risks and benefits of a new tobacco product to the health of the population as a whole in determining whether the marketing of that product would be appropriate for the protection of public health. FDA declines to create a streamlined pathway for certain tobacco product categories or manufacturers that permits the submission of significantly less information than required by this rule because it would result in FDA having insufficient information to make its statutorily required determinations under section 910(c) of the FD&C Act. Consistent with the deeming final rule,[11] we also decline the request to exempt products from the requirements of PMTA or from premarket review more broadly. Section 910 of the FD&C Act establishes the procedures that must be followed before a new tobacco product can be authorized for marketing and it applies to all new tobacco products.

B. Required Content and Format (§ 1114.7)

1. General

As explained in § 1114.7(a), the rule requires each PMTA to contain sufficient information necessary for FDA to determine whether the grounds for denial of an application listed in section 910(c)(2) of the FD&C Act apply to the PMTA, which includes the following sections:

- General information (as described in § 1114.7(c));
- descriptive information (as described in § 1114.7(d));
- product samples (as described in § 1114.7(e));
- labeling (as described in § 1114.7(f));
- statement of compliance with part 25 (21 CFR part 25) (as described in § 1114.7(g));
- summary (as described in § 1114.7(h));
- product formulation (as described in § 1114.7(i));
- manufacturing (as described in § 1114.7(j));
- health risk investigations (as described in § 1114.7(k));
- the effect on the population as a whole (as described in § 1114.7(l)); and
- certification statement (as described in § 1114.7(m)).

As described in section VIII.B, if the application does not appear to contain these sections and the information required therein (except for product samples), the Agency may refuse to accept the application for review under § 1114.27(a)(1). As described in section VIII.B, if a PMTA does not contain sufficient information required by these sections to permit a substantive review, including substantive information regarding broad areas of scientific information noted where appropriate in this document, FDA may refuse to file the application under § 1114.27(b)(1).

2. Format

Section 1114.7(b) provides the general requirements for the format of the application and would require the applicant to submit the application with the appropriate FDA form(s) (*i.e.,* Form FDA 4057 (Ref. 10) and Form FDA 4057b (Ref. 11)). Section § 1114.7(b)(1) would require the application and any amendments to contain a comprehensive index and table of contents and be well organized, legible, and written in the English language. The comprehensive index would include the listing of files and data associated with those files (*e.g.,* for an application that is electronically submitted, the comprehensive index would include the listing of files and associated metadata). FDA is also requiring that documents that have been translated from another language into English must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person who made the translation (*e.g.,* education and experience). This information would help FDA ensure that the English language translations of documents are complete and accurately reflect the content of the original documents.

As described in § 1114.49, FDA is requiring that the PMTA and all supporting documents be submitted to FDA in an electronic format that the Agency can process, review, and archive, unless the Agency has previously granted a waiver from these requirements. An application would not be considered received until CTP's Document Control Center has received an application that the Agency can process, review, and archive. Applicants that are unable to submit their applications in electronic format may seek a waiver from the electronic filing requirement, in accordance with § 1114.49.

FDA received several comments regarding PMTA format, as discussed below.

(Comment 16) One comment stated that FDA must address inconsistencies between the ENDS PMTA Guidance and the PMTA Proposed Rule, citing

[11] See the deeming final rule (81 FR 28974) for responses to similar comments requesting alternative or abbreviated PMTA pathways and exemptions from the requirements of premarket review.

differences such as marketing plans and application organization.

(Response 16) FDA will update the ENDS PMTA Guidance to ensure it is consistent with the requirements and recommendations in this rulemaking. When updated, the ENDS PMTA Guidance will provide updated important product-specific recommendations for applicants submitting PMTAs for ENDS. In addition, if applicants wish to discuss the development of a PMTA, the applicant may request a meeting as set forth in the guidance for industry and investigators entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products.'' [12]

(Comment 17) One commenter stated that while the proposed rule notes FDA's intent to provide information regarding acceptable technical specifications for electronic submissions, it was not aware of FDA having done so and requested that the final rule contain clear and consistent expectations for electronic submissions so that industry can properly plan and prepare applications in advance of submission.

(Response 17) Applicants can visit FDA's web page for more information on electronic submission, including electronic submission file formats and specifications. As of the date of the publication of this rule, this information is located at: *https://www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions.* This web page also contains a link to the document ''Electronic Submission File Formats and Specifications,'' which provides additional helpful information. As mentioned in the proposed rule, FDA intends to update this information as needed to accommodate changes in technology.

FDA has created these format requirements using its authority under sections 701 and 910 of the FD&C Act to efficiently enforce premarket review requirements. The requirements in § 1114.7(b) are intended to address some of the problems we have seen with applications to date. For example, some applications have been submitted to FDA in a proprietary or password protected format without providing FDA access or password information. Following up with an applicant to obtain access or password information takes time and contributes to delays. In addition, some electronic submission files have not been of a static format, and thus, the pages reformat, repaginate, rebullet, or redate each time the document is accessed. For example, Microsoft Word files can change upon opening by FDA reviewers, while PDF files remain as the applicant intended. Receiving applications with these issues affects our ability to cross-reference, share (internally), and efficiently evaluate information. Also, FDA is required under regulations governing Federal records to maintain many files long-term, and in a ''sustainable'' format (for more information on sustainable formats, please refer to National Archives and Records Administration Bulletin 2014–04, *https://www.archives.gov/records-mgmt/bulletins/2014/2014-04.html*), § 1114.7(b) will ensure that these files can be managed, opened, and read by the Agency for the duration of the retention period.

Finally, § 1114.7(b)(2) will allow an applicant to include content in a PMTA by cross-reference to a tobacco product master file (TPMF) or a pending MRTPA for the same tobacco product submitted under section 911 of the FD&C Act. A TPMF is a file that is voluntarily submitted to CTP that contains trade secret and/or confidential commercial information about a tobacco product or component that the owner does not want to share with other persons. TPMFs are a beneficial tool for manufacturers, component suppliers, and ingredient suppliers, and can assist the tobacco product submission process. TPMFs allow individuals to rely on the information contained in a TPMF in a submission to FDA without the TPMF owner having to disclose the information to those individuals. TPMFs are typically used to prevent the disclosure of information that contains trade secrets or confidential commercial information. One situation in which TPMFs might be useful in submitting a PMTA is where an applicant is seeking marketing authorization for a new tobacco product that is made using a component or part, or ingredient that is purchased from another tobacco product manufacturer (*e.g.,* blended tobacco or an e-liquid). Applicants must demonstrate they have the right to reference the TPMF to be able to include content by cross-reference, such as by having the master file holder provide a letter of authorization. Applicants must specify the master file number and clearly identify the specific content that it is incorporating into its PMTA. For FDA's current thinking on the use of TPMFs, please consult the guidance for industry entitled ''Tobacco Product Master Files.'' [13]

(Comment 18) A number of comments submitted similar concerns about the lack of data standardization, stating that FDA should standardize the data required to be submitted and allow companies to rely on the same pool of standardized data where it applies to similar aspects of their new tobacco product, such as submitting the same ingredients, to improve the efficiency for both application submission and review.

(Response 18) When companies want to rely on the same pool of data, FDA encourages the use of shared resources, such as tobacco product master files, where appropriate.

Applicants may also include content in a PMTA by cross-reference to a pending MRTPA for the same tobacco product.[14] FDA recommends that applicants seeking to market a new tobacco product that has not previously received marketing authorization as a modified risk tobacco product (MRTP) submit a single application to seek both a marketing granted order and a modified risk granted order (*i.e.,* a combined PMTA and MRTPA); however, where an applicant chooses to submit a separate PMTA and MRTPA, FDA recommends that an applicant submit the full text of any common content (*e.g.,* the manufacturing or product formulation sections) in a PMTA and include it in the MRTPA by cross-reference. This approach would prevent any transcription errors and would allow for a more effective review by FDA because the content would only need to be reviewed once to be considered as part of both applications.

Under this rule, except as described in subpart B, FDA will not consider content included by cross-reference to any other sources of information outside of a submission. An applicant may use internal cross-references for any content that would need to be referenced in multiple sections of a PMTA (*i.e.,* include the full text of the content in one section and use cross-references to

[12] Available at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance*

[13] Available at: *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

[14] FDA has not included MRTPAs that resulted in a modified risk order in the list of documents that an applicant may cross-reference as part of a PMTA. Because a new tobacco product must receive premarket authorization under section 910 of the FD&C to be introduced or delivered for introduction into interstate commerce, FDA does not intend to act on a MRTPA unless the product has a pending application seeking, or has already received, marketing authorization under section 910, or is a Pre-Existing Tobacco Product. Such an approach will allow FDA to efficiently enforce section 911 of the FD&C Act by focusing its efforts on only those applications that could potentially result in a tobacco product being introduced to the market.

the content in other sections), rather than including the full text of the same information multiple times. If an applicant wishes to include information it has previously submitted to FDA other than a master file or a pending MRTPA (*e.g.,* portions of an SE Report or previously submitted PMTA for a different product), the applicant must include the full text of such information in its PMTA. FDA is implementing this restriction because cross-referencing information from other types of applications (*e.g.,* SE Reports, previously submitted PMTAs for different products) can make review difficult and contribute to delays in the review process.

(Comment 19) One comment stated that FDA should amend the application format requirements so that it allows PMTAs to include information by cross-reference to parts of previously filed PMTAs for different products that contain studies applicable to the new tobacco product.

(Response 19) The format requirements of § 1114.7(b) permit an applicant to cross-reference a tobacco product master file or a pending MRTPA for the same tobacco product. FDA declines to revise § 1114.7(b) to broadly allow an applicant to cross-reference information contained in any previously filed PMTA because it could result in a process in which FDA would have to pull information from a variety of sources to have a complete PMTA for review, which would increase the potential for error and decrease the efficiency of FDA's review. Additionally, permitting an applicant to broadly cross-reference information presented for different products would not necessarily result in a more efficient review process. FDA is limiting the ability of applicants to cross-reference content from previously reviewed PMTAs to specific circumstances set forth in §§ 1114.15 and 1114.17 where it would facilitate application review. Where an applicant intends to submit the same information in multiple applications submitted at different periods in time, FDA recommends establishing a TPMF containing the information so that it could be included by cross-reference in each application.

An applicant may also submit a single premarket submission for multiple products (*i.e.,* a bundled PMTA) and a single, combined cover letter and table of contents across all products; however, when FDA receives a premarket submission that covers multiple new tobacco products, we intend to consider information on each product as a separate, individual PMTA and it is important to identify the content that pertains to each product.

(Comment 20) Multiple comments requested additional information regarding how they should bundle multiple PMTAs for related or similar tobacco products into a single submission. One comment requested that FDA formally clarify whether e-liquid manufacturers and manufacturers of closed-system devices may bundle applications for multiple flavors of e-liquid that share common nicotine strengths, package sizes, propylene glycol/vegetable glycerin ratios, or other characteristics. Another comment requested information regarding how a manufacturer should submit PMTAs for products that are used together but may be sold separately (*e.g.,* closed e-liquids, such as cartridges or pods that are not intended to be refillable, and the e-cigarette with which the e-liquids would be used).

(Response 20) FDA recommends that an applicant group PMTAs for products in the same subcategory (see § 1114.7(c)) that are produced by the same manufacturer into a single submission because they will likely share a significant amount of application content. An applicant grouping PMTAs together by subcategory would be required to use Form FDA 4057b to identify the products that are contained in the grouped submission. Additionally, FDA recommends an applicant group PMTAs for a new tobacco product and its components or parts into a single submission where an applicant seeks to sell the components or parts separately. As discussed in section VIII.B.3., FDA generally considers an open e-cigarette, also referred to as a refillable e-cigarette, to be an e-cigarette that includes a reservoir that a user can refill with an e-liquid of their choosing. A closed e-cigarette is an e-cigarette that includes an e-liquid reservoir that is not refillable, such as a disposable cigalike, or that uses e-liquid contained in replaceable cartridges or pods that are not intended to be refillable. For example, if a manufacturer wanted to sell a closed e-cigarette and the closed e-liquids (*e.g.,* nonrefillable cartridges or pods) that could be used with the e-cigarette separately, it should group a PMTA for the e-cigarette and PMTAs for each of the e-liquids into a single submission. FDA does not recommend grouping open e-liquids and open ENDS devices that will be sold separately in a single submission except for instances where the applicant is seeking a marketing granted order for the e-liquids that have been designed by the manufacturer to be used solely in a particular open ENDS device. FDA reminds applicants that we intend to consider information on each product as a separate, individual PMTA, so it is important to identify the content that pertains to each product. If an applicant does not clearly identify the content in the submission that makes up the PMTA for each product, FDA may refuse to accept or refuse to file the submission.

3. General Information

Section 1114.7(c), including table 1, lists the information that must be included in the general information section of the PMTA. This information consists of general administrative information that includes the type of submission, the new tobacco product with unique identifiers, and contact information. Specifically, table 1 to § 1114.7(c)(3)(iii) provides for the information needed to help ensure that we are able to identify and evaluate each product more accurately and efficiently. This table includes, among other categories, requirements to submit general information related to ENDS product category and several subcategories of ENDS. FDA generally considers ENDS to be electronic nicotine delivery systems that deliver aerosolized e-liquid when inhaled. The term ''e-cigarette'' refers to an electronic device that delivers e-liquid in aerosol form into the mouth and lungs when inhaled; it is also sometimes referred to as an aerosolizing apparatus. An open e-cigarette, also referred to as a refillable e-cigarette, is an e-cigarette that includes a reservoir that a user can refill with an e-liquid of their choosing. A closed e-cigarette is an e-cigarette that includes an e-liquid reservoir that is not refillable, such as a disposable cigalike, or that uses e-liquid contained in replaceable cartridges or pods that are not intended to be refillable. For additional information on ENDS, consult the ENDS PMTA Guidance.

In this final rule, we have revised table 1 to § 1114.7(c)(3)(iii) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. For example, the table includes a waterpipe head as a subcategory of waterpipe. A waterpipe head is a container that is typically made of materials like clay, marble, or glass and is used to contain coal and tobacco during a waterpipe smoking session.

Additionally, the cigarette product category no longer lists noncombusted cigarettes as a subcategory. Instead, for purposes of PMTA review, a ''heated tobacco product'' category has been added to the identification tables. Under this revised taxonomy, some tobacco

products may fit under more than one category. This PMTA review category should be used for (among others) tobacco products that meet the definition of a cigarette but are not combusted (products that do not exceed 350° C). Heated tobacco products (HTP) can be used with e-liquids, other types of tobacco filler, or consumable (*e.g.,* wax, oils). If, however, a tobacco product can only be used with e-liquids, it should be captured under ''ENDS'' and not the HTP category. To ensure we have all the information we need to efficiently and effectively review your application, if the product that is the subject of your application is a heated tobacco product and is not an ENDS product, you should submit information under § 1114.7(c)(3)(iii) under the heated tobacco product category and comply with the design parameter requirements for HTPs in table 22 to § 1114.7(i)(2)(ii).[15] FDA believes these product categorizations will help ensure that applications include the most relevant information for their product, which in turn will facilitate FDA's review and ability to reach an authorization decision.

Other changes to table 1 to § 1114.7(c)(3)(iii) include FDA's clarification under the ''cigar'' category to designate ''leaf-wrapped'' cigars as *unfiltered* to more accurately describe the product category, as ''leaf-wrapped'' cigars typically do not include filters; under the ''waterpipe'' category, ''waterpipe'' diameter has been added to distinguish between waterpipes of different sizes (width/diameter and height) where all other uniquely identifying information is the same; and under the ''pipe tobacco filler'' category, ''tobacco cut style'' has been added to distinguish between different cut pipe tobacco filler, *e.g.,* standard cut, such as shag cut, bugler cut, loose cut, etc.; or a pressed cut, such as flake, cube cut, roll cake, etc. or a mixture. Additionally, FDA has removed the requirement to provide tobacco cut size from the unique identification requirements for smokeless tobacco and cigar tobacco filler. A specific numerical value for this field is not necessary to uniquely identify the specific product to which the PMTA pertains, as it can be described further through identification of additional properties (*e.g.,* fine cut, long cut). However, to fully characterize the tobacco product and evaluate its health effects, information to determine tobacco cut size is required under § 1114.7(i)(2)(ii) for the product categories specified in that section.

Additionally, across all product categories, the subcategory of ''co-package'' has been removed from § 1114.7(c). If an applicant submits a PMTA for a co-packaged tobacco product, the unique identification of this co-packaged product would require the specific items needed to identify each product within the co-package. For example, if the co-package is a pouch of roll-your-own (RYO) tobacco filler that contains rolling papers inside the pouch, the applicant would identify the tobacco product as a co-packaged product and provide the unique identification for both the RYO tobacco filler and the rolling papers.

The PMTA must contain the following information using the FDA-provided form(s) (*i.e.,* Form FDA 4057 (Ref. 10) and Form FDA 4057b (Ref. 11)), as appropriate:

- Applicant name, address, and contact information;
- the name, address, and contact information for the authorized representative or U.S. agent (for a foreign applicant). As required by § 1105.10(a)(5) for application acceptance, a foreign applicant must identify a U.S. agent (*i.e.,* an individual located in the United States who is authorized to act on behalf of the applicant for the submission) to help FDA ensure adequate notice is provided to applicants for official Agency communications, assist FDA in communicating with the foreign applicant, and help the Agency to efficiently process applications and avoid delays; and
- information to uniquely identify the product. Providing unique identifying information is important to aid in FDA's review because it ensures FDA has information readily available to distinguish the tobacco product from other tobacco products, including additional new tobacco products in a bundled submission (*i.e.,* more than one application contained in a single submission), and assists FDA in performing its acceptance and filing reviews. The required unique identifying information includes:
  - The manufacturer;
  - product name(s), including the brand and subbrand (or other commercial name(s) used in commercial distribution); and
  - product category; product subcategory; and product properties, as provided by the table in § 1114.7(c). The applicant must select and provide the appropriate category, subcategory, and product properties for the new tobacco product. As discussed previously, if an applicant submits a PMTA for a co-packaged tobacco product, the unique identification of this co-packaged product must include the specific items needed to identify each product within the co-package. For example, if the co-package is a pouch of RYO tobacco filler that contains rolling papers inside the pouch, the applicant must identify the tobacco product as a co-packaged product and provide the unique identification for both the RYO tobacco filler and the rolling papers. This product-specific information is required under sections 910(b)(1)(B) and (G) of the FD&C Act and this rule requires its inclusion in the general information section of the submission to help FDA quickly check whether the product is within CTP's purview and identify the specific product that is the subject of the submission. For more information regarding product properties and why specific properties are a required part of an application, see the discussion of § 1114.7(i)(1) in section VIII.B.9. It is important to note that for the characterizing flavor product property, the applicant must state ''none'' if it does not consider the product to have a characterizing flavor. FDA encourages applicants that have questions regarding how to describe their product's characterizing flavor to contact FDA prior to submission.

For each type of tobacco product, the applicant should also include any additional properties to fully identify the tobacco product, if applicable. For example, use of product descriptors such as ''extra-long'' should be identified. While failure to include such additional properties to help uniquely identify the tobacco product would not serve as the basis for FDA refusing to accept an application under § 1114.27(a)(1), it would likely slow down the substantive review process.

FDA received a few comments regarding § 1114.7(c)(3), as discussed below.

(Comment 21) One comment stated that § 1114.7(c)(3)(iii) should be amended to require disclosure of all flavoring agents regardless of whether they constitute characterizing flavors and all solvents rather than just propylene glycol and glycerin in all new tobacco products.

(Response 21) We decline to make this proposed edit, because such information is already required as part of the full listing of all of the product's ingredients, additives, and constituents

[15] Note that the purpose of the unique identification tables in § 1114.7(c)(3)(iii) is to explain what information we need to identify and evaluate different types of products, and § 1114.7(i)(2)(ii) explains the design parameters needed for product characterization (see discussion below). The categorization of HTPs in § 1114.7(c)(3)(iii) and (i)(2)(ii) does not extend to other legal requirements beyond those associated with unique identification and product characterization for premarket review.

in § 1114.7(i)(1)(ii). Section 1114.7(c)(3)(iii), entitled ''general information,'' is intended to allow FDA to quickly determine whether the product is under CTP's jurisdiction and readily identify the specific product that is the subject of the application. A complete listing of all flavoring agents and solvents in this section would not further the purpose of this section.

(Comment 22) One comment requested that FDA amend § 1114.7(c)(3)(iii) to remove the ''dissolvable'' tobacco product subcategory and replace it with design parameters for an ''oral tobacco-derived nicotine (OTDN)'' subcategory. The comment stated that not only does ''dissolvable'' more appropriately describe a product trait, dissolvable products are less prevalent on the market today than OTDN products.

(Response 22) FDA declines to remove the ''dissolvable'' tobacco product subcategory and replace it with ''oral tobacco-derived nicotine (OTDN).'' In 2009, the Family Smoking Prevention and Tobacco Control Act authorized FDA to regulate, among other things, smokeless tobacco products, the definition of which includes some dissolvables that contain finely ground tobacco. While design parameters of the dissolvable tobacco products may resemble those of OTDN, the OTDN subcategory could imply that such products only contain nicotine that is derived from tobacco, and not finely ground tobacco. This narrow definition would exclude dissolvable tobacco products that contain finely ground tobacco. As discussed in section VIII.B.3., applicants are required to identify the product category and subcategory in a PMTA to help FDA quickly check whether the product is within CTP's purview and identify the specific product that is the subject of the submission. Where an applicant believes its new tobacco product, such as OTDN, does not fit within a product category set forth in the rule, it should identify the product category as ''other.''

(Comment 23) One comment stated that FDA should remove the requirement to identify the category and subcategory of the tobacco product in § 1114.7(c)(3), because applications should compare their products to all other tobacco products and product categories are not contemplated under section 910(b) of the FD&C Act. The comment also stated that there is no justification to support the potential for users to switch between products within categories when real-world evidence shows that current users may switch to products from different categories.

(Response 23) FDA declines to remove the requirement to identify a product's category and subcategory. Not only does this information allow FDA to identify the product, it provides important context for information contained in the application, including but not limited to health risks associated with product design and its constituents, product and packaging design risks and misuse hazards, principles of operation, and warning statement requirements. Specifically, identifying a product's category and subcategory ensures that FDA is able to distinguish between products that have the same brand and subbrand, but a different category or subcategory, which may be associated with different health risks, design risks or even have different warning statement requirements. For example, if an applicant submits a PMTA for a product that has the same brand and subbrand as another product but has been identified as smokeless tobacco, FDA will review the product labeling to ensure it complies with category specific applicable requirements such as the Comprehensive Smokeless Tobacco Health and Education Act. Additionally, understanding the category will allow FDA to determine whether the application meets the requirement in § 1114.27(b)(1)(ii)(B) to compare the health risks of the new tobacco product to the health risks of products in the same product category and products in at least one different product category.

Section 1114.7(c) also includes the following requirements:

- The type of PMTA. The applicant is required to state the type of PMTA the applicant is submitting (*i.e.,* PMTA, supplemental PMTA, or resubmission);
- whether the applicant requests that FDA refer the PMTA to the Tobacco Products Scientific Advisory Committee (TPSAC). An applicant should briefly describe its justification for a request to refer the PMTA to TPSAC. FDA retains the discretion to refer an application to TPSAC but will consider an applicant's request as part of its determination;
- identifying information regarding any prior submissions relating to the new tobacco product, including STNs, where applicable. The types of prior submissions include premarket applications, such as PMTAs, SE Reports, and exemption requests, as well as other submissions to FDA including MRTPAs and submissions related to investigational tobacco products. The regulatory history of a tobacco product can provide useful context for FDA's review of a submission;
- dates and purpose of any prior meetings with FDA regarding the new tobacco product;
- if the tobacco product has previously been commercially marketed [16] in the U.S., the dates during which the tobacco product was marketed;
- address and the Facility Establishment Identifier (FEI) number(s), if available, of the establishment(s) involved in the manufacturer of the new tobacco product. This information will assist the Agency with environmental impact considerations and determinations under part 25 by helping FDA understand the location of manufacturing and scale of products that would be manufactured. Additionally, it helps FDA schedule and conduct facility inspections;
- a brief statement regarding how the PMTA satisfies the content requirements of section 910(b)(1) of the FD&C Act. This could consist of a table reproducing the section 910(b)(1) requirements and listing the sections or page numbers of the PMTA that satisfy the requirements. FDA is requiring this brief statement under authority of sections 701(a) and 910(b)(1)(G) of the FD&C Act, which will allow FDA to more quickly locate application content necessary to determine whether a PMTA should be accepted and filed for further review under § 1114.27;
- a brief description of how permitting the marketing of the new tobacco product is expected to be appropriate for the APPH. This description should be no more than a sentence or two that highlights the key product characteristics and study results the applicant believes would make the marketing of the product APPH (*e.g.,* the product delivers significantly lower levels of a specific HPHCs to users than the tobacco products they are currently consuming, which studies indicate may result in decreased morbidity and mortality); and
- a list identifying all enclosures, labels, and labeling being submitted with the application. This list will help FDA identify application content and ensure a PMTA contains all the information the applicant intended to submit.

FDA received several comments regarding these requirements (§ 1114.7(c)(4) through (12)), as discussed below:

(Comment 24) One comment stated that FDA should refer all PMTAs to

[16] As described in Section IV.B.4., this includes products that were commercially marketed in test markets.

TPSAC and should make all PMTAs available for public comment. The comment stated that if referring all applications to TPSAC is unfeasible, FDA should at least refer applications from major tobacco companies and representative applications from smaller companies.

(Response 24) We decline to take the comment's suggestion. Under section 910(b)(2) of the FD&C Act, FDA has the discretion, on its own initiative or upon the request of an applicant, to refer a PMTA to TPSAC for reference and for submission of a report and recommendation respecting the application. Referring an application to TPSAC is a lengthy process that requires extensive time and resources, including the significant back-and-forth process with an applicant to redact trade secrets and confidential commercial information in an application before it can be made publicly available. Receiving and reviewing public comments also requires significant time and resources. It would not be feasible to redact all PMTAs, receive and consider public comments, and receive and consider TPSAC's report and recommendations prior to acting on the expected high volume of applications the comment is suggesting go to TPSAC within the 180-day review period required by section 910(c) of the FD&C Act.

(Comment 25) Multiple comments stated that FDA should require applicants to specify whether the new tobacco product is a deemed tobacco product that has been on the market prior to the deadline for submitting a PMTA and, if so, require the submission of information regarding the marketing of the product prior to application submission, including items such as prior sales, labeling, advertising, and marketing strategy. One comment also requested that FDA require an applicant describe whether the prior marketing of its product has been APPH and deny applications where this has not been the case.

(Response 25) FDA has amended the rule to require a PMTA to specify the prior dates, if any, during which the tobacco product was initially marketed. Additionally, the requirement in § 1114.7(k) to submit full reports of investigations that are published or known to, or which should reasonably be known to, an applicant includes the time period during which an applicant previously marketed a deemed tobacco product. While information relating to the prior marketing of a tobacco product may inform FDA review of a PMTA, FDA declines to require an applicant to describe whether it believed its prior marketing of a product was APPH, or necessarily deny an application where prior marketing was not APPH. FDA will make its own determination as to whether permitting the marketing of the new tobacco product is APPH based on all of the contents of the application. In addition, FDA has authority to include postmarket requirements to help ensure that marketing of the product after authorization continues to be APPH.

4. Descriptive Information

Section 1114.7(d) requires applicants to provide descriptive information that outlines the major aspects of the new tobacco product, which is required to be submitted under section 910(b)(1)(A), (D), and (G) of the FD&C Act. This information includes:

- A concise description of the new tobacco product (*e.g.,* the product is a portioned smokeless tobacco product made using a blend of burley and bright tobacco);
- a statement identifying all tobacco product standards issued under section 907 of the FD&C Act that are applicable to the new tobacco product and a brief description of how the new tobacco product fully meets the identified tobacco product standard(s). If the new tobacco product deviates from such standard(s), if applicable, the rule requires the application to include adequate information to identify and justify those deviations;
- the product name(s) as designated on the product's label;
- a description of problems identified in prototypes that are the subject of studies contained in the application, or previous or similar versions of the new tobacco product that were marketed, if any. This includes information regarding any health risks such as overheating, fires, or explosions as well any information regarding manufacturing issues related to the product, such as packaging defects that could pose a health risk. If there are previous or similar versions that were marketed or that are the subject of studies in the application, the rule requires the applicant to include a bibliography of all reports regarding the previous or similar version of the product, whether adverse or supportive. FDA requires this information under section 910(b)(1)(A) and (G) of the FD&C Act to assess whether any known issues with a predecessor product that could affect the health risks of the new tobacco product have been addressed; and
- any restrictions on the sale, distribution, advertising, or promotion of the new tobacco product (as described in section 910(c)(1)(B) of the FD&C Act) that the applicant proposes to be included as part of a marketing granted order, if issued. The applicant may choose to propose restrictions on the sales and distribution of the tobacco product to help support a showing that the marketing of the product is appropriate for the protection of the public health (*e.g.,* a restriction that decreases the likelihood that those who do not currently use tobacco products will initiate tobacco product use with the new tobacco product). If an applicant does not wish to propose any additional restrictions, it must explicitly state that it proposes no restrictions. As described in § 1114.31, FDA may consider these proposed restrictions during its review of the PMTA and, where appropriate, include applicant proposed restrictions in the marketing granted order for the product together with any additional restrictions FDA may require.

FDA received many comments regarding the descriptive information requirements, as discussed below.

(Comment 26) Multiple comments requested that FDA revise the requirement in § 1114.7(d)(4). One comment stated that section 910(b)(1)(B) of the FD&C Act limits review to the new tobacco product that is the subject of the application and does not permit review of other products. The comments also stated that the terms ''previous or similar version,'' ''prototype,'' and ''problem'' are so vague that they would leave applicants guessing at what information must be included. The comments concluded by stating that a product's effects on public health should be determined based on data about the product in its current form.

(Response 26) FDA disagrees with the comments statement that FDA cannot require this information or consider it during product review. FDA is requiring the submission of information regarding prototypes and previous or similar versions of the tobacco product to assess whether an applicant has addressed any known issues with a predecessor product that could affect the health risks of the new tobacco product. The terms ''previous or similar version,'' or ''prototype,'' mean any previous generation, model, or version of a tobacco product that has undergone testing or was on the market in other countries, such as first-generation ENDS products that underwent aerosols or battery testing, and was subsequently modified as a result of testing, adverse experiences, or other design concerns that could impact the public health. Rather than using section 910(b)(1)(B) of the FD&C Act, as cited by the comments as authority for this requirement, FDA

bases its authority for this provision on section 910(b)(1)(G) of the FD&C Act, which requires applicants to submit other information relevant to the subject matter of the application as the Secretary may require.

The information required in § 1114.7(d)(4) will allow FDA to review information regarding risks present in closely related products and determine whether the applicant has addressed such risks in the development of the product that is the subject of the PMTA. FDA declines to adopt the comments' proposed approach that would require FDA to ignore information about known problems and related health risks that could be present in the tobacco product under review. We note that information about known problems and related health risks (*e.g.,* product class effects such as mouth ulcers in moist tobacco) would be informative and could be used to bridge health effect information. Specifically, this information could help FDA to determine the validity and applicability of the studies that relied on a prototype.

5. Samples of New Tobacco Products and Components or Parts

Section 910(b)(1)(E) of the FD&C Act requires an applicant to submit samples of a tobacco product and its components as FDA may reasonably require. After FDA accepts a submission, FDA will determine whether it will require product samples and, if so, issue instructions on how and where to submit the samples, and the number of samples that are required. Section 1114.7(e) requires an applicant to submit samples of the finished tobacco product and its components in accordance with instructions issued to the applicant after a PMTA is accepted for review, as well as to submit additional samples if required by FDA during application review. FDA generally expects that product samples will be a required part of a PMTA and that an applicant should be prepared to submit them in accordance with FDA instructions within 30 days after submitting a PMTA. There may be situations in which sample submission may not be necessary, including, in some circumstances, PMTAs that are resubmitted for the same product after a marketing denial order (such as resubmissions as described in § 1114.17) or PMTAs submitted for modifications to an authorized product where the modifications do not require review of new samples as part of the PMTA evaluation process. Presubmission meetings with FDA may help provide additional information about whether product samples will need to be included in a PMTA; however, in most situations, FDA will only be able to determine the need for product samples after a PMTA is accepted for review.

FDA received many comments regarding product samples, as discussed below.

(Comment 27) One comment agreed that requesting samples after a PMTA submission has been accepted makes sense; however, it stated that providing information regarding the quantity and type of samples that will be required for submission in advance is important to ensure that the samples FDA requires are actually available at the time of request.

(Response 27) As described in section VIII.B.5, FDA generally expects that product samples will be a required part of a PMTA and that an applicant should be prepared to submit them in accordance with FDA instructions within 30 days after submitting a PMTA. Because the quantity and type of samples need for testing may vary based upon a number of factors including product category and specific product characteristics, FDA intends to determine the quantity and type that will be required after application acceptance. However, as noted in section VIII.B.5., presubmission meetings with FDA may help provide additional information about whether product samples will need to be included in a PMTA.

(Comment 28) We received multiple comments regarding FDA's proposal to require an applicant to submit product samples only after an application is accepted for review. One comment stated that the start of FDA's 180-day review period should not be postponed until samples are received and should instead begin at the time the application is otherwise complete except for samples. Another comment requested that FDA amend the rule to allow applicants to submit product samples as part of its initial PMTA to avoid delays. The comment stated that the costs of the delaying the start of substantive review outweigh any minor savings gained by postponing inevitable product sample submission. The comment also noted that under FDA's proposed approach, FDA could indefinitely delay filing an application for review by not requesting product samples after application acceptance.

(Response 28) We decline to make the requested revisions. FDA will have applicants submit samples (if required by FDA) after acceptance of an application rather than as part of an initial submission. This timing will help FDA to determine the need for samples, allow the samples to be tracked and identified as part of the correct application, and facilitate the submission of samples to testing facilities that are adequately prepared to accept them (*e.g.,* one that has a refrigerated unit if the product needs to be stored at a certain temperature). Additionally, by having applicants submit samples after FDA accepts an application, applicants will be able to avoid the effort and expense of submitting samples if the application is not accepted for review or if samples are not required. It will also allow FDA to avoid similar concerns with respect to storage and the return of samples for applications where FDA refuses to accept a PMTA. As described in § 1114.27, if required by FDA, product samples will be necessary for application filing and FDA intends to refuse to file a PMTA for a lack of product samples if the applicant has not submitted samples in accordance with FDA's instructions by the time FDA is prepared to make its filing determination.

FDA intends to notify an applicant if it determines after PMTA acceptance that product samples are not required for PMTA filing; however, even in such a situation, FDA may request product samples during substantive review after an application is filed, as needed. FDA generally expects that, where required, samples will be requested within 30 days after application submission. Applicants may discuss the need for product samples during a presubmission meeting with FDA, which may speed up the sample submission process.

6. Labeling and Description of Marketing Plans

Section 1114.7(f) of the rule requires that a PMTA contain specimens of labeling and describe the applicant's marketing plans for the new tobacco product.

a. *Labeling.* Section 910(b)(1)(F) of the FD&C Act requires that a PMTA contain specimens of the proposed labeling to be used for the tobacco product. Section 1114.7(f)(1) elaborates on this requirement and requires the application to contain specimens of all proposed labeling for the new tobacco product, including labels, inserts, onserts, instructions, and other accompanying information.

FDA received comments regarding the submission of labeling, as described below.

(Comment 29) One comment stated that FDA's proposal to require ''specimens of all proposed labeling'' in § 1114.7(f)(1) is outside the scope of its authority under section 910 of the FD&C

Act and requested that FDA remove the word ''all'' from the requirement. The comment stated that the statute requires the submission of specimens proposed to be used, which connotes a typical example of a larger whole and, as such, is not compatible with the requirement to provide ''all'' proposed labeling.

(Response 29) FDA disagrees with the assertion that § 1114.7(f)(1) is outside of its authority and declines to interpret the term ''specimens'' as used in section 910(b)(1)(F) of the FD&C Act to mean a representative sample. FDA's interpretation of section 910(b)(1)(F) in § 1114.7(f)(1) is consistent with how it interprets similar statutory requirements to submit specimens of labeling for both new drug applications and premarket approval applications for medical devices.[17] Not only did FDA's interpretation of these requirements for drugs and devices exist when Congress enacted the same requirement in the Tobacco Control Act, section 905(i)(1)(B) of the FD&C Act demonstrates Congress understands how to require a representative sample when it intends to do so. It did not do so here. Furthermore, requiring specimens of all proposed labeling is important to FDA's review of an application, because FDA must deny a PMTA under section 910(c)(2)(C) of the FD&C Act where it finds, based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular. This requirement to deny a PMTA based upon any particular of the proposed labeling is at odds with the comment's suggestion that Congress intended FDA to review only a general representation of what an applicant proposes to use.

The labeling specimens are required to include all panels and reflect the actual size and color proposed to be used for such tobacco product. The labels must include any warning statements required by statute or regulation, such as the Federal Cigarette Labeling and Advertising Act, the Comprehensive Smokeless Tobacco Health and Education Act, or the minimum required warning statements contained in 21 CFR part 1143. For products that are required to provide rotational warning statements, the applicant should submit labeling with each of the required warnings in the rotation.[18]

As described in § 1114.33, product labeling is an important part of FDA's review of an application, because FDA must deny a PMTA under section 910(c)(2)(C) of the FD&C Act where it finds, based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular. Additionally, product labeling can be an important part of FDA's determination under section 910(c)(2)(A) of the FD&C Act of whether there is a showing that permitting the marketing of the product would be APPH because it can be used to help show perception of the risks of the product and the ability of individuals to understand the labeling, including any instructions for use, as described in § 1114.7(k)(1)(iv).

b. *Description of Marketing Plans.*—i. General. In the proposed rule, the marketing plans provision in proposed § 1114.7(f)(2) would have required an applicant to submit detailed information about all plans it had developed to market its new tobacco product. In response to comments and on FDA's own initiative, we have revised the requirement to submit information concerning the applicant's plans to market the new tobacco product. Rather than requiring all of the detailed information required in proposed § 1114.7(f)(2), FDA has revised this section to require only a high-level description of several key aspects of these plans that directly inform FDA's APPH determination. FDA notes that, pursuant to Section 910(b)(1)(G) of the FD&C Act, the Agency may require additional information related to marketing plans on a case-by-case basis, if the agency determines during review that additional information is needed to help determine if a product is appropriate for the protection of the public health. FDA's discussion of the comments is included below.

(Comment 30) One comment stated that FDA should clarify the scope of marketing information it expects to see in a PMTA and explain how it plans to engage in a science-based review of labeling and marketing plans, noting that the rule provides little detail as to what specific marketing information the Agency expects to see. The comment stated that it is unclear whether FDA is proposing to require submission of information about top-line product messaging or specific pieces of the advertising and marketing strategies for their use. The comment noted that it is also unclear to what extent FDA expects to see results of consumer research. In addition, the comment stated that it remains unknown how the Agency plans to review labeling and marketing plans and what specific considerations or methodologies will guide assessment of consumer risk perception, comprehension, and use intentions.

(Response 30) FDA has revised § 1114.7(f)(2) to require only high-level marketing plan information that it generally expects applicants will have developed prior to seeking marketing authorization for their products. The description of marketing plans now required by § 1114.7(f)(2)—including intended audience, how the applicant would target the intended audience and what other groups would foreseeably be exposed, and how exposure would be limited for individuals below the minimum age of sale—seeks information necessary for FDA to properly evaluate the extent of youth exposure to marketing materials for the product and youth access to the product. Discussion of these items will not require applicants to conduct consumer research; however, where an applicant had undertaken such research, the results of such research will be required by § 1114.7(f)(2) or (k)(1)(iv). As discussed in section VIII.B.6.b., this information will allow FDA to consider whether an applicant has addressed potential concerns about the marketing of its product, such as tobacco product use initiation by individuals under the minimum age of sale, and will help FDA to assess whether the plans to market the product are consistent with the applicant's discussion of the likelihood of changes in tobacco product use behavior in the application. These considerations will help FDA to determine whether there is a showing that permitting the tobacco product to be marketed is appropriate for the protection of public health.

(Comment 31) One comment stated that the marketing plan requirements seem to be based on the premise that companies will have developed marketing plans by the time of application submission, which fails to account for the small vape shops that currently serve as both retailers and manufacturers who are unlikely to have undertaken consumer research. The comment requested that FDA edit the marketing plan requirements to apply only ''as applicable'' to companies that have conducted such research.

(Response 31) The requirement to provide descriptions of marketing plans does not require applicants to undertake market or consumer research. Rather,

[17] See the interpretation of section 505(b)(1)(F) of the FD&C Act (21 U.S.C. 355(b)(1)) in 21 CFR 314.50(e)(2)(ii) (50 FR 7493, February 22, 1985) for new drug application, and the interpretation of 515(c)(1)(F) (21 U.S.C. 360e(c)(1)(F)) in 21 CFR 814.20(b)(10) for premarket approval applications for medical devices.

[18] For more information on rotational warning statement requirements, see *https://www.fda.gov/tobacco-products/products-guidance-regulations/labeling-and-warning-statements-tobacco-products.*

§ 1114.7(f)(2) requires PMTAs to contain a discussion of several key high-level aspects of the applicant's plans to market the product. The discussion of these items will not require consumer research; however, be aware that § 1114.7(k)(1)(iv) requires applicants to submit reports of all information published or known to, or which should reasonably be known to, the applicant concerning investigations regarding the impact of the product and its label, labeling, and advertising, to the extent that advertising has been studied, on individuals' perception of the product and use intentions. This will include any consumer research that the applicant has undertaken or used to develop the aspects of its marketing plan identified in § 1114.7(f)(2).

(Comment 32) One comment stated that FDA should amend the marketing plan requirements in § 1114.7(f)(2) to include specific language about dual use because the reality is that most adult users of tobacco products become dual users.

(Response 32) We have edited § 1114.7(f)(2) to include polyuse as an example tobacco use behavior that descriptions of marketing plans may address in describing target audiences. FDA requires descriptions of marketing plans to inform our determination of whether the new product is appropriate for the protection of public health. As part of FDA's determination of the risks and benefits to the health of the population as a whole (which includes youth, young adults, and other vulnerable populations), FDA will consider the potential for long-term dual use among current users. FDA reviews the descriptions of marketing plans in conjunction with the other submitted information, which can include tobacco product perception and use intention studies and actual use studies to assess the likelihood that current users will switch completely to the new product or become a dual or polyuser of tobacco products. To the extent that the description of marketing plans contains information about the target audience by psychographic characteristics including tobacco use patterns, FDA will consider whether dual use is likely given the description of the marketing plans and the other submitted information.

(Comment 33) One commenter stated that the marketing plan requirements are outside of what the FD&C Act allows FDA to review as part of a PMTA. The commenter stated that the structure of the FD&C Act shows that Congress did not intend for FDA to review marketing plan information as part of a PMTA because where Congress found such information to be relevant to FDA's analysis, it expressly added such a requirement to the statute (*e.g.,* section 905(i)(1) of the FD&C Act). The commenter stated that in contrast, in section 910 of the FD&C Act Congress required that PMTAs must contain only ''specimens of the proposed labeling to be used for [the] tobacco product.'' The commenter concluded that the fact that Congress omitted a broader requirement for advertisements in section 910 of the FD&C Act but included the requirement for only ''specimens'' of labeling shows that Congress did not consider broader information relevant to FDA's evaluation of a PMTA. The commenter also states that FDA's claim of authority under section 910(b)(1)(G) is ineffective because it does not grant FDA the limitless authority to require content; rather, FDA only has the authority to require information under 910(b)(1)(G) of the FD&C Act that is reasonable and reasonably explained, which the commenter maintains that FDA has failed to do here.

(Response 33) As discussed in Response 30, FDA has revised § 1114.7(f)(2) to require only high-level marketing plan information that it generally expects applicants will have developed prior to seeking marketing authorization for their products. But even so, we disagree with the commenter's position that FDA lacks statutory authority to require marketing plans as part of a PMTA. In describing the required contents of a PMTA in section 910(b)(1)(G), Congress explicitly authorized FDA to require ''such other information relevant to the subject matter of the application.'' This provision demonstrates that Congress intended for FDA to apply its expertise with respect to review of scientific applications and the overall administration of the Tobacco Control Act to determine what additional information would be ''relevant'' to whether the application meets the requirements to receive marketing authorization.

We have determined that the description of marketing plans required by § 1114.7(f)(2) is relevant to the subject matter of a PMTA. To issue a marketing granted order for a new tobacco product, FDA must determine that permitting such tobacco product to be marketed would be APPH, which requires FDA to consider the likelihood that those who do not use tobacco products, including youth, will start using them. Determining the extent to which youth will be exposed to marketing materials for the product is critical to that consideration. As explained by Congress in enacting the Tobacco Control Act, tobacco advertising, marketing, and promotion substantially contribute to youth trial and uptake of tobacco use. See, *e.g.,* Tobacco Control Act section 2(5) (tobacco advertising and marketing contribute significantly to the use of tobacco products by adolescents.); *id.* section 2(15) (advertising, marketing and promotion of tobacco products have resulted in increased use of such products by youth.); *id.* section 2(20) (children are exposed to substantial and unavoidable tobacco advertising that increases the number of young people who begin to use tobacco); *id.* section 2(22) (tobacco advertising expands the size of the tobacco market by increasing consumption of tobacco products including tobacco use by young people). Congress enacted the Tobacco Control Act against the backdrop of years of litigation exposing previous tobacco product marketing campaigns in which companies successfully targeted and recruited new youth smokers. See, *e.g., United States* v. *Philip Morris USA, Inc.,* 449 F. Supp. 2d 1, 616 (D.D.C. 2006) (''As the following evidence demonstrates, Defendants have utilized the vast amount of research and tracking data they accumulated on youth smoking initiation, tastes and preferences by employing themes which resonate with youth in their marketing campaigns. Defendants have focused their attention on young people under the age of twenty-one in order to recruit replacement smokers and have emphasized the popularity, physical attractiveness, and 'coolness' of their youth brands. Above all, Defendants have burnished the image of their youth brands to convey rugged independence, rebelliousness, love of life, adventurousness, confidence, self-assurance, and belonging to the 'in' crowd.'' (internal citation omitted)), *aff'd in part, rev'd in part on other grounds,* 566 F.3d 1095 (D.C. Cir. 2009); see also 449 F. Supp. 2d at 616–39.

A well-established body of scientific evidence confirms the continuing impact of tobacco product marketing on initiation and use by individuals under the minimum age of sale. See, *e.g.,* Dep't of Health & Human Servs., *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* 170 (2016) (''An analysis of the 2011 National Youth Tobacco Survey found that adolescents who reported frequent exposure to protobacco advertising at the point of sale and on the internet (*e.g.,* seeing ads most of the time or always) had significantly higher odds of ever using e-cigarettes, and there was a dose-response association between the number of marketing channels to which

they were exposed and ever use[.]''); Dep't of Health & Human Servs., *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General* 598 (2012) (''[T]here is strong empirical evidence, along with the tobacco industry's own internal documents and trial testimony, as well as widely accepted principles of advertising and marketing that support the conclusion that tobacco manufacturers' advertising, marketing, and promotions recruit new users as youth and continue to reinforce use among young adults[.]''). Companies marketing newer forms of tobacco products have employed some of the same techniques, as well as newer innovations, to attract the youth market. For example, ENDS manufacturers have used social media, including influencers, to help create an image for their products as being cool and having sex appeal, sponsored music festivals, and created products with youth-appealing cartoon images (see, *e.g.,* Refs. 12 through 15).

The descriptions of marketing plans required by § 1114.7(f)(2)—including intended audience, how the applicant would target the intended audience and what other groups would foreseeably be exposed, and how exposure would be limited for individuals below the minimum age of sale (*e.g.,* avoiding online social media without access restrictions)—seeks information necessary for FDA to properly evaluate the extent of youth exposure to marketing materials for the product and youth access to the product. Accordingly, this information is directly relevant to the subject matter of a PMTA, including FDA's consideration of the likelihood that youth will use the tobacco product and its determination that permitting the product to be marketed would be APPH.

Because Congress clearly and unambiguously authorized FDA to require additional relevant information, that should be ''the end of [the] analysis.'' *Zuni Pub. Sch. Dist. No. 89* v. *Dep't of Educ.,* 550 U.S. 81, 93 (2007) (citing *Chevron, U.S.A., Inc.* v. *Natural Res. Def. Council, Inc.,* 467 U.S. 837 (1984)). But even if Congress has not ''directly'' addressed ''the precise question at issue,'' FDA's interpretation is a ''permissible construction of the statute,'' *Chevron,* 467 U.S. 837 at 843, on a matter where the Agency's expertise plays a significant role in resolving important questions related to the administration of the statute. *Barnhart* v. *Walton,* 535 U.S. 212, 222 (2002).

In determining to require the submission of descriptions of marketing plans as part of a PMTA, FDA considered the information it needed to be able to evaluate whether the statutory requirements for PMTA authorization are met, as well as the context and purpose of the PMTA requirement. As discussed above, a well-established body of historical and scientific evidence and Congress's own findings in enacting the Tobacco Control Act support FDA's reasonable conclusion that potential exposure to tobacco product advertising, marketing, and promotion is relevant to, and indeed a critical factor in, FDA's statutorily required determination of the likelihood that nonusers, including youth, will use a new tobacco product. Moreover, based on this evidence, as well as the expertise it has developed regarding tobacco product marketing over more than a decade of administering the Tobacco Control Act, FDA has rationally concluded that the required descriptions of marketing plans will directly inform its assessment of who may be exposed to the applicant's labeling, advertising, marketing, and promotion and, as a result, its consideration of the potential impact on youth initiation and use. FDA's assessment of who may be exposed to tobacco product marketing materials and activities will include individuals below the minimum age of sale, recently raised from 18 to 21 years. For example, information regarding how the applicant will target the intended audience, such as the marketing channels and tactics an applicant expects to use, will permit FDA to determine the extent to which youth would be exposed to and influenced by marketing for the product. (See, *e.g.,* Refs. 13, 16, and 17) As another example, a description of the ways in which an applicant would limit exposure to tobacco product marketing materials and activities for individuals below the minimum age of sale will inform FDA's assessment of the potential for youth exposure to these materials and activities.

Submission of descriptions of marketing plans also supports the Tobacco Control Act's mandate that FDA protect youth from the dangers of tobacco use. See, *e.g.,* Tobacco Control Act section 3(2), (7) (purposes of the Tobacco Control Act include to ensure that FDA has authority to address issues of particular concern to public health officials, especially the use of tobacco by young people, and to ensure that tobacco products are not sold or accessible to underage purchasers). In enacting the Tobacco Control Act and giving FDA this mandate, Congress recognized the substantial impact of exposure to tobacco product advertising, marketing, and promotion on youth tobacco use. See, *e.g.,* Tobacco Control Act section 2(15) (advertising, marketing and promotion of tobacco products have resulted in increased use of such products by youth.). Based on this context and the ample scientific evidence supporting the powerful impact of marketing on youth tobacco use, FDA reasonably concluded that determining the extent to which youth may be exposed to marketing materials for a new tobacco product is critical to its evaluation of the potential for youth to use the new tobacco product and to its ability to fulfill its mandate to protect youth from the dangers of tobacco use. To that end, the requirement for descriptions of marketing plans seeks information that directly informs FDA's assessment of the extent to which youth may be exposed to marketing materials for the new tobacco product, as well as information to help FDA determine whether any concerns about youth use of the product and the corresponding increases in health risks would be mitigated, such as information regarding the extent to which an applicant would restrict access to the tobacco product for individuals below the minimum age of sale.

Contrary to the comment, Congress's inclusion of an advertising requirement in non-PMTA-related sections of the FD&C Act, such as section 905(i)(1), and omission of the requirement in section 910(b)(1)(F) of the FD&C Act, does not demonstrate Congress's intent to exclude description of marketing plans from PMTAs. Congress's explicit authorization in 910(b)(1)(G) of the FD&C Act that FDA may require ''such other information relevant to the subject matter of the application'' defeats the commenter's inference by omission argument. See *Adirondack Med. Ctr.* v. *Sebelius,* 740 F.3d 692, 697 (D.C. Cir. 2014) (the ''*expressio unius* canon'' is a ''poor indicator of Congress' intent'' where there is a ''broad grant of authority'' to the Agency; instead, '' 'Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved' '' (quoting *Cheney R.R. Co.* v. *I.C.C.,* 902 F.2d 66, 68–69 (D.C. Cir. 1990)). Indeed, Congress did not ''omit'' an advertising requirement from section 910(b)(1) but rather left its inclusion to FDA's discretion and judgment. As explained above, FDA has reasonably exercised its discretion in construing section 910(b)(1)(G) of the FD&C Act to require descriptions of marketing plans based on the Tobacco Control Act's context and purpose, ample scientific evidence,

and the Agency's own expertise developed over a decade of administering the statute.

(Comment 34) The commenter also stated that the marketing plans requirement potentially limits speech, raising First Amendment concerns. The commenter stated that the requirement places more than an incidental burden on protected expression, and the government cannot show it directly advances a substantial government interest that is drawn narrowly to achieve that interest. In terms of the alleged burden, the commenter stated that the requirement would distract and deter manufacturers from the focused development and implementation of robust marketing plans—ultimately burdening the right of consumers to receive, and manufacturers to provide, information about products determined by FDA to be appropriate for the protection of the public health. Additionally, the commenter asserted that the requirement would significantly chill protected speech due to the threat that FDA might disclose information about applicants' marketing plans to TPSAC or the public and thereby compromise an applicant's competitive strategy.

The commenter also asserted that the proposed requirement for manufacturers to report ''total dollar amount(s) of media buys and marketing and promotional activities'' would have been particularly burdensome and lacked justification. It stated that there was no evidence in the record that reporting such information for truthful advertising and marketing of a product with a PMTA order would directly advance the government's interest. The commenter also asserted that FDA's proposed request for marketing plans would not yield meaningful information given the amount of time it could take for FDA to review an application, the evolving tobacco product landscape, and the likelihood that the applicant's marketing plans would change.

In arguing that the government has not justified these burdens, the commenter asserts that the marketing plans requirement is a content-based burden on speech in that it applies only to applicants who wish to engage in the marketing of tobacco products, and therefore the government's justification is subject to strict scrutiny under *Reed* v. *Town of Gilbert,* 135 S. Ct. 2218, 2226 (2015), or at least heightened scrutiny under *Sorrell* v. *IMS Health Inc.,* 564 U.S. 552 (2011). The commenter states that FDA's required marketing disclosures are not narrowly tailored nor do they directly advance a compelling government interest, so they cannot meet the higher standard for content-based restrictions.

(Response 34) As discussed in Response 30, FDA has revised § 1114.7(f)(2) to require only high-level marketing plan information that it generally expects applicants will have developed prior to seeking marketing authorization for their products. That noted, we do not agree that the requirement for descriptions of marketing plans raises First Amendment concerns for several reasons. First, we disagree that the requirement to submit descriptions of marketing plans burdens speech. Federal Agencies routinely require regulated industry to disclose information to the government. The FD&C Act contains several premarket authorization requirements, including for drugs and devices, which have existed for decades, and whose constitutionality is not seriously questioned. Indeed, in the proliferation of lawsuits challenging various aspects of the Tobacco Control Act, there have been few direct challenges to the PMTA requirements, and any related challenges have been resolved in the government's favor. See *Nicopure Labs., LLC* v. *FDA,* 266 F. Supp. 3d 360, 391–95, 409 (D.D.C. 2017) (upholding FDA's decision to apply PMTA requirements to deemed tobacco products as permissible under the Administrative Procedure Act, and upholding the statutory PMTA requirement under the Due Process clause of the Constitution), *aff'd on other grounds,* 944 F.3d 267 (D.C. Cir. 2019) (PMTA rulings were not appealed); see also, *e.g., Nicopure Labs.,* 944 F.3d at 284–90 (D.C. Cir. 2019) (rejecting First Amendment challenge to the Tobacco Control Act requirement that manufacturers obtain premarket review of MRTPs).

To the extent that the commenter contends that the requirement to provide a description of its marketing plans to FDA would impinge on an applicant's ability to market its tobacco products, FDA is not aware of any evidence to support that contention (and the commenter cites none). The comment's assertion that the requirement would distract and deter manufacturers from the focused development and implementation of robust marketing plans strains credulity given tobacco manufacturers' incentives to market their products and the significant resources tobacco product manufacturers commit to marketing their products each year. S*ee Edenfield* v. *Fane,* 507 U.S. 761, 766 (1993) (''A seller has a strong financial incentive to educate the market and stimulate demand for his product or service.''). The Federal Trade Commission reported that advertising and promotional expenditures by major cigarette manufacturers totaled $8.401 billion in 2018 (Ref. 18).

FDA has considered the comment's position regarding the proposed § 1114.7(f)(2) requirement that applicants provide ''total dollar amount(s) of media buys and marketing and promotional activities.'' FDA has revised § 1114.7(f)(2) to no longer require total dollar amounts of media buys and marketing and promotional activities. In addition, FDA has revised this section to require only high-level information that it expects applicants will generally have developed prior to seeking marketing authorization for their products. For example, revised § 1114.7(f)(2)(i) and (ii) require an applicant to provide a discussion of the intended audience for the marketing materials and activities for the tobacco product and how the applicant would target those marketing materials and activities to the intended audience. Based on its experience, FDA expects that an applicant will generally have considered its intended audience and how it will target its marketing materials and activities to that audience by the time it submits its PMTA. Discussion of these items will not require applicants to conduct consumer research; however, where an applicant has undertaken such research, such as conducting tobacco product perception and intention studies, it will be required to be included in the PMTA as set forth in § 1114.7(k)(1)(iii), where applicable. Applicants will be required to provide the descriptions of marketing plans identified in this section based on the plans they have developed as of the time of submitting their PMTA, and where an applicant has not developed plans relating to one or more items in § 1114.7(f)(2), they would be required to state that in their application.

The comment's concern that commercial speech would be chilled due to the perceived risk that FDA would disclose an applicant's description of its marketing plans to TPSAC or the public and thereby compromise confidential commercial information (CCI) in those marketing plans is unwarranted. FDA generally may not make information in an application publicly available to the extent that the information constitutes trade secrets or CCI. See 5 U.S.C. 552(b)(4); 18 U.S.C. 1905; 21 U.S.C. 387f(c); 21 CFR 20.61(c); *id.* § 1114.47(a) (FDA will determine the public availability of any part of a PMTA under this section and part 20 (21 CFR part 20)). The Tobacco Control Act does not require FDA to refer PMTAs (or any

information contained therein) to TPSAC, instead committing that decision to the Secretary's discretion. See 21 U.S.C. 387j(b)(2) (providing that the Secretary ''may'' refer PMTAs to TPSAC ''on the Secretary's own initiative; or . . . upon the request of an applicant''). If the Secretary finds it appropriate to consult the TPSAC on an issue that requires consideration of CCI contained in the description of marketing plans, FDA may share that information only with TPSAC members who are subject to the same restrictions with respect to disclosure of CCI as any other FDA employee. See 21 CFR 20.84; *id.* 21 CFR 14.86(a)(2). Additionally, if the Secretary refers a PMTA to TPSAC, § 1114.47(b)(4) of this rule provides that CCI contained in the application generally will not be available for public disclosure. FDA may close a portion of a TPSAC meeting to allow discussion of an applicant's CCI to take place without disclosing the CCI to the public. See 21 CFR 14.27(b)(3) (allowing portions of an advisory committee meeting to be closed if they concern the review of trade secrets and CCI).

FDA also disagrees with the commenter's assertion that FDA's requirement for marketing plans as originally proposed would not yield meaningful information given the amount of time it might take for FDA to review an application, the evolving tobacco product landscape, and the likelihood that the applicant's marketing plans would change. Because we have revised § 1114.7(f)(2) to require a discussion of high-level items, rather than the submission of details that are more subject to change (*e.g.,* media buys, dollar amount, specific tactics), we generally do not expect the information contained in the applicant's description of marketing plans to change significantly after the submission of the application. However, under § 1114.9, FDA may request, or an applicant may submit on its own initiative, an amendment to its PMTA containing information that is necessary for FDA to complete its review of the application, including information regarding any alterations or updates to the required description of marketing plans. As described in section VIII.C., so long as such an amendment does not require significant review time, it will not be considered a major amendment for which the review period will be extended by up to 180 days and even where such an amendment is major amendment, FDA anticipates it would generally take less than 180 days to complete review thereof.

Second, even if the requirements of § 1114.7(f)(2) restricted speech, they would readily pass muster under the intermediate scrutiny test for commercial speech articulated in *Central Hudson Gas & Elec. Corp.* v. *Pub. Serv. Comm'n,* 447 U.S. 557 (1980). Under that test, Agencies may regulate speech where the regulation advances a substantial government interest and the regulation is no more extensive than necessary to serve that interest.

It is well established that FDA has a substantial interest in protecting youth from tobacco products. See *Lorillard Tobacco Co.* v. *Reilly,* 533 U.S. 525, 564–66 (2001); see also *Discount Tobacco City & Lottery, Inc.* v. *United States,* 674 F.3d 509, 519–20, 541 (6th Cir. 2012). Youth are a significant population of concern for reasons that have been extensively documented in scientific research and in the Tobacco Control Act. For example, youth are especially susceptible to addiction due to their ongoing and incomplete brain development. See 2012 Surgeon General's Report. In addition, most tobacco use is established in adolescence and age of initiation plays a significant role in the progression from tobacco experimentation to regular use. See *id.; see also, e.g.,* Tobacco Control Act section 2(1) (''The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.''); *id.* section 2(4) (''Virtually all new users of tobacco products are under the minimum legal age to purchase such products.''). FDA has a statutory mandate to protect youth from these dangers of tobacco product use. See, *e.g.,* Tobacco Control Act section 3(2), (7) (purposes of the Tobacco Control Act include to ensure that FDA has authority to address issues of particular concern to public health officials, especially the use of tobacco by young people, and to ensure that (tobacco products) are not sold or accessible to underage purchasers).

The requirement for applications to contain descriptions of marketing plans clearly and directly advances FDA's substantial interest in protecting youth from the dangers of tobacco product use. As explained in section VIII.B.6.b, it is well established that exposure to tobacco product labeling, advertising, marketing, and promotion has a direct and powerful impact on youth trial and uptake of tobacco product use. See, *e.g.,* Tobacco Control Act section 2(5) (''Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.''); 2016 Surgeon General's Report at 170 (''An analysis of the 2011 National Youth Tobacco Survey found that adolescents who reported frequent exposure to protobacco advertising at the point of sale and on the internet (*e.g.,* seeing ads most of the time or always) had significantly higher odds of ever using e-cigarettes, and there was a dose-response association between the number of marketing channels to which they were exposed and ever use[.]''); 2012 Surgeon General's Report at 598 (''[T]here is strong empirical evidence, along with the tobacco industry's own internal documents and trial testimony, as well as widely accepted principles of advertising and marketing that support the conclusion that tobacco manufacturers' advertising, marketing, and promotions recruit new users as youth and continue to reinforce use among young adults[.]'').

Accordingly, determining the extent to which youth may be exposed to marketing materials for a new tobacco product is critical to FDA's evaluation of the potential for youth use of the new tobacco product. The requirement for descriptions of marketing plans seeks information that directly informs the extent to which youth may be exposed to these marketing materials, including information regarding the intended audience for the materials, how the applicant plans to target the materials to that audience and what other groups would foreseeably be exposed to those materials, and how the applicant plans to limit youth exposure to the materials. In addition, the requirement seeks information to help FDA determine whether any concerns about youth use of the product and the corresponding increases in health risks may be mitigated, such as information regarding how the applicant plans to limit youth access to the product. Moreover, the requirement for descriptions of marketing plans is no more extensive than necessary to permit FDA to make these determinations, as it requires minimal, high-level information that FDA expects an applicant to have at the time of submitting its application.

In addition, the requirement for descriptions of marketing plans clearly and directly advances FDA's substantial government interest in ensuring that permitting the marketing of new tobacco products would be APPH. Under section 910(c)(2)(4) of the FD&C Act, a key consideration of the APPH determination is whether permitting the marketing of the product would increase or decrease the likelihood that those who do not use tobacco products, including youth, will start using them. Among nonusers, youth are a significant population of concern for the reasons already explained above. Determining the extent to which youth would be

exposed to marketing materials for the product is therefore critical to FDA's evaluation of the likelihood that youth will initiate tobacco use with the new tobacco product. Accordingly, by providing FDA with certain high-level information necessary to help determine potential youth exposure to marketing materials for a new tobacco product, the requirement for descriptions of marketing plans directly advances and is reasonably tailored to FDA's substantial interest in ensuring that permitting the marketing of the new tobacco product is APPH.

Finally, we disagree with the commenter's assertion that § 1114.7(f)(2)'s disclosure requirements are subject to strict scrutiny under *Reed* v. *Town of Gilbert,* 135 S. Ct. 2218, 2226 (2015), or at least heightened scrutiny under *Sorrell* v. *IMS Health Inc.,* 564 U.S. 552 (2011). In *Reed* v. *Town of Gilbert,* the Court applied strict scrutiny to content-based restrictions on noncommercial speech in public fora. *Reed* had nothing to do with commercial speech doctrines, see 135 S. Ct. at 2224–25, and it has not been understood to alter the applicability of *Central Hudson.* Likewise, *Sorrell* ''did not mark a fundamental departure from *Central Hudson's* four-factor test, and *Central Hudson* continues to apply'' to regulations of commercial speech, regardless of whether they are content based. *Retail Digital Network, LLC* v. *Prieto,* 861 F.3d 839, 846 (9th Cir. 2017) (en banc); *accord Vugo, Inc.* v. *City of New York,* 931 F.3d 42, 50 (2d Cir. 2019), *cert. denied,* 140 S. Ct. 2717 (2020) (''No Court of Appeals has concluded that *Sorrell* overturned *Central Hudson.* We agree with our sister circuits that have held that *Sorrell* leaves the *Central Hudson* regime in place, and accordingly we assess the constitutionality of the City's ban under the *Central Hudson* standard.''); *Missouri Broad. Ass'n* v. *Lacy,* 846 F.3d 295, 300 n.5 (8th Cir. 2017) (''The upshot [of *Sorrell*] is that when a court determines commercial speech restrictions are content- or speaker-based, it should then assess their constitutionality under *Central Hudson.*'') (quotation marks omitted; alteration in original); *Nicopure Labs., LLC* v. *FDA,* 266 F. Supp. 3d 360, 411 (D.D.C. 2017) (''[T]he *Sorrell* opinion did not alter or replace the *Central Hudson* intermediate scrutiny standard to be applied to commercial speech.''), *aff'd,* 944 F.3d 267, 290 (D.C. Cir. 2019) (''*Sorrell*'s concerns about suppression of advertising messages in the marketplace of ideas are inapposite here.'').

(Comment 35) Multiple comments expressed concerns about the difficulty of creating marketing plans for the first year of product marketing given that the time it has taken FDA to review PMTAs to date has been unpredictable. Specifically, comments stated that the requirement for marketing plans in proposed § 1114.7(f)(2) did not take into account the considerable external variables that inform marketing plan decisions including competitor activities, FDA actions and State or Federal legislation. Comments noted that FDA's evaluation of the IQOS PMTA, for example, stretched over 2 years. The comments requested more flexibility in their marketing plans, including the potential to amend their plans during application review, to avoid being locked into outdated plans that do not account for the use of new technology or to allow for adjustment.

(Response 35) FDA has revised and narrowed the scope of § 1114.7(f)(2) to require an applicant's description of its marketing plans to discuss certain key, high-level aspects of its plans to market the product for the first year after receiving a marketing granted order. FDA notes that the applicant's description of its marketing plans does not by itself create rigid requirements regarding the way in which an applicant must market its new tobacco product; however, where an applicant proposes a specific restriction on its marketing of the new tobacco product to support an APPH finding as part of its description of its marketing plans (*e.g.,* avoiding online social media without access restrictions), FDA might incorporate such proposals into the restrictions on the sales and distribution of a new tobacco product in a marketing granted order as set forth in § 1114.31(b). Additionally, FDA will monitor an applicant's implementation of its marketing plans as described in the application to ensure the marketing of the new tobacco product continues to be APPH. Applicants are required to report information about the marketing of their product under § 1114.41(a)(1)(xi), and FDA may require submission of marketing plan changes in advance of implementation under § 1114.31(b)(3).

An applicant may alter or update its description of its marketing plans during the course of application review by submitting an amendment; however, as described in the response to comment 34, we generally do not expect an applicant's approach to the high-level items in § 1114.7(f)(2) to change significantly after the submission of an application. As described in section VIII.C., where such an amendment requires significant review time (*e.g.,* significant changes to the intended audience(s) and how the marketing material and tactics would be targeted thereto), it will be considered a major amendment for which the review period will be extended by up to 180 days; however, FDA will review such amendments promptly and generally expects review of such changes will require fewer than 180 days.

ii. Requirements for description of marketing plans. Section 1114.7(f)(2) requires a PMTA to contain a description of the applicant's plans to market the new tobacco product, for at least the first year the product would be marketed after receiving a marketing granted order, in a way that permits FDA to determine whether this information is consistent with the applicant's discussion of the increased or decreased likelihood of changes in tobacco product use behavior, including switching (*i.e.,* complete transition to a different tobacco product), initiation, cessation, and polyuse (*i.e.,* using the new tobacco product in conjunction with one or more other tobacco products), under § 1114.7(l), and whether permitting the new tobacco product to be marketed would be APPH. This section requires descriptions of actions to market the new tobacco product that would be taken by the applicant, on behalf of the applicant, or at the applicant's direction, and of any restrictions on the sales and distribution of the new tobacco product that the applicant is proposing to be included in the marketing granted order under section 910(c)(1)(B) of the FD&C Act. As set forth below, the description of an applicant's plans to market a product will contain information that is important to FDA's consideration of the likelihood of changes in tobacco product use behavior (including initiation and cessation) under section 910(c)(4) of the FD&C Act. The described changes in tobacco product use behavior, when considered as part of FDA's determination of the risks and benefits of the new tobacco product to the population as a whole under section 910(c)(4) of the FD&C Act, form part of the basis upon which FDA must make its finding of whether there is a showing that permitting the marketing of the new tobacco product would be APPH under section 910(c)(2)(A) of the FD&C Act. While the criteria for FDA to accept and file the application in § 1114.27 can be satisfied with only some discussion of the four items in § 1114.7(f)(2)(i) through (iv), FDA encourages applicants to provide more detailed information to help inform FDA's substantive APPH determination.

An understanding of how an applicant plans to market a new tobacco product for at least an initial period of time will help FDA determine the potential for increases in health risks related to marketing of the new tobacco product, such as the potential for youth initiation. If FDA determines that the potential increases in health risks outweigh the potential benefits, FDA would not be able to determine that the marketing of the new tobacco product would be APPH and would issue a marketing denial order.

Section 1114.7(f)(2)(i) requires a PMTA to contain a description of the specific group(s) to which the labeling, advertising, marketing, promotion, and other consumer-directed activities for the new tobacco product would be targeted (*i.e.,* the intended audience(s)). As used in § 1114.7(f)(2), the term ''other consumer-directed activities'' includes any other types of action regarding the new tobacco product taken by the applicant, on behalf of the applicant, or at the applicant's direction that may directly or indirectly impact information about the tobacco product that reaches consumers (*e.g.,* use of third parties or social media influencers to reach consumers). Additionally, the labeling, advertising, marketing, promotion, and other consumer-directed activities for a new tobacco product are collectively referred to as ''marketing materials and activities'' in this document for ease of reference. An applicant would need to provide the characteristics it has used to identify the specific group(s) to which its marketing materials and activities would be targeted, such as age-range(s) (including young adult audiences ages 21 to 24 years, if applicable) and other demographic characteristics, details of tobacco use behaviors (*e.g.,* dual use), and psychographic characteristics. Examples of other demographic characteristics include, but are not limited to, race, ethnicity, socioeconomic status and geographic location (*e.g.,* urban, rural). Such information will be informative to FDA in identifying potential impacts of marketing on specific populations, including vulnerable populations. Examples of types of psychographic characteristics include, but are not limited to, hobbies, interests, risk-taking behaviors, purchase behaviors, and online search behaviors. Based on our experience, FDA generally expects that applicants will have conducted or otherwise obtained market or consumer research to determine its intended audience(s). Where an applicant has conducted such research and has used the results to determine its intended audience, FDA recommends an applicant discuss such information in this section.

As a general example, the description of the intended audience(s) could include, for example, a statement that the applicant would target its marketing materials and activities for the new tobacco product to all current adult cigarette smokers, with a focus on cigarette smokers aged 26 to 54 years who are seeking alternatives to combustible cigarettes.

Section 1114.7(f)(2)(ii) requires the applicant's description of its marketing plans to contain a discussion of the ways in which the applicant would target its marketing materials and activities for the new tobacco product to reach the intended audience(s) described in paragraph (i) and what other group(s) would foreseeably be exposed to the marketing materials and activities as a result. A discussion of these aspects of the plans can provide information that is important to FDA's evaluation of the increased or decreased likelihood of changes in tobacco product use behavior under section 910(c)(4) of the FD&C Act. Describing how an applicant would target the marketing materials and activities for the new tobacco product to intended audiences could help FDA determine whether the applicant's descriptions of its marketing plans are consistent with information in the application regarding the likelihood of changes in tobacco product use behaviors, such as current tobacco product users switching to the new tobacco product.

A discussion of the ways in which the applicant would target the marketing materials and activities for a new tobacco product to reach the intended audience(s) can include items such as: how the applicant would use key insights about its intended audience(s) to tailor its marketing approach; the types and sources of data, technologies, and methodologies the applicant would use to develop, implement, and track targeted paid media plans (*e.g.,* first and second-party age-verified data, public records, industry-standard syndicated research services, and embedded tracking pixels in digital advertising); and the marketing channels and tactics an applicant expects to use.

Additionally, this information will help FDA determine whether the identified audiences and not other audiences, such as individuals below the minimum age of sale, would be exposed to the marketing materials and activities for the new tobacco product. Describing the other groups that would foreseeably be exposed to the marketing materials and activities for the new tobacco product will help FDA understand the potential for other groups to be affected by the plans to market the new tobacco product. For example, where an applicant's plans to target its marketing materials and activities to an intended audience of adult consumers has the potential to reach individuals below the minimum age of sale, an applicant would have to note that potential and describe whether the potential would be limited under paragraph (iii). FDA is requiring a discussion of an applicant's plans to target its marketing materials and activities to the intended audience(s) and the other groups that could foreseeably be exposed to those materials as a result of such targeting because, as discussed in the following paragraphs, there is a well-established body of scientific evidence regarding the effect of advertising and marketing on tobacco product behavior (see *e.g.,* Refs. 19–22).

Section 1114.7(f)(2)(iii) requires the applicant's description of its marketing plans to contain a discussion of the ways in which, for individuals below the minimum age of sale, access to the new tobacco product would be restricted and exposure to the marketing materials and activities for the new tobacco product would be limited. Describing the ways in which an applicant would restrict access to the new tobacco product by individuals below the minimum age of sale would be an important part of FDA's consideration under section 910(c)(4) of the FD&C Act regarding the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application. Limiting the potential for youth to access the new tobacco product is one way to help mitigate the potential for youth initiation with the new tobacco product (Refs. 23 and 24). For example, an applicant could propose to restrict the sale and distribution of its new tobacco product to adult-only facilities and limit the quantity of its product that an adult customer (other than scientific researchers or research institutions) may purchase within a given period of time to limit the potential for resale to youth.

Describing the ways in which an applicant would plan to limit the exposure of individuals below the minimum age of sale to the marketing materials and activities for the new tobacco product would also help FDA assess the potential for initiation with the new tobacco product by this group. Examples of how applicants could limit the exposure of individuals below the

minimum age of sale to the marketing materials and activities could include actions such as utilizing services that compare consumer information against independent, competent, and reliable data sources, such as public records, before granting users access to the applicant's tobacco product website(s), using only first- or second-party age-verified data to target paid digital advertising, and limiting sales to adult-only stores. Applicants could also restrict or avoid the use of marketing practices that are not or cannot be targeted in ways that would limit exposure of individuals below the minimum age of sale and choose tactics more narrowly targeted to current adult users of tobacco products, such as avoiding online social media without access restrictions to promote the tobacco product and, instead, choose actions such as paper or electronic mail directed only to current smokers at or above the minimum age of sale.

FDA is requiring the description of an applicant's plans to market the new tobacco product to contain a discussion of an applicant's plans to target the marketing materials and activities to reach the intended audience(s) and limit the exposure of individuals below the minimum age of sale to such materials and activities, because there is a well-established body of scientific evidence regarding their effect on tobacco product use behavior (see *e.g.,* Refs. 19–22). The impact of tobacco marketing tactics on youth and young adult tobacco use behavior in particular has been well documented. The 2012 Surgeon General's report entitled ''Preventing Tobacco Use Among Youth and Young Adults,'' (the 2012 SGR) synthesizes more than 30 years of research on the topic and outlines the findings demonstrating that product labeling, advertising, marketing, and promotion influence youth tobacco use by shaping attitudes, beliefs, and risk perceptions, and promoting pro-tobacco social and cultural norms (Ref. 9). The 2012 SGR states that the strong empirical evidence, along with the tobacco industry's own internal documents and trial testimony, as well as widely accepted principles of advertising and marketing, support the conclusion that tobacco manufacturers' advertising, marketing, and promotions recruit new users as youth and continue to reinforce use among young adults (Ref. 9). The 2012 SGR states that this evidence is sufficient to conclude that marketing efforts and promotion by tobacco companies show a consistent dose-response relationship in the initiation and progression of tobacco use among young people (Ref. 9). The 2012 SGR also states that research conducted by the tobacco industry consistently demonstrates that the brand imagery portrayed on packages is particularly influential during youth and young adulthood—the period in which smoking behavior and brand preferences develop. The 2016 Surgeon General's report entitled, ''E-Cigarette Use Among Youth and Young Adults,'' similarly synthesizes research on e-cigarettes and concluded that e-cigarette manufacturers used tactics similar to those used to market conventional cigarettes to youth and young adults (Ref. 15).

The National Cancer Institute (NCI) made a similar conclusion in its monograph, ''The Role of the Media in Promoting and Reducing Tobacco Use,'' that the total weight of evidence—from multiple types of studies, conducted by investigators from different disciplines, and using data from many countries—demonstrates a causal relationship between tobacco advertising and promotion and increased tobacco use (Ref. 20). As such, the direct role of tobacco product marketing and related activities in increasing tobacco use in the United States, especially among youth, and the high rates of youth-exposure to tobacco marketing due to its ubiquity, are two key rationales cited by NCI for restricting tobacco product marketing and related activities (Ref. 20). A variety of research has found that exposure to advertising is associated with susceptibility to use tobacco products and the actual use of tobacco products (see *e.g.,* Refs. 25–33). For example, research has found that the use of certain kinds of imagery, such as logos and cartoons, have an impact on youth tobacco initiation (see, *e.g.,* Refs. 34–36) and that a key tactic of tobacco companies seeking to attract and recruit youth users is to use advertising and marketing with aspirational imagery and themes known to resonate with younger audiences, such as independence, popularity, rebelliousness, attractiveness, and being cool (Ref. 9).

An analysis of the 2011 National Youth Tobacco Survey (NYTS) found that adolescents who reported frequent exposure to tobacco advertising at the point of sale and on the internet had significantly higher odds of ever using e-cigarettes and that there was a dose-response association between the number of marketing channels to which they were exposed and whether they used tobacco products (Refs. 15 and 33). An analysis of 2014 NYTS data assessing exposure to e-cigarette advertising in different channels (*i.e.,* internet, print, television and movies, retail stores) found that as the number of channels of e-cigarette marketing exposure increased, the likelihood of use and susceptibility also increased (Refs. 15, 37, and 38). Thus, providing information regarding the ways in which an applicant would target the marketing materials and activities for the new tobacco product to reach the intended audience(s) and limit the exposure of individuals below the minimum age of sale to such items can provide valuable insight into the potential that youth would initiate tobacco product use.

Finally, § 1114.7(f)(2)(iv) requires the description of an applicant's marketing plans to contain a concluding summary discussing how the applicant's plans for marketing the new tobacco product are consistent with the applicant's discussion regarding the increased or decreased likelihood of changes in tobacco product use behavior (including switching, initiation, cessation, and polyuse) under § 1114.7(l) and permits FDA to determine whether permitting the marketing of the new tobacco product would be APPH. This section requires an application to contain a discussion of how each of the items in § 1114.7(f)(2)(i) through (iii) are consistent with the applicant's discussion regarding the increased or decreased likelihood of changes in tobacco product use behavior by both current users and nonusers of tobacco products. This includes, but is not limited to: How the planned targeting of intended audience(s) is consistent with discussions regarding the likelihood of changes in tobacco product use behavior such as by current adult users, including switching, quitting, and polyuse; and how, for individuals below the minimum age of sale, restrictions on access to the new tobacco product and limitations on exposure to the marketing materials and activities for the new tobacco product are consistent with discussions regarding the likelihood of tobacco product use initiation, including among youth. For example, where an applicant expects current adult cigarette smokers to use its new tobacco product, the applicant would be required to explain its basis for concluding that its planned marketing is consistent with that expectation, such as providing an explanation of how the applicant determined its selected marketing channels and tactics would reasonably reach its intended users. Similarly, if an applicant claims its marketing plans would adequately prevent or reduce youth initiation, the applicant would be required to explain its basis for such a conclusion by

providing explanations of any measures or controls the applicant would use to restrict youth access to the product (*e.g.,* selling the product only in brick-mortar retail locations), using competent and reliable third-party services to verify the age and identity of product purchasers, implementing purchase quantity limits) and limit youth exposure to the product's marketing materials and activities (*e.g.,* restricting its marketing to channels and tactics where it is possible to target delivery of advertising to only age-verified adults).

An applicant can use this portion of the summary as an opportunity to help show the description of its marketing plans are consistent with its expectations for the potential initiation by current nonusers of tobacco products. For example, where conclusions drawn from tobacco product perception and use intention studies contained in a PMTA show the potential for current nonusers to initiate tobacco product use with the new tobacco product, an applicant could discuss how its plans to market the tobacco product, such as advertising at only point-of-sale locations for tobacco products or sending direct mail marketing to individuals of legal purchasing age who have opted-in to such communications, would mitigate the potential for initiation by nonusers and aligns with the applicant's discussion of such potential under § 1114.7(l).

In addition to the basic requirements of § 1114.7(f)(2), to help inform FDA's APPH determination, applicants may develop and submit more detailed plans to implement specific marketing campaigns. Not only would this provide an applicant the opportunity to further address any concerns about the potential for youth to initiate tobacco product use with the new tobacco product, it would be an opportunity for an applicant to more concretely show how it would target its marketing materials and activities to reach the intended audience(s).

The types of more detailed marketing plan information an applicant could develop and submit as part of a PMTA include materials such as strategic creative briefs, media and distribution channels, specific tactics, and the intended scope of each marketing activity (*e.g.,* information such as the expected reach and frequency of audience exposures to the marketing, and timing and duration of the marketing activities), and the information described in the items listed below. These details, if provided, should be provided as part of the appropriate discussion under § 1114.7(f)(2) (if applicable) and can include:

- A description of specific insights about the intended audience(s) (*e.g.,* findings from consumer research) that have informed the applicant's marketing plans, including its strategic approach, key messages and themes, creative direction, and potential tactics or marketing channels. This could include product-specific insights (*e.g.,* an audience's impressions of one product being just as harmful as another, preference of a certain brand), as well as other beliefs, interests, motivations, or behaviors that can be used to tailor an applicant's approach to marketing the product. This could also include information regarding where the intended audience(s) tends to consume marketing and advertising (*e.g.,* television programs the intended audience(s) watches, social media influencers the intended audience(s) follows, websites and retail locations the intended audience(s) frequents) that can be used to tailor an applicant's approach, select relevant marketing tactics, and use relevant marketing channels. The applicant should describe such insights in either paragraph (i) or (ii), as appropriate, and state the source of such data;
- plans to use owned, earned, shared, or paid media to create labeling for, advertise, market, or promote the tobacco product. While media categories overlap, owned media typically consists of a company's own media properties and content they control, such as the company's product-branded website or mobile application. Earned media typically consists of unpaid media publicity or coverage of a company's brand or product that the company did not commission or pay for, such as a news article about the product or an influencer talking about a company's product without compensation. Examples of plans to use earned media can include, but are not limited to, pitching articles to news outlets, using unsolicited consumer reviews or testimonials to promote the product, and inviting influencers or reporters to attend a product launch event. Shared media typically consists of social media properties, such as a company's social media accounts and content, including interactions with other social media users and their content, such as comments, ''likes,'' and responses to comments. Paid media typically consists of content that a company pays to place and promote in media properties it does not own, such as advertising appearing on television and radio, in and around retail stores, and in digital media, including content shared by a celebrity who a company pays to promote the tobacco product;
- plans to use (or not use) partners, influencers (*e.g.,* celebrities, cultural icons, individuals with substantial followers on social media), bloggers, or brand ambassadors to create labeling for, advertise, market, or promote the tobacco product;
- plans to conduct (or not conduct) consumer engagements, including events at which the tobacco product will be demonstrated; and
- plans to use public relations or other communications outreach to promote the tobacco product. Public relations could consist of actions such as using a public relations firm to promote the tobacco product. Other communications to promote the product could consist of actions such as direct mail to consumers.

7. Statement of Compliance With Part 25

A PMTA must contain an environmental assessment (EA) prepared in accordance with § 25.40 or a valid claim of a categorical exclusion, if applicable. Pursuant to § 25.15(a), all submissions requesting FDA action require the submission of either a claim of categorical exclusion or an EA. In accordance with § 25.40(a), an EA must include, at a minimum, brief discussions of: The need for the proposed action; alternatives to the proposed action as required by section 102(2)(E) of the National Environmental Policy Act of 1969 (NEPA); the environmental impacts of the proposed action and alternatives; the Agencies and persons consulted during the preparation of the EA; and the relevant environmental issues relating to the use and disposal of the tobacco product. Although applicants may wish to review the categorical exclusions specific to tobacco product applications at § 25.35, the only categorical exclusion currently available for a marketing order is for provisional SE reports that receive an SE order in the SE premarket pathway, not for PMTAs. If the applicant believes the action would qualify for an available categorical exclusion, the applicant must state under § 25.15(a) and (d) that the action qualifies for a categorical exclusion, cite to the claimed exclusion, and state that to the applicant's knowledge no extraordinary circumstances exist under § 25.21.

Failure to include an EA in a PMTA is grounds for FDA to refuse to accept an application and failure to include an adequate EA is sufficient grounds under § 25.15 for FDA to refuse to file the PMTA or refuse to issue a marketing

granted order. (See the discussion of §§ 1114.27 and 1114.29 in section IX.)

8. Summary

Section 1114.7(h) requires the application to contain a summary of the application contents in sufficient detail to provide FDA with an adequate understanding of the data and information in the application. FDA requires the summary under authority of sections 701(a) and 910(b)(1)(G) of the FD&C Act because it provides FDA with an understanding of the information contained in the PMTA and allows FDA to plan and conduct a more efficient review of the detailed technical information the summary describes. The summary also helps reviewers understand the product and the accompanying scientific data more quickly and allows applicants to highlight information they believe demonstrates their product should receive a marketing granted order.

The summary should discuss all aspects of the PMTA and synthesize the application in a well-structured, unified manner. The summary should serve as a briefing document that highlights the most important aspects of the application, with each section of the summary consisting of a brief explanation of information that the applicant believes contributes to a finding that permitting the marketing of the product would be APPH. The applicant must summarize the content included in the PMTA in a manner that describes the operation of the product, the health risks of the new tobacco product, the product's effect on tobacco use behavior of current users, the product's effect on tobacco use initiation by nonusers, and the product's effect on the population as a whole. The summary must describe the new tobacco product's potential effects on youth, young adults, and other relevant vulnerable populations. After reviewing comments on the proposed rule, FDA has added vulnerable populations to this requirement in the final rule to ensure the summary specifically accounts for those groups that may be disproportionately affected or more likely to use the new tobacco product. The summary must contain the following items, where applicable:

- A summary of the product formulation section of the application. This section should provide a high-level description of the product formulation section of the application, highlighting information such as key ingredients, constituent levels, and design aspects of the product. See the discussion of § 1114.7(i) in section VIII.B.9;
- a summary of the manufacturing section of the application. This section should provide an overview of the manufacturing section of the application, including activities at each facility, and highlight information such as major aspects of the manufacturing and controls, especially those that the applicant believes contribute to a finding that permitting the marketing of the product would be APPH (*e.g.,* an aspect of the manufacturing process that results in lower levels of HPHCs than other tobacco products in the same category). See the discussion of § 1114.7(j) in section VIII.B.12;
- a summary of the health risk investigations section of the application. This section should briefly describe and synthesize the findings of each investigation describing the following items, and explicitly identify areas in which there is a lack of information, if any:
  - The health risks of the tobacco product to both users and nonusers of the product (including youth, young adults, and other relevant vulnerable populations) and whether the tobacco product presents less health risk than other tobacco products, such as the risk of cancers (*e.g.,* lung, mouth, pancreatic), heart disease, stroke, or lung disease, compared to other categories of tobacco products and other tobacco products within the category, if known. See the discussion of § 1114.7(k)(1)(i) in section VIII.B.13.a.iii.;
  - The impact the product and its marketing will have on the likelihood of changes in tobacco use behavior of tobacco product users (including youth, young adults, and other relevant vulnerable populations), including cessation, switching (*i.e.,* to a different tobacco product), and polyuse (*i.e.,* using the new tobacco product in conjunction with one or more other tobacco products). See the discussion of § 1114.7(k)(1)(ii) in section VIII.B.13.a.iv.;
  - the impact the product and its marketing will have on the likelihood of tobacco use initiation by tobacco products nonusers, especially youth, young adults, and other relevant vulnerable populations, including among never users and former users, and the likelihood of polyuse and switching behaviors. See the discussion of § 1114.7(k)(1)(iii) in section VIII.B.13.a.v.;
  - How users and nonusers perceive the risk of the tobacco product based upon label, labeling, and advertising (if any has been studied). This includes how the label, labeling, and advertising affect use intentions. See the discussion of § 1114.7(k)(1)(iv) in section VIII.B.13.a.vi.;
  - whether users are able to understand the labeling and instructions for use, and use the product in accordance with those instructions. See the discussion of § 1114.7(k)(1)(iv) in section VIII.B.13.a.vi.; and
  - the impact of human factors on the health risks to product users and nonusers including, for example, how various use and misuse scenarios may impact the health risks posed by the product. See the discussion of § 1114.7(k)(1)(v)) in section VIII.B.13.a.vii..

The rule also requires the summary to contain a concluding discussion demonstrating how the data and information contained in the PMTA both constitute valid scientific evidence and establish that permitting the marketing of the new tobacco product would be APPH as determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product. The rule also requires the summary to identify any key or pivotal studies on which an applicant is relying to establish that permitting the marketing of the new tobacco product would be APPH. FDA recommends that this discussion include estimates of the effect that the new tobacco product may have on the health of the population as a whole, such as effects on tobacco use initiation switching and cessation, and reductions in premature mortality, or increases in life-years lived. The estimates should integrate all of the information in the PMTA regarding the product and its potential effects on health, including, but not limited to adverse experiences, tobacco use behavior, and tobacco use initiation to provide an overall assessment of the potential effect that permitting the product to be marketed has or may have on overall tobacco-related morbidity and mortality.

As an illustration, an applicant may make an overall assessment of whether the product will likely have a net benefit on population health by accounting for potential reductions in disease risk (compared to other tobacco products) and the potential for current tobacco users to switch to the new tobacco product, and weighing that against the potential for nontobacco users to use the tobacco product and the accompanying potential increases in disease risks among those new tobacco product users. An applicant should provide quantitative assessments in the concluding discussion wherever possible; however, an applicant may provide qualitative assessments where

appropriate for the type of investigation(s) on which the assessment is based (*e.g.,* focus group or interview-type studies).

The summary's concluding discussion must also briefly describe why the data and scientific information on which the applicant relies in concluding that permitting the marketing of the product would be APPH constitute valid scientific evidence. Section 910(c)(5)(A) of the FD&C Act requires FDA to make its determination of whether permitting the marketing of a new tobacco product would be APPH, where appropriate, on the basis of well-controlled investigations; however, under section 910(c)(5)(B) of the FD&C Act, where FDA determines that there exists valid scientific evidence other than well-controlled investigations that is sufficient to evaluate the product, FDA may use such evidence. As discussed in more detail in section IX.D regarding § 1114.31, FDA considers valid scientific evidence to be evidence gathered using well-established or standardized methodologies from which it can be concluded by qualified experts that there is reasonable assurance of the reliability of its findings. Thus, if an application contains information regarding another tobacco product (*e.g.,* published literature, marketing information) with appropriate bridging studies and describes the relationship to the product that is the subject of the application, FDA will review that information to determine whether it is valid scientific evidence sufficient to demonstrate that permitting the marketing of a product would be APPH.

9. Product Formulation

Section 910(b)(1)(B) of the FD&C Act requires that a PMTA contain a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product. Section 1114.7(i) implements FDA's interpretation of this statutory requirement, together with its authority under section 910(b)(1)(G) of the FD&C Act, by requiring a PMTA to contain the following information:

a. Components or parts, materials, ingredients, additives, and constituents. Under the rule, the application is required to contain a full statement (*i.e.,* a listing) of the product components or parts, materials, ingredients other than tobacco, tobacco ingredients, HPHCs, and the container closure system.

i. Components or parts. Section 1114.7(i)(1)(i) requires the application to state the quantity, function, and purpose of, and where applicable, target specifications of each component or part in the product. This information should also include an explanation of how each component or part is, or can be, integrated into the product design, and the purpose and function of each component or part. Where the tobacco product contains software components, the rule requires:

- A description of the software or technology (*e.g.,* Bluetooth);
- a description of the purpose of the software or technology, such as monitoring where the tobacco product is located, activated, or used;
- a description of the data collected by the software and how this information will be used by the applicant.

FDA received comments regarding this section, as discussed below.

(Comment 36) One comment stated that the rule should be amended to state that FDA will issue a marketing denial order if the application does not include specific assurances and evidence that there will be no communication between the device and any external source, and that the software would not be programmed to increase consumption.

(Response 36) We agree that understanding how any software in a product may function is important to the review of an application. For example, software used in or with some consumer products may have functions and purposes that are not immediately clear, such as use monitoring and location tracking functions, and may be able to function in conjunction with other electronic devices, such as a smart phone. We decline to prohibit all communication between a new tobacco product and external sources as part of this rulemaking because product standards are outside the scope of this rulemaking; however, we will consider information regarding software (if applicable) as part of substantive review. For example, if the product has software features that could help prevent youth use of the tobacco product, FDA would review this information as part of the determination of whether permitting the marketing of the new tobacco product would be APPH. This information is especially important as it may not be readily apparent from a component or part's identity what function and purpose it may serve.

(Comment 37) One comment stated that FDA should amend § 1114.7(i)(3)(ii) to also require specification of software or other controls in an e-cigarette to limit the intensity of use, including minimum inter-puff interval and maximum number of puffs per hour that the device will deliver because, unlike with combusted cigarettes, there are no obvious indicators for consumers of how quickly they are consuming the product.

(Response 37) As discussed in section VIII.B.10., FDA requires the PMTA to contain a full narrative description of the way in which a typical consumer will use the new tobacco product. This includes, for example, a description of how a consumer operates the product, where applicable, whether and how a consumer can change the product design and add or subtract ingredients, the length of time it takes for a user to consume a single unit of the product, and whether the product incorporates a heating source and, if it does, a description of the heating source. As described above, the presence of software or other controls in an e-cigarette to limit the intensity of use would be relevant to FDA's review of an application and a required part of a PMTA submission under § 1114.7.(i)(1)(i); however, FDA declines to require such controls in all e-cigarettes as part of this rule because it would constitute a product standard that is outside the scope of this rule.

ii. Materials. Section 1114.7(i)(1)(ii) requires the application to contain information for each material in the product because materials can affect the performance of the product. FDA considers materials to be part of ''components'' under section 910(b)(1)(B) and the required materials information is relevant to the subject matter of a PMTA under section 910(b)(1)(G) because it is needed to fully characterize the tobacco product and understand its health risks. For example, in portioned smokeless tobacco products, the materials used in the pouch can affect the rate at which nicotine is released and specifications such as pouch fabric air permeability can provide information about how quickly nicotine can be delivered to the consumer. For ENDS, the material used in the construction of an electrical heater coil influences its resistance and the temperature reached by the coil, which in turn may affect the type and amount of HPHCs produced in aerosol. The rule requires a PMTA to contain:

- The material name and common name (if applicable);
- the component or part of the tobacco product where the material is located;
- the subcomponent or subpart where the material is located (if applicable);
- the function of the material;
- quantities (including ranges or means and acceptance limits) of the materials(s) in the new tobacco product;

• specifications (including quality, grades, and suppliers) of the materials used for the new tobacco product (including any specification variations, if applicable); and

• any other material properties that fully characterize the new tobacco product, such as pouch material porosity or air permeability for portioned smokeless products. While failure to include additional material properties to fully characterize the tobacco product would not serve as the basis for FDA refusing to accept or file an application under § 1114.27(a)(1), it may slow down the substantive review process.

FDA received comments regarding this section, as described below.

(Comment 38) One comment requested that FDA clarify the scope of the materials that an applicant would have to describe in a PMTA, specifically requesting that FDA require PMTAs for e-cigarettes to contain information on only those materials that are reasonably expected to have contact with the e-liquid and not materials found in items such as the exterior plastic casing, electronic circuitry, and batteries. The comment stated that this would align with FDA's current approach set forth in the guidance entitled ''Listing of Ingredients in Tobacco Products.'' [19]

(Response 38) FDA declines to limit the scope of the materials in an ENDS for which an applicant would have to provide information in a PMTA to only those materials that are reasonably expected to have contact with the e-liquid. As discussed in section § 1114.3, FDA defines material to mean an assembly of ingredients. Materials are assembled to form the tobacco product, or components or parts of the tobacco product. This includes both those materials that are in contact with the e-liquid as well as any other materials in the product, such as those used in the exterior plastic casing, electronic circuitry, and batteries. FDA declines to limit the scope of materials for ENDS because they are components or parts with the potential to introduce, diffuse, leach or extract to become part of the e-liquid formulation or constituents during storage and use. For example, batteries and solder joints of the product have been shown to be the potential source of metals contamination in e-liquid or aerosol (Ref. 39). Furthermore, defective or damaged batteries on their own may lead to battery failure or overheating, resulting in thermal runaway; thermal runaway has been identified as an immediate threat in e-cigarettes, particularly due to the metal enclosure of the e-cigarette batteries that allow the dangerous build-up of gasses (Ref. 40). In addition, the guidance for industry, entitled ''Listing of Ingredients in Tobacco Products,'' discusses FDA's current enforcement policy for ingredient listing submission requirements under section 904(a)(1) of the FD&C Act. While FDA does not intend to enforce ingredient listing requirements for component and parts such as electrical components, batteries, and electronic circuitry, FDA recognizes that the ingredients of these other components and parts can also be important in determining the public health impact of tobacco products. As the guidance states, FDA will receive ingredient information for these other components and parts during our premarket review of new tobacco products. This is consistent with the rule's requirement to include information on materials in a PMTA.

iii. Ingredients other than tobacco. Section 1114.7(i)(1)(iii) requires that the application contain information on ingredients other than tobacco (tobacco ingredients are addressed in § 1114.7(i)(1)(iv)). The application must contain:

• International Union of Pure and Applied Chemistry (IUPAC) chemical name and common name (if applicable);

• Chemical Abstracts Service (CAS) number or FDA Unique Ingredients Identifier (UNII). Both the IUPAC and CAS or UNII are required to ensure FDA has the relevant information associated with each identifier and to allow FDA to efficiently differentiate between similar ingredients;

• the function of the ingredient;

• the quantity of the ingredient in the tobacco product, with the unit of measure (including ranges or means, and acceptance limits) reported as mass per gram of tobacco for nonportioned tobacco products and as mass per portion for portioned tobacco products (with any specification variation, if applicable);

• the specifications (including purity or grade and supplier); and

• for complex purchased ingredients, each single chemical substance reported separately.

Additionally, FDA recommends that an application contain any other ingredient information to fully characterize the new tobacco product, as applicable. While failure to include other ingredient information to fully characterize the tobacco product would not serve as the basis for FDA refusing to accept or file an application under § 1114.27(a)(1), it may slow down the substantive review process.

iv. Tobacco ingredients. Section 1114.7(i)(1)(iv) requires information regarding tobacco ingredients, including:

• The type(s) of tobacco (*e.g.,* Bright, Burley, reconstituted). This information is important to determining the public health impact of the products because different types of tobacco have different constituent profiles. In the proposed rule, we also included a requirement to specify the grade(s) of the tobacco and we have removed this due to the general lack of standardized grading systems.

• the quantity, with the unit of measure (including ranges or means, and acceptance limits), of each tobacco ingredient in the new tobacco product reported as mass per gram of tobacco for nonportioned tobacco products and as mass per portion for portioned tobacco products (with any specification variation, if applicable);

• the specification(s) of tobacco used for the new tobacco product (with any specification variation, if applicable); and

• a description of any genetic engineering that impacts characteristics of the tobacco product, such as the constituent profile.

Additionally, FDA recommends a PMTA contain any other information about tobacco ingredients to fully characterize the new tobacco product, as applicable, such as country of origin, which can reflect different constituent levels (Ref. 41). While failure to include other information about tobacco ingredients to fully characterize the tobacco product would not serve as the basis for FDA refusing to accept or file an application under § 1114.27(a)(1), it may slow down the substantive review process. If the new tobacco product does not contain tobacco (*e.g.,* rolling paper or tipping paper), this section of the application must specifically state that the product does not contain tobacco.

FDA requires in § 1114.7(i)(1) that ingredient quantities be reported as mass per gram of tobacco for nonportioned tobacco products and as mass per portion for portioned tobacco products. These specific measurements provide consistent, complete information that allows FDA to understand the ingredient quantities. In contrast, if ingredient quantities were reported as percentages, FDA would have to make assumptions about the denominator used to calculate the percentage. For example, if xylitol were reported as 10 percent of a portioned moist snuff, FDA would not able to determine if xylitol was 10 percent of the mass of the tobacco filler or of the entire product (containing filler, paper, etc.). For more information on uniquely

[19] Available at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

identifying components, ingredients, and additives and reporting their quantities, please refer to FDA's guidance for industry entitled ''Listing of Ingredients in Tobacco Products.''

v. Constituents. Section 1114.7(i)(1)(v) requires a full statement of the constituents, including HPHCs and other constituents, contained within, or emitted from (including its smoke or aerosol), the product, including any reaction products from leaching or aging. FDA considers constituents to be properties of the new tobacco product, a full statement of which is required to be in a PMTA by section 910(b)(1)(B) of the FD&C Act. The constituents contained within, and delivered from, the product can be detected through constituent testing on the product. The constituent testing should reflect the various conditions under which consumers may use the product (*e.g.,* light use, typical use, and heavy use) and the types of products that consumers are likely to use in conjunction with the product. For example, an open (refillable) e-cigarette should be tested with a variety of e-liquids that consumers are likely to consume using the e-cigarette. The reports of constituent testing must be conducted in the manner required by, and include all information that is specified in, § 1114.7(i)(1)(v), including the full test data.

FDA published an initial list of the constituents that it has identified as HPHCs in the **Federal Register** of April 3, 2012, which it intends to update periodically by providing the public with notice and the opportunity to submit comments. FDA recently proposed the addition of 19 constituents to the established list of HPHCs.[20]

The constituent testing data FDA requires for all products include:

- The constituent names in alphabetical order;
- the common name(s);
- the CAS number;
- the mean quantity and variance with unit of measure;
- the number of samples and measurement replicates for each sample. As stated in § 1114.7(i)(4)(iv), the testing must be conducted using a sufficient sample size and number of replicates to substantiate the results of the type of testing conducted;
- a description of method procedure, method validation information, and rationale for selecting each test method (as required by § 1114.7(i)(4)(v));
- the name and location of the testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization (as required by § 1114.7(i)(4)(i));
- the length of time between dates of manufacture and date(s) of testing (as required by § 1114.7(i)(4)(ii));
- storage conditions of the tobacco product before it was tested. It is important for FDA to understand the storage conditions before testing because they could affect the quantity of volatile organic compounds or promote microbial growth in the tobacco product (as required by § 1114.7(i)(4)(iii));
- reports of constituent testing that include test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria, line data, and a summary of the results, for each applicable parameter (as required by § 1114.7(i)(4)(vi)); and
- complete descriptions of any smoking or aerosol generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable (as required by § 1114.7(i)(4)(vii)).

Multiple comments provided feedback or requested clarification related to these provisions, as discussed below.

(Comment 39) One comment requested additional clarification regarding the HPHCs for which an applicant must conduct testing when submitting a PMTA for an ENDS. The comment noted the proposed addition of 19 constituents to the established list of HPHCs and sought further information regarding what must be submitted in a PMTA.

(Response 39) The rule requires each applicant to submit information regarding all constituents contained in and emitted from the product, which could include both constituents that are contained within the established list of HPHCs and those that are not on the list. FDA's recommendations regarding constituents in an ENDS for which a prospective applicant might want to consider testing, as appropriate for its specific product, are discussed elsewhere in this document (see Response 35).

(Comment 40) One comment stated that while consideration of the constituents on FDA's list of HPHCs is important, FDA should not give it undue emphasis because there are other toxins in tobacco products that are not on this list. The comment stated an application's exposure assessment should cover the full range of exposures generated by the new product and that FDA should revise the rule to clearly state that evidence of biological and clinical effects of the product will be given more weight than measures of exposure.

Another comment stated that the definitions of the terms ''constituent'' and ''HPHC'' are so broad that the requirement in § 1114.7(i)(1)(v) to report all constituents contained within or emitted from the product could be difficult for applicants. The comment stated that there are practical constraints on the number, capacity, and capability of laboratories equipped to conduct the testing. The comment also expressed concern that FDA could potentially refuse to file an application in which an applicant omitted a constituent. The comment suggested that FDA revise the rule so that an application would be required to contain only information for ''relevant'' constituents and HPHCs, rather than all constituents. Specifically, the comment recommended that the inclusion of constituent and HPHC information should be based on a comprehensive risk assessment of the particular product.

(Response 40) FDA declines to make revisions in response to these comments. An application is not required to contain testing for all HPHCs on the initial list; rather, it must contain testing for HPHCs that are contained within and can be delivered by the type of product and contain a description of why the HPHCs that were tested are appropriate for the type of product. FDA declines to limit the scope of the constituents that must be reported in a PMTA to only those that an applicant considers to be relevant because it may impair FDA's ability to determine the health risks of a new tobacco product. As discussed in the rule, the constituents contained within and delivered from a tobacco product directly relate to its health risks. The HPHC list can be helpful to applicants in preparing a description of why the HPHCs for which it tested are appropriate for the product type, including, where appropriate, why an applicant did not test for certain HPHCs. For example, a PMTA for a smokeless tobacco product would not be required to contain testing results for HPHCs that are a byproduct of combustion (*e.g.,* carbon monoxide) where the product does not contain or deliver such constituents. However, a PMTA for an inhaled tobacco product that an applicant claims aerosolizes a substance but does not combust it, such as an e-cigarette or heated tobacco product, should provide evidence, such as testing for HPHCs that result from complete or incomplete combustion, to demonstrate that the product is not combusted. For recommendations on constituent testing

[20] 84 FR 38032 (August 5, 2019).

for ENDS products, please see the ENDS PMTA Guidance.

Additionally, FDA declines to revise the rule to assign weight to different types of evidence. Finding that there is a showing that permitting the marketing of a new tobacco product would be APPH is a complex determination that must be made with respect to risks and benefits to the population as a whole, considering the likelihood of changes in tobacco product use behavior (including initiation and cessation) caused by the marketing of the new tobacco product. When determining whether the marketing of a particular new tobacco product would be APPH, FDA will evaluate the factors in light of available information regarding the existing tobacco product market, tobacco use behaviors, and the associated health risks at the time of review.

(Comment 41) One comment requested FDA provide greater detail regarding the ranges of constituents that would be acceptable in a PMTA.

(Response 41) FDA does not set limits for what constitutes acceptable ranges for constituents as a part of this rulemaking. FDA's APPH determination will include a consideration of constituent levels and their resulting health risks; however, FDA must also consider of a variety of information related to health risk and tobacco product use behaviors. FDA recommends that applicants take all the necessary steps in controlling and mitigating any circumstances that may affect the constituent yields generated from a new tobacco product as this may impact the risks and benefits associated with the new tobacco product on the population health as a whole, when compared to other products on the market.

(Comment 42) One comment stated the final rule must provide greater detail regarding the appropriate validated methodologies or regimens required for testing.

(Response 42) As discussed in § 1114.7(i)(1)(v), for combusted or inhaled tobacco products, constituent smoke or aerosol yields from the new product must be determined using intense and nonintense smoking or aerosol-generating regimens, where established. Two smoking or aerosol-generating regimens are required, where established, to understand the way that constituent yields delivered by a tobacco product can change over a range of different smoking conditions. If constituent yields were only reported from a single smoking or aerosol-generating regimen, FDA would have limited and potentially misleading information about constituent yields produced by a given tobacco product. Many studies demonstrate that different smoking regimens result in different constituent yields from the same product (Refs. 42 and 43). By requiring both an intense and a nonintense smoking or aerosol generating regimen, where established, FDA will have a better understanding of quantities of each constituent that may be produced by the tobacco product when used under different conditions. If no intense and nonintense smoking or aerosol-generating regimens (*e.g.,* International Organization for Standardization (ISO) and Health Canada Intense (HCI) regimens for cigarettes, Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) regimens for cigars) have been established and an applicant must use an alternative regimen, an applicant should provide an explanation as to why the alternative regimen provides comparable results. For ENDS products, for example, where intense and nonintense regimens may have not been established, the application must contain an explanation of why the alternative regimen provides comparable results to the intense and nonintense regimens.

(Comment 43) One comment stated that manufacturers of premium cigars should not be required to submit information regarding HPHCs and other constituents. The comment stated that not only is there a lack of testing standards, the variability inherent in premium cigars would render the results of any constituent testing worthless for assessing a product.

(Response 43) As stated in § 1114.1(d) and described in section VII.A., this rule does not apply to ''premium'' cigars. To the extent this comment is applicable to products other than ''premium'' cigars, such as large cigars that do not meet the definition of ''premium'' cigar, FDA disagrees with this comment. Each applicant that submits a PMTA is required by § 1114.7(i)(1)(v) to conduct constituent testing and submit the results as part of their application. Understanding the constituents contained within and emitted from a tobacco product is a crucial component of being able to determine its health effects, which is why FDA will refuse to accept a PMTA (under § 1114.27(a)(1)), as appropriate, where it lacks constituent testing information required by § 1114.7(i)(1)(v). Where a product's ingredients have natural variability that could affect constituent testing results, FDA recommends an applicant submit scientific evidence justifying why the results reflect the natural variability of the ingredients in the new tobacco product. This evidence could include items such as scientific literature establishing the variability of the product, information related to international or national testing standards, or data from an investigation with sufficient sample size to demonstrate attributes affecting variability of the test results (*e.g.,* weight, smoke efficiency, crop year to crop year, region to region). Additionally, CORESTA [21] have established and published methods on how to generate cigar smoke to quantitatively compare HPHCs found in cigar smoke.

vi. Container closure system. Section 1114.7(i)(1)(vi) requires that the application contain a description of the container closure system for the new tobacco product, if applicable, including information describing how the container closure system protects and preserves the product from damage during transport, environmental contaminants, and leaching and migration of constituents into the new tobacco product. The description must also contain information describing design features developed to prevent the risk of accidental exposure, if any (*e.g.,* child resistant packaging for e-liquids). These descriptions are important to FDA's review of the product because they help demonstrate that the product used by consumers is in the same condition as that described in the application and manufactured by the applicant and provide information regarding whether the container closure system has any features that could prevent accidental exposure.

Additionally, evidence demonstrates that the container closure system used can change the characteristics of the product. For example, substances within the packaging materials can affect product moisture (*e.g.,* when the manufacturer changes the container closure system of a moist snuff from plastic to fiberboard), which can affect microbial stability and TSNA formation during storage (Ref. 44). Another example is when menthol or other

[21] CORESTA standards that applicants might consider include CORESTA Reference Method (CRM) 46: Atmosphere for Conditioning and Testing Cigars of all Sizes and Shapes; CRM 47: Cigars—Sampling; CRM 64: Routine Analytical Cigar-Smoking Machine—Specifications, Definitions and Standard Conditions; CRM 65: Determination of Total and Nicotine-Free Dry Particulate Matter using a Routine Analytical Cigar-Smoking Machine—Determination of Total Particulate Matter and Preparation for Water and Nicotine Measurements; CRM 66: Determination of Nicotine in the Mainstream Smoke of Cigars by Gas Chromatographic Analysis; CRM 67: Determination of Water in the Mainstream Smoke of Cigars by Gas Chromatographic Analysis; CRM 68: Determination of Carbon Monoxide in the Mainstream Smoke of Cigars by Non-Dispersive Infrared Analysis.

ingredients are applied to the inner foil of a cigarette package to become incorporated into the consumed product (Ref. 1). The container closure system may also be intended or reasonably expected to affect the characteristics of a tobacco product by impacting the rate of leaching into, and ultimately, the amount of substances found in, the consumable tobacco product. In fact, it has been demonstrated that compounds in the container closure system may diffuse into snuff and affect its characteristics (Ref. 2). Thus, for example, packaging material that affects the characteristics of a tobacco product by impacting the moisture level or shelf life of a tobacco product is a container closure system (*e.g.,* a plastic container compared to a metal container of smokeless tobacco) because a difference in tobacco moisture is reasonably expected to affect microbial growth in the product, extraction efficiency, and total exposure to nicotine or the carcinogens NNN or NNK. For additional examples of container closure systems, see the ENDS PMTA Guidance.

vii. Statement of tobacco blending, reconstitution, and manipulation. Finally, the rule requires a PMTA to contain a full statement of the tobacco blending, reconstitution, or manipulation, where applicable. This may include manufacturer specifications, and tobacco types, and quantities. This information is important because it helps FDA understand the characteristics of the tobacco product. Information on tobacco types and quantities used by an applicant (where applicable) will help FDA understand the composition of tobacco used, which can provide important information since the tobacco types and quantities may impact the tobacco chemistry (*e.g.,* the nicotine content) and, thereby, the chemical composition of the tobacco product (Ref. 45).

b. Other properties. Section 1114.7(i)(2) describes additional parts of FDA's interpretation of the requirement in section 910(b)(1)(B) of the FD&C Act to provide a full statement of the product properties and, together with FDA's authority under section 910(b)(1)(G), requires the applicant to provide a full description of the properties of the tobacco product that includes:

i. Product dimensions and construction. The product dimensions and the overall construction of the product using a diagram or schematic drawing that clearly depicts the finished product and its components with dimensions, operating parameters, and materials. Under the definition of finished tobacco product (which includes all components and parts, sealed in final packaging), the dimensions and schematic drawings are required to include the final packaging. The diagram or schematic is an annotated graphical representation that will help FDA understand the applicant's nomenclature, how the components and parts function together, and the overall principles of operation of the finished tobacco product.

ii. Design parameters and test data. All design parameters of the product and test data, specifying nominal values or the explicit range of values as well as the design tolerance (*i.e.,* upper and lower range limits), where appropriate. Changes in design parameters can change the health impact of the tobacco product by affecting the level of constituents that reach the user or nonuser and are also necessary to fully characterize a tobacco product. Given the potential health impacts associated with changes in design parameters as well as the importance of design parameters in fully characterizing a product, the PMTA review process does not simply note or link these parameters to the product and any associated constituents. Instead, during PMTA review, FDA evaluates how products are manufactured, and the controls put in place during production. For the PMTA pathway, FDA reviews whether each design parameter meets its specification through test data, determining whether each parameter is adequately controlled via documented processes, determining whether safeguards are in place against hazards and foreseeable misuse, and assessing how the applicant deals with nonconforming products. FDA believes it is necessary to review sufficient information to ensure that products marketed under the PMTA pathway have the necessary manufacturing and control processes in place. Tables 1 through 22 in § 1114.7(i)(2)(ii)(B) provide the parameters that are required for different categories of tobacco products. As part of the full description of the properties of the tobacco product, the rule also requires, as included in the tables, a quantitative description of the performance criteria, including test protocols, test data, and a summary of the results, for each applicable design parameter and manufacturing step. The test data is a required part of the PMTA to demonstrate the product consistently meets the nominal values or range of values as well as the design tolerance. While test data is a required part of the PMTA, FDA does not require test data for all the parameters for which it requires target and range. For example, for parameters that are observational (*e.g.,* number of waterpipe holes), FDA would not seek test data on that parameter. Also, some design parameters are machine settings (*e.g.,* tobacco cut size), calculated (*e.g.,* denier per filament (DPF)), provided by suppliers (*e.g.,* certificate of analysis for base paper porosity), or can be extrapolated from other design parameter test data (*e.g.,* filter pressure drop test data is more informative than filter length test data). Test data would not be needed for such parameters. In addition, in tables 1 through 22, FDA has clarified alternative terminology for ''porosity'' understanding that applicants may refer to this term as ''permeability'' for several design parameters as well as adding units of measure for several design parameters. The design parameters, their importance to understanding their impact on public health, and methods for applicants to provide this information are described below.

One way an applicant can provide the information needed for a product's required design parameters is with a Manufacturing Data Sheet Specification (MDSS) document. The MDSS is a document typically maintained by manufacturers, describing all the parameters that are controlled by the manufacturer during manufacture of their tobacco products. There will be cases where the design parameters on the MDSS will not directly translate into one of the product-specific design parameters in section 1114.7(i)(2)(ii). In these cases, additional information would need to be submitted to provide the complete characterization necessary. There may also be instances (*e.g.,* for novel tobacco products in one of the categories described in table 1 to § 1114.7(c)(3)(iii)) where one or more of the required design parameters do not apply to the tobacco product described in the PMTA. In these instances, an applicant must justify why the required design parameter does not apply or how an alternative design parameter(s) would satisfy one or more of the required design parameters. Similarly, for test data, an applicant must justify why the required test data does not apply or how alternative test data should be considered by FDA in lieu of the required test data. Further, there may be instances where the tobacco product may not fit into any of the categories described in table 1 to § 1114.7(c)(3)(iii). In these instances, the applicant must provide design parameters that would fully characterize their product. Additionally, if there are

design parameters beyond what FDA is requiring that would characterize the tobacco product, applicants should provide those to aid in FDA's scientific review. While failure to include additional design parameters to fully characterize the tobacco product beyond what FDA is requiring under this rule would not serve as the basis for FDA refusing to accept or file an application under § 1114.27(a)(1), it may slow down the substantive review process.

Applicants should also state whether the ranges or tolerances associated with each design parameter correspond to product or process controls, and what actions the applicant takes when test data falls outside of these specified ranges. As an example of product and process controls, a smokeless tobacco product may have set design parameters (also known as product specifications) for pH and oven volatiles (OV). The applicant may establish process controls for the fermentation process by setting lower and upper temperature and humidity limits for specified time durations. At the end of the fermentation process, a sample may be tested to verify that the tobacco product meets the established pH and OV design parameter limits. For any design parameters that are provided that are not included in the tables to § 1114.7(i)(2)(ii)(B), applicants must provide test data or process information to demonstrate that these parameters or their associated processes are adequately controlled.

Table 1 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be contained in a PMTA for cigarettes. In this final rule we have revised table 1 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include: (1) Removal of the proposed requirement for applicants to provide cigarette draw resistance, as FDA determined that requiring this parameter was unnecessary and not as informative as pressure drop as draw resistance could be modified by the user by puffing more or less intensely; (2) removal of cigarette paper base paper basis weight and tipping paper basis weight, as they are not as informative as other design parameters, such as cigarette paper base paper porosity; (3) removal of plug wrap parameters, as the effects of plug wrap are not as informative as cigarette paper parameters; (4) removal of cigarette mass, paper width, filter diameter, tipping paper width, and tobacco rod length, as these parameters can be either calculated from other required design parameters or are not as informative as other required parameters; (5) removal of filter mass and filter tow crimp index, as these parameters have less of an impact on the filter efficiency than other required design parameters that will affect the smoke constituents that are exposed to users and nonusers; (6) removal of filter ventilation position of holes, filter ventilation number of holes, and filter ventilation number of rows as filter ventilation, which is still required, is affected by these parameters; (7) the inclusion of filter efficiency as an alternative to DPF, total denier, or filter density, if available, as these parameter have a direct effect on filter efficiency and vice versa; (8) the option to provide cigarette diameter as an alternative to cigarette circumference as FDA is able to calculate the necessary information based on either one; and (9) the option for the applicant to provide cigarette paper band diffusivity in lieu of cigarette paper band porosity, if applicable (also described as permeability). FDA has clarified terminology for cigarette paper band porosity, as applicants may refer to this term as permeability, and also provided an alternative to providing cigarette paper band porosity or permeability—band diffusivity, while not preferred, is an acceptable alternative if it is currently not part of an applicant's practice to specify cigarette paper band porosity. While there are minor differences (porosity is more relevant during active puffing, whereas diffusivity is more relevant during smoldering), the addition of diffusivity as an alternative parameter allows flexibility to applicants who do not directly measure porosity or permeability (see Ref. 46).

Additionally, FDA has revised certain proposed parameters for test data, which includes: (1) Removal of puff count as this was duplicative of information that an applicant would submit with smoke constituent data since puff count is determined in a smoking machine using either the ISO or HCI smoking regimen or other applicable regimen; (2) removal of cigarette draw resistance, as explained above; (3) removal of cigarette mass, cigarette paper base paper and tipping paper basis weight, as explained above; (4) removal of plug wrap parameters, as explained above; (5) removal of tipping paper width and tipping paper perforation, as explained above; (6) removal of tipping paper length and width, tobacco rod length, cigarette paper length and width, cigarette length, cigarette diameter, cigarette paper band width, cigarette paper band space, filter diameter and length as these are measured parameters, that are not needed as test data; (7) removal of filter tow crimping index and filter mass, as explained above. The finalized parameters listed in table 1 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes in these parameters may affect the cigarette's impact on the public health, as described below:

- Cigarette length may alter tobacco biomarker levels (Ref. 47);
- cigarette circumference or diameter may affect filter efficiency and, in turn, smoke constituent yields (Ref. 48); puff count can directly affect smoke constituent yields (Ref. 49);
- tobacco filler mass may affect smoke constituent yields (Ref. 50);
- tobacco rod density may modify burn properties and smoke constituent yields (Refs. 51 and 52);
- tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 53);
- tobacco moisture may affect puff count (Ref. 54);
- cigarette paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 55);
- cigarette paper base paper porosity or permeability may affect smoke constituent yields (Ref. 55);
- cigarette paper band porosity or permeability may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Ref. 56);
- cigarette paper band diffusivity may affect smoke constituent yields because it mimics air flow during smoldering (Ref. 57);
- cigarette paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 58);
- cigarette paper band space may affect ignition propensity and, in turn, puff count (Ref. 59);
- filter efficiency may affect smoke constituent yields (Ref. 58);
- filter DPF, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 60);
- filter pressure drop may affect smoke constituent yields (Ref. 61);
- tipping paper, including length, may affect smoke constituent yields (Ref. 62); and
- filter ventilation may affect smoke constituent yields (Ref. 48).

Table 2 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be contained in a PMTA for

portioned and nonportioned smokeless tobacco products. We have revised table 2 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include: (1) Removal of portion thickness, as it is an unnecessary parameter because it is the pouch effective area that may result in an increase of the release level of nicotine, unprotonated nicotine, and could affect TSNA levels, and the pouch effective area can be calculated from other required design parameters, *i.e.,* pouch length and pouch width; (2) removal of pouch material nicotine dissolution extent, as nicotine dissolution rate provides the nicotine exposure to the user over time, and therefore was considered redundant and unnecessary; (3) addition of pouch material thickness as this parameter influences the release level of nicotine and can affect TSNA levels; [22] (4) option to provide tobacco particle size in lieu of tobacco cut size, as tobacco particle size can impact the use profile of the product and thereby affect the rate and total delivery of HPHCs similar to tobacco cut size. FDA has revised certain proposed parameters for test data, which includes the removal the portion length, width, portion thickness, and material thickness, as these are measured design parameters that can be obtained from the supplier of the portion or pouch, and (5) clarification of requiring certain parameters ''if applicable'' for portioned product properties. While these parameters are needed for all portioned smokeless products, not all portioned products are pouched, so the pouch-specific properties should only be reported if applicable, and thus FDA has added ''if applicable'' to pouch material porosity or permeability and pouch material basis weight.

The finalized parameters in table 2 to § 1114.7(i)(2)(ii)(B) are a necessary part of the applications because they are needed to fully characterize the product and changes in these parameters may affect the smokeless tobacco product's impact on public health, as described below:

- Tobacco cut size may alter the particle surface area and accessibility of saliva to get to the surfaces of the tobacco, thereby affecting the amount and rate of constituents released from the product (Ref. 63);
- tobacco moisture may affect microbial growth in the product, extraction efficiency, and total exposure to nicotine, NNN, and NNK (Refs. 3 and 64);
- portion mass may affect user exposure to a tobacco product and, in turn, HPHCs contained in each portion (Ref. 65);
- portion length may affect the constituents in each portion (Ref. 65);
- portion width may result in a surface area difference, which is proportional to the amount and rate of constituents released from the product (Ref. 66);
- pouch material basis weight, pouch material air permeability, and pouch material thickness influences the interactions between the tobacco and oral cavity, thereby potentially affecting the amount and rate of constituents released from the product (Refs. 67, 141, and 142; [23]) and
- nicotine dissolution rate is a function of tobacco cut size and pouch materials, thereby potentially affecting the amount and rate of constituents released from the product (Ref. 68).

Table 3 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be contained in a PMTA for RYO tobacco rolling paper products. In this final rule, we have revised table 3 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include the option to provide RYO paper band diffusivity in lieu of RYO paper band porosity (also described as permeability). FDA has clarified terminology for RYO paper band porosity, as applicants may refer to this term as permeability, and also provided an alternative to providing cigarette paper band porosity or permeability—band diffusivity, while not preferred, is an acceptable alternative if it is currently not part of an applicant's practice to specify cigarette paper band porosity. While there are minor differences (porosity is more relevant during active puffing, whereas diffusivity is more relevant during smoldering), the addition of diffusivity as an alternative parameter allows flexibility to applicants who do not directly measure porosity or permeability (see Ref. 46). Additionally, FDA has revised certain proposed parameters for test data, which includes the removal the paper length, width, band space, and band width as these are measured design parameters that are not needed as test data.

The finalized parameters listed in table 3 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes in these parameters may affect the rolling paper's impact on public health, as described below:

- RYO paper length and RYO paper width may alter the surface area that is available for tobacco packing, thereby affecting the smoke constituent yields (Ref. 61);
- RYO mass per paper may be a result of a surface area or basis weight difference and, in turn, may affect puff count and smoke constituent yields (Refs. 55 and 61);
- RYO paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 55);
- RYO paper base paper porosity may affect smoke constituent yields (Ref. 55);
- RYO paper band porosity may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Ref. 56);
- RYO paper band diffusivity may affect smoke constituent yields because it mimics air flow during smoldering (Ref. 57);
- RYO paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 58); and
- RYO paper band space may affect ignition propensity and, in turn, puff count (Ref. 59).

Table 4 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be contained in a PMTA for RYO tobacco tubes. We have revised table 4 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include the addition of: (1) The option to provide tube diameter as an alternative to tube circumference, as FDA is able to calculate the information necessary based on either one and (2) the option for the applicant to provide tube paper band diffusivity in lieu of tube paper band porosity or permeability, if applicable. FDA has clarified terminology for RYO paper band porosity, as applicants may refer to this term as permeability, and also provided an alternative to providing cigarette paper band porosity or permeability—band diffusivity, while not preferred, is an acceptable alternative if it is currently not part of an applicant's practice to specify cigarette paper band porosity. While there are minor

[22] See, *e.g.,* Gale, N., G. Errington, and K. McAdam, Group Research & Development, British American Tobacco, ''Effects of Product Format on Nicotine and TSNA Extraction from Snus Pouches,'' Presentation at the 67th Tobacco Science Research Conference, Williamsburg, VA, September 15–18, 2013. Available at: *https://www.researchgate.net/publication/299854728_Effects_of_Product_Format_on_Nicotine_and_TSNA_Extraction_from_Snus_Pouches.*

[23] See response 45 for additional information.

differences (porosity is more relevant during active puffing, whereas diffusivity is more relevant during smoldering), the addition of diffusivity as an alternative parameter allows flexibility to applicants who do not directly measure porosity or permeability (see Ref. 46). FDA has revised certain proposed parameters for test data, which includes the removal of tube length, tube paper width, tube circumference, tube paper band width, and tube paper band space, as these are measured design parameters.

The finalized parameters listed in table 4 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes in these parameters may affect the RYO tube's impact on public health, as described below:

- Tube mass may affect smoke constituent yields (Ref. 50);
- tube length may alter tobacco biomarker levels (Ref. 47);
- tube circumference or diameter may affect filter efficiency and, in turn, smoke constituent yields (Ref. 48);
- tube paper width may affect smoke constituent yields (Ref. 50);
- tube paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 55);
- tube paper base paper porosity may affect smoke constituent yields (Ref. 55);
- tube paper band porosity may affect smoke constituent yields since band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Ref. 56);
- tube paper band diffusivity may affect smoke constituent yields because it mimics air flow during smoldering (Ref. 57);
- tube paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 58); and
- tube paper band space may affect ignition propensity and, in turn, puff count (Ref. 59).

Table 5 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be contained in a PMTA for RYO tobacco filtered tubes. In this final rule we have revised table 5 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include: (1) The option to provide tube diameter as an alternative to tube circumference, as FDA is able to obtain the information necessary from calculations based on what the applicant submits; (2) the option for the applicant to provide filter efficiency as an alternative to DPF, total denier, or filter density (Ref. 60); (3) the option for the applicant to provide diffusivity in lieu of paper band porosity or permeability, as described in previous design parameter sections, is an acceptable alternative if it is currently not part of an applicant's practice to specify paper band porosity; (4) removal of filter mass, filter diameter, and filter tow crimping index as these parameters are considered as not as important as other parameters such as DPF and total denier, and therefore deemed unnecessary; (5) removal of plug wrap length, width, basis weight, and porosity as plug wrap parameters contribute to ventilation; however, filter ventilation and paper porosity have more of an effect on ventilation and therefore, plug wrap parameters were considered unnecessary; (6) removal of tipping paper width, basis weight, and perforation are considered unnecessary because they have little effect on the airflow and are not combusted during use; and (7) removal of filter ventilation position of holes, filter ventilation number of holes, and filter ventilation number of rows as these parameters are considered redundant because the filter ventilation is affected by these parameters. The alternatives (filter efficiency and diffusivity) are also provided under test data for this product category. Further, FDA has revised certain parameters for test data that were previously proposed in the PMTA rule, which include: (1) Removal of the tube mass, tube length, tube diameter, tube paper length, nonfilter tube length, tube width, tube paper band width and space, filter length, filter mass, and filter diameter as these are measured design parameters and (2) removal of filter tow index, plug wrap length, plug wrap width, and tipping paper basis weight for reasons described above.

The finalized parameters listed in table 5 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes in these parameters may affect the filtered tube's impact on public health, as described below:

- Tube mass may affect smoke constituent yields (Ref. 50);
- tube length may alter tobacco biomarker levels (Ref. 47);
- tube circumference or diameter may affect filter efficiency and, in turn, smoke constituent yields (Ref. 48);
- tube paper length directly correlates to non-filter tube length, which may affect smoke constituent yields (Ref. 50);
- tube paper width may affect smoke constituent yields (Ref. 50);
- tube paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 55);
- tube paper base paper porosity may affect smoke constituent yields (Ref. 55);
- tube paper band porosity may affect smoke constituent yields since band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Ref. 56);
- tube paper band diffusivity may affect smoke constituent yields because it mimics air flow during smoldering (Ref. 57);
- tube paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 58);
- tube paper band space may affect ignition propensity and, in turn, puff count (Ref. 59);
- filter efficiency may affect smoke constituent yields (Ref. 58);
- filter DPF may affect filter efficiency and, in turn, smoke constituent yields (Ref. 60);
- total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 43);
- filter pressure drop may affect smoke constituent yields (Ref. 61);
- tipping paper length may affect smoke constituent yields (Ref. 62); and
- filter ventilation may affect smoke constituent yields (Ref. 48).

Table 6 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be contained in a PMTA for RYO tobacco. In this final rule, we have revised table 6 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. This change includes the removal of the requirement for the applicant to provide filler mass as this is provided as part of unique identification of the tobacco product under § 1114.7(c).

The finalized parameters listed in table 6 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes in these parameters may affect the RYO tobacco's impact on public health, as described below:

- Tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 53) and
- tobacco moisture may affect puff count when used with rolling paper (Ref. 54).

Table 7 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be contained in a PMTA for RYO tobacco paper tips. In this final rule, we have revised table 7 to

§ 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. This includes the replacement of the requirement for the applicant to provide RYO paper base paper perforation, and instead provide RYO paper porosity. RYO porosity was found to directly convey the smoke constituent exposure to users, while paper perforation was less indicative of the exposure of smoke constituents when accounting for additional design parameters. FDA has also revised certain parameters for test data that were proposed previously in the PMTA rule, which include: (1) Removal of the tip length and width and tip mass as these are measured design parameters; and (2) replacement of paper perforation to paper porosity, as described above.

The finalized parameters listed in table 7 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes may affect the paper tip's impact on public health, as described below:

- RYO paper tip length and RYO paper tip width may alter the surface area that is available for tobacco packing, thereby affecting the smoke constituent yields (Ref. 61);
- RYO paper tip mass may be a result of a surface area or basis weight difference and, in turn, may affect puff count and smoke constituent yields (Refs. 55 and 61);
- RYO paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 55);
- RYO paper base paper porosity may affect smoke constituent yields (Ref. 55); and
- RYO paper tip ventilation may affect smoke constituent yields (Ref. 48).

Tables 8 through 12 to § 1114.7(i)(2)(ii)(B) describe the design parameters and information on performance criteria that must be contained in a PMTA for products categorized as cigars. Cigarettes (outside the category of heated tobacco products) and cigars are similar, as they are both cylinders filled with a blend of processed tobacco that is generally smoked. Both are generally lit with a fire source, which burns the tobacco as the user inhales at one end; thus, they are consumed and deliver nicotine in a similar manner. A main difference between cigarettes and cigars is that cigars are either wrapped in a tobacco leaf (wrapper and binder) or a material containing tobacco, whereas non-HTP cigarettes are wrapped in paper (cigarette paper) or a material that does not contain tobacco. Additionally, cigars come in a wider variety of sizes and some types of cigars may be thicker in diameter and contain more tobacco filler than cigarettes. Despite these differences, for both types of tobacco products, no matter the size, air is pulled through the tobacco column, which aids in tobacco combustion and nicotine delivery. Cigarette paper commonly has an established porosity (permeability), that is set during manufacturing, while cigar wrapper properties are based on the tobacco used as the wrapper. Although cigars and cigarettes are wrapped in different materials, both cigar wrappers and binders, as well as cigarette papers, have inherent permeabilities/porosities, which may affect smoke constituent yields. Cigars may be filtered (containing filter tow or other materials), unfiltered, or unfiltered with tips made of wood or plastic, while most cigarettes have filters (containing filter tow) and do not contain tips. If a cigar does contain a filter, it will be similar to cigarette filters and contain tow. Based on FDA's experience with cigarettes under the SE pathway, as well as the similarities between the two products, FDA has used established design parameter information from cigarettes to develop some of the design parameter requirements for cigars. Tables 8 through 12 to § 1114.7(i)(2)(ii)(B) describe in more detail the parameters for each subcategory of cigars.

Table 8 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be contained in a PMTA for filtered, sheet-wrapped cigars. In this final rule we have revised table 8 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include (1) the addition of cigar wrapper and binder band space, as these parameters affect smoke constituents; (2) the addition of cigar minimum and maximum diameter (mm), as the shape of cigars can differ, with the tips being narrower than the center of the cigar, affecting the rod density, which in turn modifies the burn properties and smoke yields; (3) providing applicants the option to provide oven volatiles as an alternative to tobacco moisture, as well as the option to provide oven volatiles instead of moisture, as this provides similar information to FDA [24] and allows the applicant flexibility to provide either parameter based on the specific manufacturing processes they employ; and (4) removing cigar length, cigar diameter, filter diameter, filter length as requirements for test data as these are measured design parameters that are not needed as test data.

Additionally, based on FDA's understanding of machine-made cigars and their similarity to cigarettes, we have also included design requirements previously recommended in the proposed PMTA rule. These design parameters include (1) cigar mass, wrapper and binder basis weight, cigar binder and wrapper length and width, cigar wrapper and binder band porosity, and cigar wrapper and binder width, as these design parameters may affect smoke constituent yields and (2) the option for the applicant to provide filter efficiency, if available, as an alternative to DPF, total denier, or filter density. We have also included test data requirements for cigar mass, puff count, wrapper and binder basis weight, and cigar minimum and maximum diameter for reasons previously discussed.

The finalized parameters listed in table 8 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes may affect the cigar's impact on public health, as described below:

- Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 69);
- cigar puff count can directly affect smoke constituent yields (Ref. 69);
- cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 70);
- tobacco filler mass may affect smoke constituent yields (Ref. 71);
- for cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 71). Similarly, for cigars, the cigar wrapper and binder basis weight may affect puff count and smoke constituent yields;
- for cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 71). Similarly, for cigars, the cigar wrapper and binder length and width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields;
- cigar wrapper porosity may affect smoke constituent yields (Refs. 72 and 73);

[24] Please note that the term ''moisture,'' has widely varying and conflicting definitions and terminology in use within the tobacco industry. It is common for ''moisture'' or ''moisture content'' to be used to refer to water content of a material but in relation to the tobacco industry it is necessary to differentiate between ''moisture'' as water content and ''moisture'' as oven volatiles. *https://www.coresta.org/sites/default/files/technical_documents/main/PTM-CTR_MoistureWaterOvenVolatiles_July2014%282%29.pdf.*

• for cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 51 and 52). Similarly, for cigars, tobacco rod density may modify burn properties and smoke constituent yields;
• for cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 54). Similarly, for cigars, the tobacco moisture may affect puff count (Ref. 54);
• for cigarettes, the tobacco cut size may result in more particulate matter (Ref. 53). Similarly, for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter;
• for cigarettes, the band porosity may affect smoke constituent yields (Ref. 56). Similarly, for cigars, the band porosity or permeability may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing;
• for cigarettes, the band width may affect smoke yields (Ref. 58). Similarly, for cigars, the wrapper band width and binder band width may affect ventilation and, in turn, smoke constituent yield;
• for cigarettes, the band space may affect puff count (Ref. 59). Similarly, for cigars, the wrapper band space and binder space may affect ignition propensity and, in turn, puff count;
• for cigarettes, the filter parameters can impact smoke yields (Ref. 60). Similarly, for cigars, the filter diameter, filter mass, filter tow crimping index, DPF, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields;
• For cigarettes, the filter pressure drop affects smoke yields (Ref. 61). Similarly, for cigars, the filter pressure drop may affect smoke constituent yields.
• for cigarettes, tipping paper length may affect smoke constituent yields (Ref. 62). Similarly, for cigars, the tipping paper, including width, and basis weight, may affect smoke constituent yields; and
• ventilation may affect smoke constituent yields (Ref. 69).

Table 9 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for unfiltered, sheet-wrapped cigars. In this final rule, we have revised table 9 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include: (1) The addition of overall diameter because cigar diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields; (2) the removal of cigar tip width (mm); (3) the option for applicants to provide oven volatiles in lieu of tobacco moisture, as this provides similar information to FDA [25] and allows the applicant flexibility to provide either parameter based on the specific manufacturing processes they employ. In addition, as compared to the proposed PMTA rule, FDA has removed certain parameters for test data, including the removal of cigar length, cigar tip length, cigar tip diameter, and cigar tip width, as FDA has determined that these parameters are not necessary as test data. Additionally, based on FDA's understanding of cigars and their similarity to cigarettes, we have also included all the design requirements previously recommended in the proposed PMTA rule except cigar burn rate and cigar draw resistance. We have also included the following test data: Puff count, tobacco rod density, tobacco cut size, cigar wrapper and binder basis weight, binder porosity, and cigar tip mass.

The finalized parameters listed in table 9 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes may affect the cigar's impact on public health, as described below:
• Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 69);
• cigar puff count can directly affect smoke constituent yields (Ref. 69);
• cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 70);
• tobacco filler mass may affect smoke constituent yields (Ref. 69);
• for cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 71). Similarly, for cigars, the cigar wrapper and binder basis weight may affect puff count and smoke constituent yields;
• for cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 71). Similarly, for cigars, the cigar wrapper length and width and binder width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields;
• cigar wrapper porosity may affect smoke constituent yields (Refs. 72 and 73).
• for cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 51 and 52). Similarly, for cigars, the tobacco rod density may modify burn properties and smoke constituent yields;
• for cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 54). Similarly, for cigars, the tobacco moisture may affect puff count;
• for cigarettes, the tobacco cut size may result in more particulate matter (Ref. 53). Similarly, for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter;
• for cigarettes, the band porosity may affect smoke constituent yields (Ref. 56). Similarly, for cigars, the wrapper and binder band porosity or permeability may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing;
• for cigarettes, the band width may affect smoke yields (Ref. 58). Similarly, for cigars, the wrapper and binder band width may affect ventilation and, in turn, smoke constituent yields;
• for cigarettes, the band space may affect puff count (Ref. 59). Similarly, for cigars, the wrapper and binder band space may affect ignition propensity and, in turn, puff count; and
• cigar tip dimensions directly influence the overall cigar draw resistance and in turn, puff count (Ref. 74).

Table 10 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for leaf-wrapped cigars. In this final rule, we have revised table 10 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include the option to provide oven volatiles instead of moisture, as this provides similar information to FDA [26] and allows the applicant flexibility to provide either parameter based on the specific manufacturing processes they employ. FDA has also revised certain parameters for test data previously discussed in the proposed PMTA rule. Specifically, FDA has removed cigar length as this is a measured design parameter for which we do not need test data. Additionally, based on FDA's understanding of leaf-wrapped cigars and their similarity to cigarettes, we have included the design requirements that were previously recommended in the proposed PMTA rule except cigar draw resistance, wrapper and binder porosity, and cigar burn rate. We have

[25] See footnote 21.

[26] See footnote 21.

also included the following parameters for test data that were previously recommended in the proposed PMTA rule: Puff count, tobacco rod density, tobacco filler mass, tobacco cut size, and wrapper and binder basis weight.

FDA has also included: (1) The overall diameter as a design parameter because cigar diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields and (2) tobacco cut size as a design parameter as it can alter the size of tobacco pieces, which may result in more particulate matter.

The finalized parameters listed in table 10 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes may affect the cigar's impact on public health, as described below:

- Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 69);
- cigar puff count can directly affect smoke constituent yields (Ref. 69);
- for cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 71). Similarly, for cigars, the cigar wrapper length and width and binder width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields;
- cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 70);
- for cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 54). Similarly, for cigars, the tobacco moisture may affect puff count;
- for cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 71). Similarly, for cigars, the cigar wrapper and binder basis weight may affect puff count and smoke constituent yields;
- for cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 51 and 52). Similarly, for cigars the tobacco rod density may modify burn properties and smoke constituent yields; and
- for cigarettes, the tobacco cut size may result in more particulate matter (Ref. 53). Similarly, for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.

Table 11 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for cigar tobacco. In this final rule, we have revised table 11 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include the option to provide oven volatiles instead of moisture, as this provides similar information to FDA [27] and allows the applicant flexibility to provide either parameter based on the specific manufacturing processes they employ. FDA has also revised certain proposed parameters for test data, which includes the option to provide oven volatiles instead of moisture, as described above. In the proposed rule, we proposed a recommended design parameter for cigar tobacco, filler mass. Based on FDA's understanding of cigar tobacco, we have decided not to include filler mass (mg) as a required design parameter. FDA has concluded that the amount of tobacco added to a cigar is generally user-dependent and so, the filler mass of the cigar tobacco as packaged does not have a direct effect on the smoke constituents.

The finalized parameters listed in table 11 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes may affect its impact on public health, as described below:

- For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 53). Similarly, for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter and
- for cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 54). Similarly, for cigars, the tobacco moisture may affect puff count.

Table 12 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for a cigar wrapper. In this final rule, we have revised table 12 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include, for both target specification and test data, the replacement of cigar maximum and minimum width with wrapper width, as not all cigar wrappers have a maximum and minimum width; additionally, in the proposed rule, we discussed recommended design parameters for cigar wrappers. Based on FDA's understanding of cigar wrappers, and because cigar wrapper basis weight affects smoke constituents as well as puff count, we have included cigar wrapper basis weight in the final rule. For test data that was previously recommended in the proposed rule, FDA has included cigar wrapper basis weight as a requirement and replaced cigar minimum and maximum wrapper width with wrapper width for the reasons discussed previously.

The finalized parameters listed in table 12 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes may affect its impact on public health, as described below:

- For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 71). Similarly, for cigars, the cigar wrapper length and width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields and
- for cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Refs. 71 and 72). Similarly, for cigars, the cigar wrapper and binder basis weight may affect puff count and smoke constituent yields.

Table 13 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for a waterpipe. Cigarette tobacco and waterpipe tobacco are similar, as they are both processed tobacco that is cut, milled, and sifted before ingredients are added to control for tobacco moisture and taste. Therefore, tobacco parameters for a cigarette can be extrapolated to tobacco parameters for a waterpipe. Additionally, the waterpipe length of the waterpipe stem causes affects the pressure drop in the waterpipe in a similar way as to the length of the cigarette filter and filter tow causes a filter pressure drop in a cigarette: Both determines the amount of suction a smoker needs to apply to the tobacco product to draw smoke through. Therefore, filter pressure drop for a cigarette can be extrapolated to the pressure drop of a waterpipe. The parameters included in table 13 apply to waterpipes generally. For products that contain a heating source or waterpipe tobacco, applications should specify information regarding the heating source and waterpipe tobacco as described in tables 14 and 15.

In this final rule, we have revised table 13 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include: (1) The removal of number of hoses as the number of hoses can vary during smoking session and (2) the change in terminology from ''bowl'' to ''base.'' Additionally, in the proposed rule, we recommended design parameters for waterpipes. Based on FDA's understanding of waterpipes, we have

[27] See footnote 21.

required the following design parameters: (1) Hose length, hose material, and hose internal diameter, which are directly proportional to air infiltration and affects toxicant yields; (2) stem length and stem internal diameter, which impacts puffing behavior and toxicant exposure; (3) pressure drop, which affects smoke constituent yields; (4) water filter efficiency, which is directly proportional to mainstream smoke and can increase exposure to HPHCs; and (5) hose air permeability and heating source type, as theses parameters have a direct correlation with toxicants and smoke constituents exposed to users and nonusers. For test data that was previously recommended in the proposed rule, FDA is requiring all the parameters except foil length, foil width, and ventilation.

Further, based on FDA's understanding of waterpipes, we have also included the following required design parameters: Base diameter, base volume, base shape, head height, head top diameter, head bottom diameter, number of holes, head volume, and head material. The shape and size of the base can affect the pressure drop or difficulty of pulling air through the waterpipe hose, while the head dimensions affect how long a smoke session lasts by controlling how much tobacco can be used during a session. Head dimensions can also affect airflow beneath and through the tobacco to make heat transfer more effective, prolonging smoking sessions. FDA has also included the following required parameter for test data: Head height, head top diameter, head bottom diameter, and head volume.

The finalized parameters listed in table 13 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes may affect its impact on public health, as described below:

- Hose dimensions (length and diameter) are directly proportional to air infiltration and affects toxicant yields (Ref. 75);
- hose material may affect hose permeability, which may affect smoke constituent yields (Ref. 75);
- stem length influences draw resistance, which can in turn impact nicotine and other toxicant delivery to the user (Ref. 76);
- stem internal diameter can impact puffing behavior and toxicant exposure, and in turn, smoke constituent yields (Ref. 76);
- for cigarettes, the pressure drop effect smoke constituent yields (Ref. 71). For waterpipes the base diameter and base volume impact how much water the base can hold and how much water the user can add to the base and the volume of water impacts the pressure drop or the difficulty of pulling air through the waterpipe hose. Similarly, for waterpipes, the pressure drop may result in differences in the difficulty of pulling air through the waterpipe and, in turn, affect smoke constituent yields (Ref. 71);
- head dimensions affect how long a smoke session lasts by controlling how much tobacco can be used during a session. Head dimensions can also affect airflow beneath and through the tobacco to make heat transfer more effective, prolonging smoking sessions. With a wider surface area, there is more room for the head to more evenly distribute heat to the tobacco. A shallower bowl makes tobacco at the bottom of the head more accessible to heat and allows for heat to be more evenly distributed to the tobacco. The more holes in the head, the more airflow, which affects the tobacco temperature. All of this causes the tobacco to reach different temperatures that affects smoke yields (Ref. 75);
- water filtering efficiency is directly proportional to mainstream smoke and can increase exposure to HPHCs (Ref. 77);
- for cigarettes, the filter pressure drop affects smoke yields (Ref. 71). Similarly, for waterpipes, the pressure drop may result in differences in the difficulty of pulling air through the waterpipe and, in turn, affect smoke constituent yields;
- heating source type affects tobacco temperature, which in turn, may affect smoke constituent yields (Ref. 78); and
- head material could aid in heat transfer, prolonging the heating of the tobacco and causing the tobacco to reach temperatures that affect smoke yields.

Table 14 in § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for waterpipe tobacco. In this final rule, we have revised table 14 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include the option for the applicant to provide oven volatiles as an alternative to tobacco filler moisture. We have provided this alternative because it will allow the applicant to provide information needed to evaluate the product without conducting additional testing as this alternative may satisfy these requirements. Additionally, in the proposed rule, we recommended a design parameter for waterpipe tobacco, filler mass. Based on FDA's understanding of waterpipe tobacco, we have decided not to include filler mass as a required design parameter for waterpipe tobacco. FDA concluded that the amount of tobacco added during a given smoking session is user-dependent and so, filler mass of the waterpipe tobacco as packaged does not have a direct impact on smoke constituents.

The finalized parameters listed in table 14 to § 1114.7(i)(2)(ii)(B) are necessary to fully characterize the product and changes may affect its impact on public health as follows:

- For cigarettes, the tobacco cut size may result in more particulate matter (Refs. 53 and 54). Similarly, for waterpipe tobacco, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter. Finer tobacco cut size may result in a decrease in filling power and in turn, a larger amount of tobacco in the bowl (Refs. 53 and 54) and
- for cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 54). Similarly, for waterpipe tobacco, the tobacco moisture may affect puff count. Moisture contributes to packing density, thus decreasing void volume (Ref. 54).

Table 15 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for a waterpipe heating source. In this final rule, we have revised table 15 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include: (1) The removal of heating source type. As there are multiple types of heating source for waterpipe, instead of asking for the source type, FDA has changed the terminology and considered all heating sources as the heating element and (2) the removal of charcoal temperature and coil temperature range, as described above, FDA considers all heating sources the heating element; therefore, the charcoal and coil temperature have been removed and replaced with ''heating element temperature.'' FDA has also revised the test data and removed test data for charcoal temperature range and coil temperature range, for reasons previously described.

Additionally, in the proposed rule, we recommended design parameters for waterpipe heating source. Based on FDA's understanding of waterpipe heating sources, we have included some of these design parameters, including those related to batteries and power delivery units (PDU). The finalized parameters listed in table 15 to

§ 1114.7(i)(2)(ii)(B) are necessary to fully characterize the product and changes may affect its impact on public health as follows:

- When combusted, heating sources such as charcoal or wood cinders expose the user to high yields of toxicants such as carbon monoxide and polycyclic aromatic hydrocarbons. Therefore, the heating source mass, density, and temperature may affect smoke constituent yields (Ref. 78);
- for ENDS, the number of elements affects resistance and distribution of heat dissipation (Ref. 79). Similarly, for waterpipe heating source, the number of heating elements can affect resistance and distribution of heat dissipation;
- for ENDS, the heating element configuration effect affect toxicant emissions and nicotine delivery (Refs. 80–84). Similarly, for waterpipe heating source, the eating element configuration may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery;
- for ENDS, the heating element diameter may affect toxicant emissions and nicotine delivery (Refs. 80–84). Similarly, for waterpipe heating source, the diameter of the heating element affects its resistance. Heating element resistance may influence heating element temperature, which in turn affects toxicant emissions and nicotine delivery;
- for ENDS, an increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions may lead to greater exposure to toxicant emissions (Ref. 83). Similarly, for waterpipe heating source the battery mAh ratings is a measure of the average amount of current the battery releases over time under normal. Current may influence the heating element temperature, which in turn affects toxicant emissions and nicotine delivery. In addition, provides understanding how long a battery will last and thus the product stability;
- for ENDS, the battery and PDU voltage impacts the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 85). Similarly for waterpipe heating sources, the battery voltage operating range and PDU voltage operating range (volts) impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes;
- for ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly, for waterpipe heating source, the battery current operating range is a measure of the current batteries put out to heat the heating element of the product. The battery should have a normal operating range as to not overheat the product and cause it to become a hazard to the user. In addition, this current range has a direct impact on the heating element, which in turn affects the smoke constituent yields;
- for ENDS, the battery and PDU voltage impacts the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 85). Similarly for waterpipe heating source the PDU voltage operating range impacts the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes;
- for ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly for waterpipe heating source, the PDU current operating range is a measure of the current output to heat the heating element of the product, which, if not adequately controlled can lead to overheating the product subsequently may harm the user. In addition, this current range has a direct impact on the heating element, which in turn affects the smoke constituent yields; and
- for ENDS, PDU current operating range and wattage range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 80 and 86). Similarly, for waterpipe heating source the PDU wattage operating range determines the amount of heat produced. PDU wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions.

Table 16 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for waterpipe foil. In this final rule, we have revised table 16 to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. Specifically, in the proposed rule, we recommended design parameters for waterpipe foil. Based on FDA's understanding of waterpipe foil, we have included the following design parameter requirements: Foil diameter, foil thickness, number of holes, and diameter of holes. We have added these parameters because foil parameters affect smoke constituent yields, and ultimately, the user's exposure to toxicants and HPHCs. FDA has also revised the required test data to include the following parameters for the reasons detailed previously: Foil diameter, foil thickness, and diameter of the holes. Waterpipe foil length and width were erroneously listed both as required parameters (in table 16) and as recommended parameters in table 16a. FDA notes that waterpipe foil length and width are included in the final rule required parameters.

The finalized parameters listed in table 16 to § 1114.7(i)(2)(ii)(B) are necessary to fully characterize the product and changes may affect its impact on public health as follows.

- Waterpipe foil length, diameter, and width are necessary because they impact the user's puffing behavior and toxicant exposure. Therefore, the foil dimensions may affect smoke constituent yields (Ref. 76);
- waterpipe foil thickness influences the distribution of heat to the tobacco, affecting tobacco temperatures and therefore smoke constituent yields (Ref. 76); and
- the number and diameter of holes impacts the path of hot gases through the tobacco mixture, which may affect smoke constituent yields (Ref. 76).

Table 17 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for a waterpipe head. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes may affect the waterpipe head's impact on public health, as described below:

- Head dimensions (height, top diameter, bottom diameter), including number of holes, and head volume, affect how long a smoke session lasts, as well as how much tobacco is used. Head dimensions can also affect airflow beneath and through the tobacco in the head, affecting heat transfer to the tobacco. The temperatures reached during smoking affect smoke yields, and user exposure to these smoke yields and
- the head material could aid in heat transfer, prolonging the heating of the tobacco and causing the tobacco to reach temperatures that affect smoke yields.

Table 18 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for a pipe. The design

parameters described in table 18 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes that may affect the pipe's impact on public health. In this final rule, we have revised the design parameters related to pipes to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include the removal of: Bore minimum diameter, bore maximum diameter, bit length, and bit diameter. We have removed these parameters because they were found to be equal to the stem and shank diameter should be equal to the bore diameter, and in addition, the length of the bit can vary and have little effect on the user's exposure to toxicants. FDA has also revised the parameters for test data to include the removal of: Bore minimum diameter, bore maximum diameter, bit length, and bit diameter for the reasons described previously. Additionally, in the proposed rule, we recommended design parameters for pipes. Based on FDA's understanding of pipes, we have added design parameters related to the bowl chamber (bowl chamber cover outer diameter, bowl chamber cover inner diameter, bowl chamber hole shape, and bowl chamber volume), shank (length and diameter), draught hole (draught hole diameter, draught hole shape, draught hole location, and draught hole dimension), screen, airway and pressure drop, and filter (filter efficiency, pressure drop, and length). These parameters are a necessary part of the application because they are needed to fully characterize the product and changes may affect the pipe's impact on public health, as described below:

- Pipe screens are used in pipes to filter and stop hot embers and tobacco from traveling up the pipe to the user;
- the bowl chamber inner and outer diameters allow FDA to calculate the chamber wall thickness. A thicker wall will lead to a cooler smoke and makes it less likely the user will burn themselves when holding the chamber. Additionally, the chamber inner diameter will affect temperature and tobacco capacity, meaning the greater the pipe surface area, the more leaf can be burned at once, and with increased temperature, this will affect smoke constituents;
- the bowl chamber hole shape is important to characterize the pipe as this may affect the airflow and tobacco temperatures, which in turn affects the burn rate and smoke constituents delivered;
- the bowl chamber volume affects the burn rate and temperature, which in turn, dictates the smoke constituents delivered to users.
- the draught hole allows the user to pull air through the tobacco to their mouth. The diameter of the draught holes affects the resistance to draw, which can impact nicotine and other toxicant delivery to the user;
- the draught hole dimensions and geometry may affect the airflow and oxygen available at the burning tobacco for the chemical reaction and thus affect smoke constituent yields;
- the draught hole location should enter the bowl directly centered and at the very bottom of the bowl. The location can affect airflow and tobacco temperatures, which in turn, affects the burn rate and smoke constituents delivered;
- the stem of a pipe delivers smoke from the bowl to the user's mouth. The length of the stem may affect the smoke temperature, which may affect how the product is consumed, while the diameter of the stem may affect resistance to draw which can impact nicotine and other toxicant delivery to the user;
- the shank of a pipe may affect the smoke temperature (length) and resistance to draw (diameter);
- for cigarettes, the filter pressure drop affects smoke yields (Ref. 62). Similarly, for pipes, the pressure drop through the air valve can affect nicotine and other toxicant delivery to the user. Air flow through an air valve can affect tobacco burn rate and tobacco temperatures which in turn, may affect smoke constituent delivery to the user. Some pipes may come with a filter; and
- for cigarettes, filter diameter, DPF, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 60). Similarly, for pipes, the filter efficiency, filter pressure drop, and filter length may affect smoke constituent yields.

Table 19 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for pipe tobacco. In this final rule, we have revised table 19 (formerly table 18 in the proposed PMTA rule) to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include allowing applicants to provide oven volatiles (%) as an alternative for tobacco moisture. We have provided these alternatives because it will allow the applicant to provide information needed to evaluate the product without conducting additional testing as these alternatives may satisfy the requirements. Additionally, in the proposed rule, we recommended design parameters for pipe tobacco. Based on FDA's understanding of pipe tobacco, we have decided not to include filler mass (mg) as a design parameter.

The finalized parameters listed in table 19 to § 1114.7(i)(2)(ii)(B) are required as part of the application because they are necessary to fully characterize the product and changes may affect its impact on public health:

- for cigarettes, the tobacco cut size may result in more particulate matter (Ref. 53). Similarly, for pipes, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter and
- for cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 54). Similarly, for pipes, the tobacco moisture or oven volatiles may affect puff count.

While demonstrating compliance with voluntary standards can provide information that is important to FDA's review, this alone would neither fulfill the reporting requirements for battery design parameters under § 1114.7(i)(2)(ii) nor render further of the battery review superfluous. As described elsewhere in this section, FDA needs a full characterization of the tobacco product—including the battery, where applicable—to complete its review. FDA provides information regarding the health impacts for each design parameter for products categorized as ENDS, as discussed elsewhere in this section.

Table 20 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for an ENDS. In this final rule, we have revised table 20 (formerly table 19 in the proposed PMTA rule) to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. These changes include (1) the removal of overall atomizer resistance (ohms), wick ignition temperature, coil temperature cut-off, and coil temperature range. We have removed these parameters because, current cut-off and heating element temperature range are now required; as such, the inclusion of these parameters would be considered redundant. We have removed wicking ignition because not all wicking materials have an ignition temperature, nor do all ENDS products have an overall atomizer resistance; (2) change in language instead of ''coil'' the phrase ''heating element'' is used to include all heating elements that may not be considered a coil; and (3) the inclusion of ventilation. Additionally, in the proposed rule, we recommended design parameters for

ENDS. Based on FDA's evolving understanding of ENDS products, we have included the following previously recommended design parameters, as required: Draw resistance puff count, atomizer tank/cartridge volume, number of heating elements, heating elements length and diameter, heating element configuration, battery voltage operating range, battery current operating range, battery nominal voltage, battery current rating, battery charging temperature limits, battery discharge temperature limits, battery end of discharge voltage, battery maximum charging current, battery maximum discharging current, battery upper limits charging voltage, PDU voltage operating range, and PDU current operating range. FDA has also revised the test data to include these parameters, as these parameters affect the heating element temperature which in turn effects the smoke constituents exposed to the users and nonusers.

The finalized parameters listed in table 20 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes may affect its impact on public health, as described below.

- The air flow rate of the ENDS can affect the coil/heating element temperature, e-liquid consumption, and aerosol characteristics such as particle number concentration, count median diameter, and $PM_{2.5}$, which impact aerosol exposure (Ref. 87);
- coil/heating element resistance may affect overall heating element resistance, thereby influencing heating element temperature. The coil/heating element's resistance, material and the voltage [28] determine the current flow and heating element temperature. The heating element temperature and temperature duration may affect toxicant emissions and nicotine delivery (Refs. 80–84);
- coil/heating element resistance and battery output voltage determine PDU wattage. PDU wattage determines the amount of heat produced by the atomizer. PDU wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions and nicotine delivery (Refs. 82 and 84);
- an increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions may lead to greater exposure to toxicant emissions (Ref. 83);
- the temperature of the coil/heating element can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in coil/heating element temperature can increase HPHC levels in the aerosol, therefore, maximum coil/heating element temperature and temperature control deviation from this maximum coil/heating element temperature can affect toxicant emissions and nicotine delivery (Refs. 80–84);
- number of coils/heating element present can affect overall atomizer resistance and distribution of heat dissipation (Ref. 79);
- the position of the coil/heating element can increase the possibility of dry puff conditions and subsequent increased toxicant emissions (Ref. 82);
- atomizer and cartridge components of e-cigarettes may be heated repeatedly and aerosolized and can contribute to increased toxicant emissions (Ref. 80);
- puff count can differ depending on other puff topography (*e.g.,* puff duration and puff flow rate), e-cigarette and atomizer design, and e-liquid parameters. Puff count can also affect total puff volume, which in turn can affect total toxicant emissions (Ref. 88). In addition, information on the puff count of ENDS can help FDA assess the health risks of the product, including how it compares to other products;
- e-liquid capacity of the atomizer tank/cartridge can affect total puff volume, which in turn can affect total toxicant emissions (Refs. 88 and 89);
- battery/PDU voltage or voltage operating range may affect the heating element temperature, thereby affecting toxicant emissions and nicotine delivery (Refs. 81–84);
- battery wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 82 and 84);
- coil/heating element resistance and battery output voltage determine PDU wattage. PDU wattage determines the amount of heat produced by the atomizer. PDU wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 82 and 84);
- PDU wattage deviation may influence heating element temperature, thereby affecting toxicant emissions (Refs. 82 and 84).
- the temperature of the coil/heating element can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in coil/heating element temperature can increase HPHC levels in the aerosol, therefore, maximum coil/heating element temperature and temperature control deviation from this maximum coil/heating element temperature can affect toxicant emissions and nicotine delivery (Refs. 81–84);
- coil/heating element resistance, number of coils/heating element, coil/heating element gauge, and coil/heating element configuration may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery (Refs. 81–84);
- battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 80 and 86);
- battery power impacts the delivery of nicotine and the total emissions of volatile aldehydes (Refs. 85 and 90);
- battery and PDU voltage impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 85);
- the draw resistance of the ENDS impacts the ease of drawing air into the ENDS to produce aerosol, which can affect nicotine and other toxicant delivery to the user (Ref. 91). For cigarettes, we evaluate filter pressure drop since it is more informative than draw resistance; however, for ENDS, there is no filter pressure drop or other similar parameter that could be used in place of draw resistance;
- inhaled aerosol temperatures can be damaging or uncomfortable to users who inhale aerosol above a certain temperature (Ref. 92); and
- ventilation may affect smoke constituent yields (Ref. 69).

Table 21 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for an e-liquid. In this final rule, we have revised Table 21 (formerly Table 20 in the proposed PMTA rule) to § 1114.7(i)(2)(ii)(B) to help ensure that FDA is able to identify and evaluate each product more accurately and efficiently. Specifically, we removed the requirement to provide the e-liquid boiling point as a required design parameter because the information it would provide is sufficiently captured by coil temperature and e-liquid composition.

The finalized parameters listed in table 21 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes

[28] Voltage, current, and resistance are used to ensure the battery and the ENDS are operating within the ''normal operating range.'' The battery manufacturer sets the normal range of the voltage and current. Understanding the resistance allows FDA to assess whether the coil is drawing more current than the battery is designed for.

may affect its impact on public health, as described below:

- The e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Refs. 88 and 89);
- aerosol parameters such as particle number concentration, count median diameter, and $PM_{2.5}$ are used to characterize the amount and size of particles to which the user is exposed. Epidemiological and clinical studies have shown that exposure to large amounts of small particles can impair lung function and is correlated with cardiovascular disease (Refs. 93 and 94);
- e-liquid viscosity impact the proportion of nicotine that is aerosolized (Ref. 95). Also, the e-liquid viscosity can affect the electronic cigarette nicotine and other toxicant delivery to the user (Refs. 79 and 88); and
- the e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Refs. 88 and 89).

Table 22 to § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria that must be provided for heated tobacco products (HTPs). HTPs currently sold in global markets can function in ways that are similar to products in other product categories. For example, some HTPs can function like ENDS products by aerosolizing e-liquids or using a battery and PDU to power the product. Other HTPs can contain tobacco filler, like a cigarette or cigar, but are heated instead of combusted. For these reasons, the properties of HTPs vary widely, but are comparable to the properties of other tobacco product categories. As such, based on FDA's experience with other similarly characterized tobacco products, the information needed from a design parameter standpoint perspective for HTPs overlaps with that of products in other categories. The parameters listed in table 22 to § 1114.7(i)(2)(ii)(B) are a necessary part of the application because they are needed to fully characterize the product and changes may affect its impact on public health, as described below:

- For cigarettes, the length, diameter, and mass can affect smoke constituent yields (Ref. 70). Similarly, for HTPs, dimensions (mass, length, width, height, and diameter) can directly affect the amount of tobacco that is heated and, in turn, affect smoke constituent yields;
- for ENDS products, the draw resistance can affect nicotine and other toxicant delivery to the user (Ref. 91). Similarly, for HTPs, the draw resistance can impact the ease of drawing air into the product to produce aerosol, which can affect smoke constituent yields;
- for ENDS, puff count can affect total toxicants emissions (Refs. 88). Similarly, for HTPs, the puff count can affect puff volume, which in turn can affect total toxicant emissions;
- for ENDS, e-liquid capacity of the atomizer tank/cartridge can affect total toxicant emissions (Refs. 88 and 89). Similarly, for HTPs, the product volume (capacity of the cartridge) can affect total puff volume, which in turn can affect total toxicant emissions;
- for ENDS, airflow rate can impact aerosol exposure (Ref. 87). Similarly, for HTPs, the airflow rate allows air to flow from the heating element to the user's mouth; some products allow the user to manually change the airflow while others have a minimum airflow that activates the product;
- for cigars, ventilation may affect smoke constituents yields. Similarly, for HTPs, ventilation may affect smoke constituent yields (Ref. 69);
- for ENDS, the battery and PDU voltage may affect the heating element, thereby affecting toxicant emissions and nicotine delivery (Refs. 81–84). Similarly, for HTPs, the battery and PDU voltage impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 85). In addition, it gives an idea of the temperature users will encounter;
- for ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 60 and 86). Similarly, for HTPs the temperature sensor is a safety feature that allows the product power to be cut off to ensure the product does not get too hot, causing the battery to vent or harm the user;
- for cigarettes, wrapper length and width may affect puff count and smoke constituents yields (Ref. 71). Similarly, for HTPS material wrapper length and width may directly influence the area through which the air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields (Ref. 71);
- for cigarettes, wrapper basis weight may affect puff count and smoke constituents (Ref. 71 and 72). Similarly, for HTPs, the material wrapper basis weight may affect puff count and smoke constituent yields;
- for cigars, the cigar wrapper porosity may affect smoke constituent yields (Refs. 72 and 73). Similarly, for HTPs, the material porosity may affect smoke constituent yields;
- for waterpipe, the heating source may affect smoke constituent yields. Similarly for HTPs, the heating element source (or a description of the type or approach) provides information on the type of heated tobacco product, such as a coil applied to the product;
- for ENDS, the temperature of the heating element can affect the chemical and physical characteristics of the aerosol delivered to the user (Refs. 81–84). Similarly for HTPs, the temperature of the heating element (heating element temperature range, operational temperature, maximum temperature) can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in heating element temperature can increase HPHC levels in the aerosol; therefore, maximum heating element temperature and temperature control deviation from this maximum heating element temperature can affect toxicant emissions and nicotine delivery;
- for ENDS, the heating element temperature may affect toxicant emissions and nicotine delivery (Ref. 84). Similarly, for HTPs, the heating element material can have a direct effect on the heat transfer to the e-liquid or tobacco, and in turn, affect the smoke constituent yields;
- for ENDS, the heating element configuration may affect toxicant emissions and nicotine delivery (Refs. 80–84). Similarly, for HTPs, the heating element configuration may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery;
- for ENDS, the heating element dimensions may affect toxicant emissions and nicotine delivery (Refs. 80–84). Similarly, for HTPs, the heating element dimensions such as length influences the overall surface area, which affects heating element resistance, which influences the heating element temperature;
- for ENDS, the heating element mass may affect toxicant emissions and nicotine delivery (Refs. 80–84). Similarly, for HTPs, the heating element mass influences the power delivery of the battery, and in turn, the heat applied to the e-liquid or tobacco, which affects the smoke constituent yields and in turn, affects the smoke constituent yields;
- for ENDS, the heating element location may affect toxicant emissions and nicotine delivery (Refs. 80–84). Similarly, for HTPs, the heating element location can affect nicotine emissions;
- for ENDS, the number of heating elements may influence the heating element temperature thereby affecting toxicant exposure and nicotine delivery

(Ref. 79). Similarly, for HTPs, the number of coils/heating element present can affect overall resistance and distribution of heat dissipation;

- for ENDS, the heating element diameter or gauge may affect toxicant emissions and nicotine delivery (Refs. 80–84). Similarly, for HTPs, the bigger the diameter of the heating element, the lower its resistance, and vice versa. Heating element resistance may influence heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery;
- for ENDS, the heating element resistance may affect toxicant emissions and nicotine delivery (Refs. 80–84). Similarly, for HTPs, the heating element resistance may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery;
- for cigars, tobacco filler mass may affect smoke constituent yields (Ref. 69). Similarly, for HTPs, the tobacco filler mass may affect smoke constituent yields;
- for cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 51 and 52). Similarly, for HTPs, the tobacco rod density may modify burn properties and smoke constituent yields;
- for cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 54). Similarly, for HTPs, tobacco moisture or oven volatiles may affect puff count.
- for cigarettes, tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 53). Similarly, for HTPs, tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 53);
- for e-liquids, the e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Refs. 88 and 89). Similarly, for HTPs, the e-liquid volume can affect the delivery of nicotine and other toxicants to the user;
- for e-liquids, the e-liquid viscosity can affect the electronic cigarette nicotine and other toxicant delivery to the user (Refs. 79 and 88). Similarly, for HTPs e-liquid viscosity impact the proportion of nicotine that is aerosolized. The e-liquid viscosity can affect the nicotine and other toxicant delivery to the user (Refs. 79 and 88);
- for ENDS, an increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions may lead to greater exposure to toxicant emissions (Ref. 83). Similarly, for HTPs the battery capacity is a measure of the charge stored by the battery. The higher the mAh rating, the higher the capacity of the battery and the longer it will last between charges. The longer the battery lasts, the more the user can inhale smoke constituents;
- for ENDS, the battery voltage operating range and PDU voltage operating range impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 85). Similarly, for HTPs, the battery and PDU voltage operating range or wattage impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes;
- for ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly, for HTPs, the battery current range gives an indication of the safe zone for the battery to charge and what is considered its normal operating region; if the battery levels go beyond the safe zone while charging, the battery could be damaged, which could cause harm to the user;
- for ENDS, the battery and PDU voltage impacts the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 85). Similarly for HTPs, the battery nominal voltage indicates how much current the battery can send out to the heating element. For the same resistance, a higher voltage will send more current (and more watts) to the heating element and it will produce more vapor. There is a link between voltage and capacity because vaping at a higher wattage will produce a higher current and that will reduce the amount of time you can vape between charges;
- for ENDS, an increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions may lead to greater exposure to toxicant emissions (Ref. 83). Similarly, for HTPs, the battery rating is a measure of the average amount of current the battery releases over time under normal use. Current may influence the heating element temperature, which in turn affects toxicant emissions and nicotine delivery. In addition, battery mAh rating provides an understanding of how long a battery will last and thus the product stability;
- for ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly for HTPs, the battery charging temperature limits gives insight on the safe range for battery charging temperatures and testing will show if the software of the battery can keep the battery in the safe zone;
- for ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly, for HTPs, battery discharge temperature limits give insight on the safe range for battery discharging temperatures and testing will show if the software of the battery can keep the battery in the safe zone;
- for ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly, for HTPs, the end of discharge voltage is the level to which the battery voltage or cell voltage can fall to before affecting the load. This helps to establish the life cycle of the battery;
- for ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly, for HTPs, the battery maximum charging current at which the battery can be charged continuously is usually defined by the battery manufacturer in order to prevent excessive charge rates that would damage the battery or reduce its capacity. Damage to batteries is a hazard to users;
- for ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly, for HTPs, the battery maximum discharge current at which the battery can be discharged continuously is usually defined by the battery manufacturer in order to prevent excessive discharge rates that would damage the battery or reduce its capacity. Damage to batteries is a hazard to users;
- for ENDS, the battery type, failure safety features, and battery conformance

to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly, for HTPs, the battery upper limits charging voltage is important to limit the maximum battery voltage during charging to prevent damage to the battery, which is a hazard to users;

- for ENDS, battery and PDU voltage can impact the total emissions of volatile aldehydes (Ref. 85). Similarly, for HTPs, the battery and PDU voltage impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 85);
- for ENDS, PDU current operating range and wattage range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 80 and 86). Similarly, for HTPS, PDU current operating range and wattage operating range may influence the heating element temperature thereby affecting toxicant emissions;
- for ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly, for HTPs, the PDU temperature cutoff is an electrical safety product that interrupts electric current when heated to a specific temperature to protect the user;
- for ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 58 and 86). Similarly, for HTPs, the current cutoff is an electrical cutoff, which is an electrical safety product that interrupts electric current when a specific condition is met (*i.e.,* temperature, current, etc.) to protect the user;
- for ENDS, the battery and PDU current operating range may influence the toxicant emissions (Refs. 82 and 84). Similarly, for HTPs, the batteries and PDU should have a normal current operating range so as to not overheat the product and cause it to become a hazard to the user. In addition, this current range has a direct impact on the heating element, which in turn affects the smoke constituent yields;
- inhaled aerosol temperatures can be damaging or uncomfortable to users who inhale aerosol above a certain temperature;
- for e-liquids, aerosol parameters such as particle number concentration, count median diameter, and particulate matter $(PM)_{2.5}$ are used to characterize the amount and size of particles to which the user is exposed (Refs. 93 and 94). Similarly, for HTPs, aerosol parameters such as particle number concentration, count median diameter, and $PM_{2.5}$ are used to characterize the amount and size of particles to which the user is exposed. Clinical studies have shown that exposure to large amounts of small particles can impair lung function and is correlated with cardiovascular disease;
- for cigarettes, filter efficiency may affect smoke constituent yields (Ref. 60). Similarly, for HTPs, filter efficiency effect smoke constituent yields;
- for cigarettes, filter pressure drop may affect smoke constituent yields (Ref. 61). Similarly, for HTPs, filter pressure drop may affect smoke constituent yields; and
- for cigarettes, filter diameter, DPF, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 60). Similarly, for the HTPs, the filter diameter, DPF, total denier, filter density, and filter length, may affect filter efficiency and, in turn, smoke constituent yields (Ref. 60).

FDA received comments regarding design parameters and test data, as required by § 1114.7(i)(2)(ii) and associated tables, as discussed below.

(Comment 44) One comment stated that the lists of product design parameters in § 1114.7(i)(2)(ii) do not reflect the subcategories of innovative tobacco products or nicotine delivery systems that exist in some of the product categories and that by requiring all parameters, FDA would have some applicants generate parameters that are not relevant to their particular subcategory. The comment suggested that FDA make the design parameters in these tables recommendations rather than required parameters.

(Response 44) FDA declines to make this change to the rule. FDA believes that design parameters are necessary to fully characterize a tobacco product and are an important consideration in determining its health effects. FDA agrees that the required lists of product design parameters in § 1114.7(i)(2)(ii) are not necessarily reflective of all subcategories of innovative tobacco products or nicotine delivery systems. However, table 1 to § 1114.7(c)(3)(iii) includes a list of tobacco product categories and subcategories, which should help the applicant to determine whether the rule includes an appropriate category and subcategory for its new tobacco product and the corresponding design parameters that must be submitted, where applicable.

(Comment 45) One comment stated that FDA should not require testing for nicotine dissolution in portioned smokeless tobacco because it does not represent the potential rate or amount of exposure. The comment also stated that because the pouch material for smokeless tobacco does not have nicotine, applicants should not be required to provide pouch material information.

(Response 45) FDA believes that nicotine dissolution testing is an effective mechanism for FDA to gain insight into product performance and relative differences in the likely experience of users. In addition, changes in pouch materials of portioned smokeless tobacco products may change the permeability of the pouch and the rate at which nicotine is released, which can affect the overall performance of the product, including the rate at which nicotine is released to consumers (Ref. 67). Additionally, a study using nicotine tablets with different polymer content shows that nicotine release can be affected by thickness and pore size of the material that encloses nicotine (Ref. 67). In this study, upon hydration, polymer in tablet formulations swells, forming a polymer gel layer and effectively acting as a permeable membrane. The tablets released nicotine at a rate controlled by swelling of the polymer followed by the diffusion through the swollen polymer gel layer. Polymer network gel swelling can affect material layer thickness (Ref. 141) and pore size (Ref. 142) which in turn can affect diffusion across the layer. Pouch materials are characterized by basis weight, air permeability, and thickness. Therefore, pouch material properties such as basis weight, air permeability and thickness are required to evaluate nicotine release from pouched smokeless tobacco products. Given the important information that nicotine dissolution testing and pouch material provide to FDA's review, FDA declines to remove the requirements for reporting pouch material information and nicotine dissolution testing in this PMTA rule.

(Comment 46) One comment stated that FDA needs to remove the proposed design parameters for cigars in § 1114.7(i)(2)(ii) from the rule and reassess its thinking as to the design parameters it requires and recommends for premarket review for cigars. The comment stated that the current proposed parameters for each type of cigar specified do not correspond to the actual design parameters that cigar manufacturers can or do use or test for

and, therefore, it would be impossible for applicants to provide the proposed parameters to FDA. The comment recommended that FDA require the reporting of design parameters only for cigar length, ring gauge, weight, and filter ventilation.

(Response 46) FDA declines to remove the design parameters for cigars. As described below, design parameters are needed to fully characterize the product and assess its impact on public health. Because these design parameters are an important component of being able to determine a product's health effects, FDA may refuse to accept or refuse to file a PMTA if it lacks design parameters information required by § 1114.7(i)(2)(ii). To ensure that FDA is able to fully determine the precise product being reviewed, FDA requires applicants provide all design parameters specific to the new product tobacco category. In an event that an applicant is unable to provide a design parameter listed in § 1114.7(i)(2)(ii) for the new tobacco product, the applicant must provide a justification and scientific evidence for why those design parameters are not relevant and do not raise public health concerns.

(Comment 47) One comment stated that it would be arbitrary and capricious to require manufacturers to submit the design parameters for pipes because the terms used are ones that pipe manufacturers neither know nor could they test for in pipes.

(Response 47) FDA disagrees with the suggestion that requiring pipe manufacturers to submit design parameters for their new tobacco products in PMTAs would be arbitrary and capricious. FDA believes that these design parameters are needed to fully characterize the product and assess its impact on public health. Because these design parameters are an important component of being able to determine a product's health effects, FDA may refuse to accept or refuse to file a PMTA if it lacks design parameters information required by § 1114.7(i)(2)(ii). For FDA to fully determine the precise product being reviewed and understand the potential health effects associated with the product, we are requiring that applicants provide all design parameters specific to the new product tobacco category. The design parameters required for pipes are measurable, and therefore test data should be easily obtained. Even if the design parameter names were not familiar to manufacturers, the manufacturers could supplement design parameter information by providing labeled images of their product that associate each component with the design parameter name used by the applicant or as discussed above, provide the information needed is with an MDSS document. FDA believes with the information provided in this rule, manufacturers should now be familiar with the required design parameters and can provide the necessary data. If FDA did not have the design parameters for the product it was reviewing, it would be unable to determine the precise product being reviewed, let alone whether the data and information contained in a PMTA are applicable.

(Comment 48) One comment stated that many of the items listed in the ENDS design parameters section apply to components or parts that do not provide a direct correlation to aerosol emissions when evaluated independently or individually. The comment suggested that measuring HPHCs is a better way to assess the product than by reviewing these design parameters.

(Response 48) Sections 1114.7(i)(1)(v) and (i)(2)(ii) require a PMTA to include both a full statement of the constituents, including HPHCs and other constituents, and of the design parameters for the new tobacco product because both provide information that is important for FDA's review. The design parameters are necessary to fully characterize the new tobacco product, which is important to FDA's accurately identifying and understanding of the product under review. As described elsewhere in this document, these design parameters can also affect the health risks of the new tobacco product. Information regarding the constituents contained in and delivered from the new tobacco product is also important because, as described in section VIII.B.13.a.iii, it directly correlates to the health risks of the new tobacco product.

(Comment 49) One comment stated that the costs associated with generating design parameter data exceeds the potential marginal benefit of the data to FDA's overall determination of whether permitting the marketing of the new tobacco product would be APPH. The comment stated that rather than providing information regarding a product's battery, it should just be able to provide a certificate of compliance with the Underwriters Laboratories 8139 standard, which would render further review of the battery by FDA superfluous. The comment also stated that even though information regarding the particles in the aerosol produced by e-cigarettes is relevant to lung and cardiovascular function, FDA does not need it to determine whether permitting the marketing of e-cigarettes would be APPH because they are far less harmful than combusted cigarettes.

(Response 49) FDA disagrees with the comment's suggestion that FDA should not require design parameters for ENDS. While FDA acknowledges there is cost associated with generating design parameter data, the design parameters of the product can change the health impact of the tobacco product by affecting the level of constituents that reach tobacco product users or nonusers and as such are an important part of the APPH determination. This information is also necessary to fully characterize a tobacco product. The differences in health risks that a new tobacco product may present compared to one other product category such as cigarettes is not, by itself, sufficient to demonstrate that permitting the marketing of a new tobacco product would be APPH. As explained in section IX.D., FDA interprets the APPH standard in 910(c)(2)(A) to require a showing that permitting the marketing of a new tobacco product would likely have at least a net benefit to public health based upon the risks and benefits to the population as a whole (which includes youth, young adults, and other vulnerable populations). Comparative health risk information is just one factor FDA may consider in making this determination. Additionally, a comparison to just one other product category may not be sufficient when current users of more than one product category may begin using the new tobacco product.

iii. Function. The rule requires the application to contain a description of how the product is intended to function. For example, this could include a description of how the energy or heating source is used in or with the product, and how the delivery of the product's output (*e.g.,* smoke, aerosol, nicotine) is controlled. This information can be critical to FDA's review of a tobacco product, including whether the product functions as intended and whether the application contains data and information that is relevant to the way in which it is intended to function. For example, if an applicant states that a product heats or aerosolizes, but does not combust tobacco or an e-liquid, it would assist FDA in determining whether the information in the PMTA shows the product functions as intended and whether the application contains appropriate information regarding this function (*e.g.,* data regarding relevant HPHCs).

iv. pH of product and nicotine formulation. The rule requires the PMTA to specify the pH of the product. The pH of the product is important for

FDA to review as part of a PMTA because it can affect the amount of unprotonated nicotine delivered to the user (Refs. 96 and 97).

The rule also requires the PMTA to specify the formulation of the nicotine in the product. The nicotine formulation information is required to state the type(s) and quantity of nicotine in the product. Type(s) of nicotine include, but are not limited to, unprotonated nicotine and nicotine salts (*e.g.,* nicotine lactate, nicotine benzoate, nicotine pyruvate). The quantity of unprotonated nicotine is important for FDA to review because the amount and speed of nicotine delivered by a tobacco product is related to the proportion of nicotine in a tobacco product that is unprotonated (Refs. 98 and 99). The types and quantities of nicotine salts in the product are important for FDA to review because nicotine salt complexes can substantially increase nicotine delivery relative to free-base nicotine in ENDS products (Refs. 100–102).

v. Fermentation process. For smokeless tobacco products and tobacco products that contain fermented tobacco (including naturally fermented tobacco), the rule requires an application to contain information on the fermentation process. The rule requires this information because the fermentation process can result in different degrees of change in the chemical constituents of the tobacco (Refs. 103–105) and affect the type and number of microorganisms in the final tobacco product, (Refs. 106–108) which could potentially affect the levels of TSNAs and stability of the tobacco products during storage. In addition, the type and amount of the fermentation inoculum can change the product as a result of directed fermentation (Ref. 109). Therefore, the application must contain the following information regarding the fermentation process:

- A description of the fermentation process;
- composition of the inoculum (starter culture) with genus and species name(s) and concentration(s) (if applicable);
- any step(s) taken to reduce microbes already present during product processing (*e.g.,* cleaning of product contact surfaces);
- specifications and test data for pH, temperature, and moisture content, or water activity;
- frequency of aeration or turning (if applicable);
- duration of fermentation;
- added ingredients;
- method used to stabilize or stop fermentation. If the applicant uses heat treatment, then it must provide the information specified in the following subsection. If an applicant uses a method other than heat treatment, it must provide the parameters of the method (*e.g.,* length of treatment, temperature) and method validation data; and
- storage conditions of the fermented tobacco prior to further processing or packaging and duration of storage (if applicable).

vi. Heat treatment process. In final rule, we have added a requirement for information on the heat treatment process, if applicable. For tobacco products that are heat treated, the rule requires an application to contain information on the heat treatment process. We have included this requirement for information because the heat treatment process can potentially reduce the microbial load, resulting in lower levels of carcinogenic TSNAs thereby altering product composition (*i.e.,* product characteristics) (Refs. 110–112). Therefore, the application must contain the following information regarding the heat treatment process:

- A description of the heat treatment process;
- the type of heat treatment;
- the conditions of heat treatment, including time, temperature, and moisture; and
- method validation data, including microbial loads (including bacteria, spores, yeast, and fungi) and TSNAs before and after heat treatment.

vii. Shelf life and stability information. In the proposed rule, § 1114.7(i)(2)(vii) would have required a PMTA for any category of tobacco product to contain tobacco product storage and stability information that establishes the microbial and chemical stability of the tobacco product throughout the stated shelf life. Upon review of public comments and further consideration, we are finalizing these requirements (with specified changes) for products other than cigarettes and RYO tobacco as explained in this section.

Shelf life and stability information is important for FDA's review of many tobacco products because bacterial communities and constituents in tobacco products can change over time (Refs. 107, 108, 113 and 114). Stability information is a particular concern with smokeless tobacco products and other tobacco products that contain fermented tobacco (including naturally fermented tobacco) because the characteristics of these products can be affected by the manufacturing process, storage conditions, and length of time on a shelf. Carcinogenic TSNA production is critically influenced by the microbial communities associated with the tobacco (Refs. 113 and 105). TSNA content in the finished tobacco products is greatly affected by a variety of factors, such as tobacco processing method(s) (*e.g.,* curing, aging, sweating, fermentation, and heat treatment), chemical additives added to control microbial activity (*e.g.,* humectants or preservatives), water activity (a_w) of the product, container closure system, and product storage conditions (*e.g.,* temperature, humidity), all of which could potentially alter microbial activity and, in turn, affect the stability of the tobacco products over the shelf life (Refs. 107, 108, 110, 113, 114, 115–120). Furthermore, some tobacco products such as smokeless tobacco products and e-liquids, have been shown to contain microbial cell wall constituents ([1→3]-β-D-glucan) and/or microbial toxins, such as aflatoxins and endotoxins (Refs. 121 and 122). These microbial components or toxins may result in increased risk to public health because they are either carcinogenic in nature or associated with the development of respiratory symptoms, reduced lung function, inflammation and asthma (Refs. 121 and 122). In addition, based on our experience, HTPs can contain high levels of humectants, which can affect product stability; therefore shelf life and stability information is required to support an application for HTPs. Humectants function to keep a product moist, thereby impacting the moisture content and water activity of the product, which in turn may impact microbial growth and product stability (Ref. 116). Thus, for many tobacco products, information obtained through stability testing and shelf life is important for FDA to consider during its review to ensure that the tobacco products are microbiologically and chemically stable during the storage and do not result in an increased risk to public health as the product sits in storage.

Under the final rule, applicants submitting a PMTA for cigarettes [29] and RYO tobacco products do not need to provide the shelf life and stability information under § 1114.7(i)(2)(vii). In our review experience, we have found that since the vast majority of cigarettes and RYO tobacco products do not contain fermented tobacco, these products generally do not present the same stability concerns as other tobacco products. Thus, after further consideration, FDA is not finalizing the shelf life and stability information

[29] See the discussion in section VIII.B.3. about how products should be categorized for purposes of PMTA review.

requirements for these products based upon its review experience with the product categories under the SE pathway. However, since we lack similar experience with novel tobacco products, such as ENDS and HTPs, we need stability information for these types of products to determine whether there is a difference in microbial factors or HPHC quantities over time. Given the Agency's lack of experience reviewing applications for novel tobacco products, at this time FDA believes information regarding these products' shelf life and stability over time is needed to ensure FDA fully understands the microbial and chemical stability of the tobacco products throughout their stated shelf life.

In addition, after review of available scientific information regarding stability testing as well as consideration of comments received in responses to the proposed rule, the stability testing requirements have been updated including changes such as the removal of identification of microbiological organisms by genus and species and removal of testing for pH, moisture content, nitrate and nitrite levels, and preservatives and microbial metabolic inhibitors. Specifically, the final rule requires an application to contain the following shelf life and stability information:

- The length of the shelf life, a description of how the shelf life is determined and a description of how shelf life is indicated on the tobacco product, if applicable. The rule would not require a tobacco product to indicate the product's shelf life; however, if it is indicated on the product, the PMTA must describe how it is determined. For example, if the tobacco product labeling has a ''use by,'' ''best by,'' or expiration date, a PMTA must contain a description of how the date is determined (*e.g.,* a certain number of days after packaging);
- stability date assessed at the beginning (zero time), middle, and end of the expected shelf life. If a tobacco product does not have a defined shelf life, provide stability data over a specified amount of time and a justification for why that time period is appropriate. For example, if an applicant believes that 2 years after the date of product manufacture is an appropriate shelf life, the applicant should provide clear justification to support this time. Stability testing must be performed for the chemical and microbial endpoints for the following items:
  - Microbial content data, including total aerobic microbial count and total yeast and mold count;
  - water activity (a_w);
  - TSNA yields (total N-nitrosonornicotine [NNN], and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone [NNK]); and
  - preservative content (if applicable).

If microbial activity during the product shelf life is detected, further information, such as endotoxin or aflatoxin levels, should be included in the PMTA.

Accelerated studies for chemical endpoints, combined with basic stability information on the components or parts and container closure system (separately), or the tobacco product (as a whole) may be used to support chemical stability of the tobacco product provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative shelf life that is beyond a date supported by actual shelf life studies, stability studies must be conducted under nonaccelerated conditions at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date is determined.

As required by § 1114.7(i)(4), the reported stability testing must be performed on test samples that reflect the final tobacco product composition and design (including the container closure system) and be conducted using a sufficient sample size and number of replicates to substantiate the results of the type of testing conducted. Section 1114.7(i)(4) also requires the application to contain the following information regarding stability testing:

- The mean quantity and variance with unit of measure;
- the number of samples and measurement replicates for each sample;
- the methods used, including a deviation(s) from the methods, associated reference(s), and full validation reports for each method;
- the name and location of the testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;
- the length of time between dates of tobacco product manufacture and date(s) of testing;
- the length of time between date of tobacco product manufacture and date(s) of testing;
- the storage conditions of the tobacco product before it was tested;
- a statement that the testing was performed on a tobacco product in the same container closure system in which the tobacco product is intended to be marketed; and
- full test data (including quantitative acceptance (pass/fail) criteria, complete data sets, and a summary of the results) for all stability testing performed.

FDA received several comments regarding shelf life and stability information, as discussed below.

(Comment 50) One comment requested that FDA clarify, with regard to shelf life and stability testing, whether changes to the product over time will form the basis of FDA's decision to issue a marketing denial order for a new tobacco product.

(Response 50) Product stability information is important for FDA to consider during its review because if a product changes over time, it may affect the health risks presented by the new tobacco product. As described in section IX.D, the health risks of a new tobacco product forms part of the basis for FDA's determination of whether it should issue a marketing granted order for the new tobacco product. This may include the health risks of a new tobacco product as it changes over time. For example, a product with a 24-month expiration date whose stability testing data demonstrates that the product may be unstable after manufacturing, with the levels of TSNAs (NNN and NNK) increasing significantly over the 24-month period shelf life above what is reasonably expected for similar products on the market, may raise additional health risks. Because NNN and NNK are carcinogenic to humans with no safe level of exposure, the increased levels of TSNAs may increase the health risks to the users. Therefore, this type of stability testing information is important for FDA to consider during its review to ensure that the tobacco products are microbiologically and chemically stable, and the product remains APPH, over the product's shelf life.

(Comment 51) One comment stated that where a product does not have an established shelf life, the rule should require an applicant to report stability data using the upper bound length of time the product will remain in storage, such as the upper 95 percent confidence interval, rather than relying on the typical period of time in which a product is sold to consumers, which it interprets to be the median time. The comment also stated that the rule should be amended to require applicants to provide regular postmarket reports on how much product has been removed because it was in storage for too long and how that product was disposed of.

(Response 51) FDA disagrees with this comment. As discussed elsewhere in this document, a PMTA is required to contain product storage and stability information that establishes the microbial and chemical stability of the product throughout the product's shelf life. For tobacco products with no established or defined shelf life, FDA recommends that applicants provide details of stability over a specified amount of time and justify why that time period is appropriate. This time period should correspond to the expected storage time of the tobacco product after the date of manufacture of the product until it is sold to consumers, as determined by the applicant. This information is product-specific, and the burden is on the applicant to show that the product is stable for the entire duration determined by the applicant. Since the expected storage time is product-specific, FDA declines to establish requirements for postmarket reports regarding product removal or disposal for all products. FDA will monitor the marketing of the product, including review of periodic reports required under § 1114.41, to determine whether there are product stability issues that were not addressed in the PMTA.

(Comment 52) One comment stated that FDA's approach for stability testing for microbiological endpoints in the form of total aerobic microbial count (TAMC), total yeast and mold count (TYMC), and testing for specific microbial organisms is not aligned with current scientific approaches. The comment also noted that the proposed testing requirements are not aligned with the current scientific approaches in addressing microbiological quality in various industries (*e.g.,* pharmaceuticals), which take into consideration the importance of water for microbiological proliferation. The comment suggested that applicants should be allowed to adopt a risk-impact assessment-based approach, whereby results of a toxicological assessment of the product taking into account its composition, manufacturing process, and typical supply chain conditions shall be used by the applicant to define and execute a stability program appropriate for the product category. The comment stated that in particular, with regards to risks associated with potential microbiological activity, scientifically justified surrogate factors can be employed such as water activity (a_w). The comment concluded by stating that FDA should not employ a one-size fits all approach for different categories of tobacco products.

(Response 52) FDA disagrees with this comment. During review of a PMTA, FDA evaluates stability of the finished tobacco product during storage. To determine the microbial and chemical stability of a tobacco product during the expected storage period, FDA evaluates the cumulative effect of all factors, such as tobacco processing (*e.g.,* fermentation, heat-treatment, curing), product composition (*e.g.,* humectants, preservatives, certain flavor compounds, metabolic inhibitors), a_w of the finished tobacco product, container closure system, and product storage conditions (*e.g.,* temperature, humidity), that could potentially affect the stability of the product during storage. A_w is a measure of the amount of water that is available for microbial growth in a product. Therefore, it only provides information on the potential of a product to support growth of microbes present in the product. Fresh tobacco leaves are colonized by a variety of microorganisms. Additionally, microbial contamination could potentially occur during tobacco processing, finished tobacco product manufacture, and/or storage. Some tobacco products such as smokeless tobacco products and e-liquids, have been shown to contain microbial cell wall constituents ([1→3]-β-D-glucan) or microbial toxins, such as aflatoxins and endotoxins (Refs. 121 and 122). These microbial components or toxins may result in increased risk to public health because they are either carcinogenic in nature or associated with the development of respiratory symptoms, reduced lung function, inflammation and asthma. Therefore, TAMC and TYMC data provide crucial information on the microbial load in the finished tobacco product and serve as an indicator for the potential of presence or absence of microbial toxins in the product. Additionally, a_w levels are influenced by several factors (*e.g.,* humectant levels, container closure system, storage conditions) and could potentially change during storage. TAMC and TYMC data are important to corroborate changes in a_w during storage and therefore crucial in evaluating the stability of the finished tobacco product during storage. FDA will evaluate shelf life and stability information of each tobacco product as part of its APPH determination.

(Comment 53) Two comments expressed additional concerns about the breadth of information required to be submitted regarding the stability of smokeless tobacco products. One comment disagreed with the proposed requirement to include analytical measurements of pH, moisture content, a_w, TAMC, TYMC, nitrate, nitrite, preservatives, and microbial metabolic inhibitors in stability studies for new smokeless tobacco products. The comment stated that because the ultimate endpoint of stability testing is to determine whether TSNA formation occurs over time, assessment of these additional parameters is burdensome, resource intensive, and unnecessary. The comment noted that not only would they have to develop validated methodologies and find laboratories to conduct the testing, the analysis of the proposed parameters would only indicate favorable conditions for increases of TSNAs and would not yield a change in total TSNAs, which are also being measured. Another comment expressed similar concerns and disagreed with the requirement to provide microbial content data that identifies detected microbiological organisms by genus and species names because it would be costly and time intensive, yield highly variable results depending on the method used, and would not alter the presence of TSNAs in the tobacco product as measured at each stability timepoint.

(Response 53) FDA has revised section § 1114.7(i)(2)(vii) of the codified to include a_w, preservative content, TSNAs (reported as separate amounts for the total TSNAs, NNN, NNK) and microbial content data including TAMC and TYMC along with identification of microbiological organisms by genus and species names. FDA disagrees with the statement that the parameters would only indicate favorable conditions for increases of TSNAs and would not yield a change in total TSNAs. Microbial-mediated reduction of nitrate results in production of nitrite, which further reacts with alkaloids present in tobacco to produce carcinogenic TSNAs (Refs. 107 and 113). Microbial-mediated nitrite production is a key determinant of TSNA levels in the final tobacco product. Several nitrate-reducing bacterial species (*e.g., Bacillus, Enterobacter, Staphylococcus, Corynebacterium, Escherichia*) and fungal species (*e.g., Candida, Fusarium, Aspergillus, Alternaria*) that are active across a wide temperature and pH range have been identified in smokeless tobacco products (Refs. 107, 113, and 123). During tobacco processing and storage, these nitrate-reducing microbial species could potentially convert nitrate to nitrite resulting in increases in TSNA levels thereby affecting product stability during storage. It is important for FDA to evaluate all of the factors that affect

microbial growth and determine if any increases in TSNAs over tobacco product storage are microbial-mediated. This information ensures that the tobacco product is microbiologically and chemically stable during the expected storage period and does not result in an increased risk to public health as the product sits in storage.

viii. Product and packaging design risks and misuse hazards. This section of an applicant's PMTA is required to contain a review and assessment of reasonably foreseeable risks associated with the design of the tobacco product and its packaging that may occur during normal use of the tobacco product or during any foreseeable misuse of the product, including user error, which may cause illness, injury, or death not normally associated with the use of the tobacco product. The review and assessment must identify the measures taken to reduce or eliminate each risk associated with the design of the tobacco product and packaging. Examples of these design risks include, but are not limited to: (1) Defects in the air permeability of fire standards compliant banding on cigarette paper that is intended to allow cigarettes to self-extinguish when left unattended; (2) software errors or flaws (*i.e.,* bugs) that occasionally result in the product performing differently than designed; (3) failure of a safety switch to shutoff a product if it exceeds a certain temperature; and (4) the failure of a battery design feature to prevent battery from overcharging. The PMTA must contain a review and assessment of each defect, describing the potential to cause illness, injury, or death and the measures taken to reduce or eliminate the defects and their potential impact. FDA is requiring this information under section 910(b)(1)(G) of the FD&C Act, because the potential for the product design or foreseeable misuse to cause illness, injury, or death provides information that informs FDA's determination of whether permitting the marketing of the product would be APPH.

FDA received one comment regarding product and packaging design risks and misuse hazards, as discussed below.

(Comment 54) One comment stated that applicants should not be required to report or assess the ways in which a tobacco product could be misused because requiring companies to do so would require judgments that are so wildly subjective that the results are unlikely to be valid or relevant.

(Response 54) FDA disagrees with this comment. As discussed above, a PMTA would not be required to contain information regarding all potential misuses; rather it would be required to contain an identification and assessment of foreseeable misuses. Prospective applicants should review section VII.13.a, which explains the ways in which applicants can include this type of information, including information bridged from investigations on similar products.

10. Principles of Operation

Section 1114.7(i)(3) describes FDA's interpretation of the full statement of the principle or principles of operation required by section 910(b)(1)(B) of the FD&C Act and requires the PMTA to contain full narrative descriptions of:

- The way in which a typical consumer will use the new tobacco product. This includes a description of how a consumer operates the product, how long a single unit of the product is expected to last (*e.g.,* total length of time of use to consume a unit, number of use sessions expected per unit), and where applicable, whether and how a consumer can change the product design and add or subtract ingredients, such as:
  - E-cigarettes that allow users to change performance features, such as the temperature, voltage, or wattage;
  - e-cigarettes that allow users to add or subtract e-liquid ingredients, such as liquid nicotine and flavoring, including instances where such manipulation is not intended by the manufacturer (*e.g.,* ways to misuse the product);
  - e-cigarettes that allow users to add, subtract, or substitute components or parts other than identical replacement parts; and
  - waterpipes that allow users to add, subtract, or substitute components or parts other than identical replacement parts, such as stems and hoses;
- a justification for an applicant's determination of what constitutes a single unit of product as described in the PMTA; and
- whether the product incorporates a heating source and, if it does, a description of the heating source.

FDA received several comments regarding these provisions, as discussed below.

(Comment 55) FDA received multiple comments in response to its request for comment regarding how the rule should require measurement of the length of time it takes a user to consume a single unit of the product. One comment stated that FDA should not require any such measurements with respect to e-cigarettes because it is the overall exposures to HPHCs from repeated use of a product that informs health risks, not the use of a single unit. Another comment had specific suggestions as they relate to ENDS, stating that for a closed ENDS, a single unit should be the amount of e-liquid in the closed ENDS; for an open ENDS, a single unit should be the amount of liquid required to fill the reservoir; and for open e-liquids, a single unit should be 2 milliliters (mL) of e-liquid regardless of the container size.

(Response 55) FDA agrees that the overall exposures to HPHCs from repeated use of a product provide the most relevant information about health risk. However, because the overall exposures come from an accumulation of individual use sessions over time, it is important for FDA to understand how the new tobacco product is likely to be used by a typical consumer in an individual use session as well as how frequently they use the product (including variable use behaviors within sessions and over time). It is also important to fully characterize the product so that FDA can determine the differences in health risks between the new tobacco product and other similar products on the market. Therefore, FDA declines to exempt e-cigarettes from reporting the length of time it takes for a user to consume a single unit of product.

In terms of what should constitute a single unit for an ENDS, FDA agrees with the comment's suggestions and recommends that applicants consider a closed e-cigarette, such as a prefilled disposable cigalike, or closed e-liquids, like cartridges or pods that are not intended to be refillable, to constitute a single unit. For an open e-cigarette, applicants consider a single unit to be the amount of e-liquid required to fill the reservoir. FDA believes these measurements of a single unit are appropriate because they are a consistent unit of measure set by the manufacturer that could be useful in providing meaningful information about product use; however, for open e-liquids, differences in how consumers use the product may make a different unit of measure more appropriate. Therefore, for open e-liquids, it may be more appropriate to consider the volume of e-liquid required to fill the container to be a single unit, rather than 2 mL of e-liquids. Due to product variability and associated differences on what may be appropriate as a single unit of a tobacco product, FDA declines to set a required unit size and requires applicants to provide a scientific justification for why the single unit used for the new tobacco product is appropriate.

11. Product Testing and Analysis Information

Section 1114.7(i)(4) requires that all testing and analyses of the tobacco product required in § 1114.7(i) be performed on test samples that reflect the final tobacco product composition and design, and that they be conducted using a sufficient sample size and number of replicates to substantiate the results of the type of testing conducted. This is required under FDA's authority in section 910(b)(1)(G), because the testing requirements are relevant to the subject matter of the application in that they help FDA determine whether the product testing and analyses are accurate and reliable. If the product that is the subject of the PMTA is a component or part, testing and analyses of the product should be performed with a range of other components or parts with which a consumer is expected to use the product (*e.g.,* an e-liquid should be tested in a representative sample of e-cigarettes in which it is may be used).

Additionally, the applicant must provide the following information about the testing and analysis:

- The name and location of the testing laboratory or laboratories and documentation showing that the laboratory is (or laboratories are) accredited by a nationally or internationally recognized external accreditation organization;
- the length of time between dates of manufacture and date(s) of testing;
- the storage conditions of the tobacco product before it was tested;
- the number of samples and measurement replicates for each sample;
- description of method procedure, method validation information and rationale for selecting each test method, including relevant voluntary testing standards;
- reports of all product formulation testing, including line data, test protocols, quantitative acceptance criteria, and a summary of the results, for each applicable parameter. Please note that an applicant must retain source data under § 1114.45; and
- complete descriptions of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable. Where the applicant is not using a widely recognized and standardized regimen, such as the ISO or HCI regimens, the PMTA must contain a complete description of the regimen.

FDA received one comment regarding constituents and stability testing, as discussed below.

(Comment 56) One comment stated that the final rule must provide greater detail regarding method validation and the number of samples and measurement replicates required for constituent and stability testing.

(Response 56) FDA declines to set requirements for a specific number of samples and replicates because the type of product and methodology of testing will vary for a PMTA and the sample size and number of replicates necessary to substantiate the type of testing may vary. Thus, FDA does not find it appropriate to establish specific requirements for testing in terms of validation methodologies, and the number of samples and replicates at this time. While FDA generally recommends testing across three batches with seven replicates per batch as advised in the ENDS PMTA Guidance, varying numbers of batches and replicates may be required to substantiate the results of testing. FDA recommends that the validation report include sufficient information to demonstrate method efficiency, specificity, sensitivity, accuracy, and precision needed for the intended purpose. In addition, FDA recommends that a PMTA contain an explanation of why the information used for testing is sufficient to support the reliability of the results, representative of their products, and does not cause public health concerns.

12. Manufacturing

Section 910(b)(1)(C) of the FD&C Act requires a PMTA to contain full descriptions of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, the tobacco product. Section 1114.7(j) provides FDA's interpretation of this requirement, together with its authority under section 910(b)(1)(G) of the FD&C Act, stating that these descriptions must include information regarding all manufacturing facilities, include descriptions of design controls, and be sufficiently detailed to demonstrate that the product meets manufacturing specifications and can be manufactured in a manner consistent with the information submitted in the PMTA.

Additionally, because FDA must, under section 910(c)(2)(B) of the FD&C Act, deny a PMTA that does not demonstrate compliance with regulations issued under section 906(e) of the FD&C Act, the descriptions contained in the manufacturing section must demonstrate the means by which the processes comply with any applicable tobacco product manufacturing practices regulation issued under section 906(e). FDA has not yet issued a regulation under section 906(e) of the FD&C Act, so demonstrating compliance with such regulations is not currently required; however, FDA intends to issue regulations under section 906(e), and once such regulations are effective, applicants must demonstrate that their methods, facilities, and controls comply with that rule to receive a marketing granted order under section 910(c)(1)(i)(A) of the FD&C Act.[30] Until a final rule issued under section 906(e) of the FD&C Act is effective, FDA will evaluate the manufacturing process information and consider whether the product can be manufactured in a manner consistent with the information submitted within the application as part of its determination of whether the marketing of the new tobacco product would be APPH. As part of this evaluation, FDA may conduct inspections as described in § 1114.27 to verify the information and data submitted in the application.

FDA received one comment regarding this issue, as discussed below.

(Comment 57) One comment stated that the proposed manufacturing information requirements in § 1114.7(j) exceed FDA's statutory authority because they constitute the equivalent of a current good manufacturing practice that must be issued in accordance with the process specified in section 906(e) of the FD&C Act. The comment further stated that FDA would, in effect, be requiring that applicants demonstrate to its satisfaction that a new tobacco product conforms with manufacturing criteria as precondition to placing that product on the market. The comment requested that FDA significantly revise § 1114.7(j) and establish regulations in accordance with section 906(e) of the FD&C Act.

(Response 57) FDA disagrees with the comment's conclusory assertion that requiring the submission of information regarding whether an applicant can manufacture the product described in its application constitutes manufacturing practice requirements.

[30] In establishing the effective date of a regulation under section 906 of the FD&C Act, FDA must provide for a ''reasonable period of time for . . . manufacturers to conform to good manufacturing practices,'' and small tobacco product manufacturers will have at least 4 additional years to comply. See section 906(e)(1)(B) of the FD&C Act. FDA anticipates that manufacturers preparing PMTA applications before any regulation under 906(e) is finalized will have sufficient time to prepare applications that demonstrate that their methods, facilities, and controls comply with such a rule before the applicable effective date. For PMTA applications submitted before any regulation under 906(e) is finalized, FDA generally expects the review of such applications will be concluded prior to the effective date.

Section 906(e) requires that FDA, in applying manufacturing restrictions to tobacco, follow a prescribed process to require manufacturers to conform to current good manufacturing practices (CGMP) or hazard analysis and critical control point (HACCP) methodology. In issuing section § 1114.7(j), FDA has neither created a requirement to conform to a CGMP or HACCP methodology, nor set forth any manufacturing practice requirements; rather, FDA has created a requirement to submit information about the manufacturing process and has identified the level of detail of such information that must be submitted in the application. Drawing upon its experience with CGMP and HACCP regulations for other regulated products, such as medical devices, FDA has embraced a similar flexible approach that does not prescribe in detail how a manufacturer must produce a specific tobacco product but rather provides a framework to provide detailed information regarding the manufacturing of a specific product.[31] As described in the following paragraphs, the process by which a tobacco product is manufactured is important to FDA's determination of whether a new tobacco product is APPH because it demonstrates the likelihood that the tobacco product that will ultimately be used by consumers meets the specifications set forth in the PMTA.

The information required under § 1114.7(j) is based on FDA's interpretation of the manufacturing information required by section 910(b)(1)(C) of the FD&C Act as supplemented by FDA's section 910(b)(1)(G) authority. The statutory requirement to submit manufacturing information under section 910(b)(1)(C) of the FD&C Act exists independently of the requirements in section 906(e) of the FD&C Act and FDA is in no way required to create a rule under section 906(e) before requiring the submission of manufacturing information and reviewing it as part of a PMTA. Only once FDA issues a regulation under section 906(e) of the FD&C Act would an applicant have to demonstrate it complies with any manufacturing practice requirements established by FDA.

The process by which a tobacco product is manufactured is important to FDA's determination of whether a new tobacco product is APPH because it demonstrates the likelihood that a tobacco product will be manufactured in accordance with the specifications set forth in the PMTA. A tobacco product that fails to conform to the PMTA's specifications, referred to as a ''nonconforming tobacco product,'' could result in a defective product and increase the product's risk compared to what would normally be expected from use of the product as characterized in the PMTA. Additionally, a nonconforming tobacco product constitutes a different tobacco product than the one authorized in the marketing granted order, which would render a nonconforming tobacco product adulterated under section 902(6)(B) of the FD&C Act. A nonconforming tobacco product can be the result of a number of issues, including design defects, failures of or problems with purchasing controls, inadequate process controls, improper facilities or equipment, inadequate training, inadequate manufacturing methods and procedures, or improper handling of the tobacco product.

Nonconforming tobacco products have been highlighted in the news. For example, in 2017, a manufacturer of smokeless tobacco products issued a voluntary recall of certain products after receiving complaints of foreign metal material, including sharp metal objects, in its smokeless tobacco products. After the recall, the manufacturer investigated whether the contamination was a result of the manufacturing practice or a deliberate act by an individual to contaminate the product. FDA is also aware of other instances where smokeless tobacco products contained rocks or metal shavings as well as other nontobacco related materials (NTRMs) (*e.g.,* glass, nails, pins, wood, dirt, sand, fabric, cloth, and plastics) in finished tobacco products. These NTRMs can cause cuts or lacerations to the lips and gums or result in broken teeth.

FDA also has observed during inspections that tobacco product manufacturers have received complaints regarding nonconforming tobacco products that contain contaminants and hazards such as biological materials (*e.g.,* mold, mildew, hair, fingernails) and chemical hazards (*e.g.,* ammonia, cleaning agents, and kerosene). Caustic cleaning chemicals may cause the consumer to experience adverse health effects not normally associated with tobacco use, such as vomiting, nausea, allergic reactions, dizziness, numbness, or headaches.

Nonconforming tobacco products may also contain higher levels of a constituent than the consumer is expecting and that the product is supposed to have as characterized by the PMTA, which may result in increased risks to health. For example, FDA is aware of the variability of nicotine among certain ENDS products and that the labeling may not accurately reflect the actual levels of nicotine in those products. In one study, researchers found that actual nicotine amounts differed from labeled amounts by more than 20 percent in 9 out of 20 original e-cigarette cartridges tested, and in 3 out of 15 refill cartridges tested (Ref. 124). FDA has observed on inspections that some e-liquid manufacturers do not have established procedures to conduct activities or maintain records of their manufacturing processes, including but not limited to calibration of equipment, documenting the identity or purity of their ingredients, and testing final product to confirm that it meets established specifications such as the concentration of nicotine. A finished ENDS product that contains a nicotine concentration higher than the established specification can be more addictive (Refs. 125 and 126). Similarly, a cigarette that does not conform to its pH specification can deliver nicotine in a different speed and amount to the user which can impact the tobacco product's toxicity and addictiveness (Ref. 59). Exposure to nonconforming products in this circumstance can result in user exposure to increased levels of nicotine, which can lead to increased addictiveness.

Nonconforming products may also contain defects that can cause the tobacco product to be more harmful. For example, an ENDS product may have a defect that contributes to an increased risk of fire and/or explosion. The ENDS product, during use or foreseeable misuse, can expose consumers to increased harm if the device catches fire or explodes resulting in serious burns that would not be expected from use of the product (*e.g.,* Ref. 127).

Given the dangers associated with nonconforming (including contaminated) tobacco products, FDA will evaluate an applicant's manufacturing process information to help determine whether the marketing of a new tobacco product would be APPH, specifically considering whether the manufacturer explains controls it would establish and maintain to prevent the manufacture and distribution of nonconforming products that may have an adverse effect on public health.

The manufacturing section of a PMTA must contain the following information in the manufacturing section to meet the requirements of § 1114.7(j) and to help FDA determine if it conforms to the requirements of section 906(e) of the

[31] See *e.g.,* Medical Devices; Current Good Manufacturing Practice (CGMP); Final Rule, 61 FR 52601 (October 7, 1996).

FD&C Act, when regulations are in effect:

- A listing of all manufacturing, packaging, storage, and control facilities for the product, including the name, address, and FEI number for each facility, if applicable, and a contact name and telephone number for a representative from each facility;
- a narrative description, accompanied by a list and summary of all standard operating procedures (SOPs) and examples of relevant forms and records for the following categories of information for all manufacturing, design controls, packing, and storage for the tobacco product:
  - Manufacturing and production process activities at each establishment, including a description of each establishment, all production steps, process controls, process specifications with relevant acceptance criteria, and monitoring and acceptance activities;
  - managerial oversight and employee training related to the manufacture, processing, packing, and installation of the tobacco product, as applicable;
  - monitoring procedures and manufacturing controls for product design, product characteristics, and changes in products, specifications, methods, processes, or procedures, including a hazard analysis that details the correlation of the product design attributes with public health risk, as well as any mitigation strategies implemented;
  - activities related to identifying and monitoring suppliers and the products supplied (including, for example, purchase controls and product acceptance activities);
  - handling of complaints, nonconforming products and processes, and corrective and preventative actions;
  - testing procedures carried out before the product is released to market, including:
- A list and summary of any standards used for all testing methods;
- validation or verification activities for all test methods used to ensure that the tobacco product meets specifications;
- documentation of accreditation information for all testing laboratories;
- complete description of smoking or aerosol-generating regimes used for analytical testing, if any;
- tobacco product specifications (including any physical, chemical, and biological specifications) and acceptance criteria for those specifications; and
- reports of release testing performed on finished products to demonstrate conformity with established specifications, including test protocols, line data, and a summary of the results for each applicable testing.

13. Health Risk Investigations

Under section 910(b)(1)(A) of the FD&C Act, a PMTA must contain full reports of all information, published or known to, or which should be reasonably known to, the applicant concerning investigations which have been made to show the health risks of the tobacco product and whether the tobacco products present less risk than other tobacco products. Section 1114.7(k) sets forth FDA's interpretation of this requirement, together with its authority in section 910(b)(1)(G), in three parts: (1) The types of investigations that are considered investigations into the health risks of the product and whether the tobacco product presents less risk than other products; (2) the documentation an application must contain to demonstrate that the application contains all published investigations; and (3) the information that constitutes a full report of an investigation.

a. Types of Investigations and Analyses

i. Interpretation of statutory language. FDA interprets the information required under section 910(b)(1)(A) of the FD&C Act, together with its authority under section 910(b)(1)(G) of the FD&C Act, to include the health risk investigations specified in § 1114.7(k)(1). Under the rule, applicants must submit full reports (as described in § 1114.7(k)(3)) of all information, both favorable and unfavorable, published or known to, or which should reasonably be known to, the applicant regarding the types of investigations described in § 1114.7(k)(1). Applicants are required to submit full reports of these investigations, regardless of whether they support or are adverse to the application, or are conducted within or outside the United States.

Section 1114.7(k)(1) requires an application to contain health risk investigations that are published, known to, or should reasonably be known to an applicant. This requirement ensures that FDA understands the full scope of the health risk investigations for a new tobacco product.

Section 1114.7(k) interprets section 910(b)(1)(A) of the FD&C Act broadly to ensure FDA has a complete understanding of the existing information about a new tobacco product; it does not set requirements for specific studies that must be contained in every single PMTA. The description of the issuance of marketing denial orders (§ 1114.33), discussed in section VIII.E, describes circumstances where FDA intends to issue a marketing denial order. The description of the issuance of marketing order (§ 1114.31) in section VIII.D contains information regarding FDA's determination of whether there is a showing that the marketing of a new tobacco product would be APPH.

FDA received many comments regarding this provision, as discussed below.

(Comment 58) Multiple comments expressed concerns about what they consider to be the breadth of the information required by proposed § 1114.7(k)(1). One comment stated that FDA should define the scope of health risk investigations that must be submitted in every PMTA so that applicants know exactly what to present in a PMTA and to reduce potential burdens on both applicants and FDA. Another comment interpreted the proposed rule as requiring information regarding investigations for each of the topics described in § 1114.7(k)(1) and requested that FDA provide information about the expected design of these studies as well as details regarding the ranges of acceptable approaches to provide consistency and reliability to the PMTA review process.

(Response 58) FDA has made edits to the codified to further clarify that FDA is not requiring an applicant to conduct an investigation into each individual topic in § 1114.7(k)(1). As described throughout this document, a PMTA must contain at least some amount of substantive information regarding each of the topic areas in § 1114.27(b)(1)(ii) to be filed for substantive review. Additionally, a PMTA must contain full reports of all investigations that are published or known to, or which should reasonably be known to an applicant, concerning the topics in § 1114.7(k)(1) to be filed for substantive review. FDA generally expects that applicants will be able to meet the substantive information requirement in § 1114.27(b)(1)(ii) by submitting investigations that are published or known to, or which should reasonably be known to, an applicant under § 1114.7(k)(1); however, in the event an application is lacking required substantive information, an applicant may need to conduct its own investigation to meet the filing requirements.

(Comment 59) Other comments stated that FDA is providing too much flexibility for applicants and should instead require applicants conduct specific types of studies, allowing for exceptions only where an applicant can demonstrate that a specific type of information is not applicable.

(Response 59) We decline to require that an applicant conduct a list of new studies as part of every application under this rule because there may be other ways in which an applicant can provide scientific information to inform FDA's review (*e.g.,* bridging, published literature). Additionally, while a PMTA must contain substantive information regarding certain categories of information set forth in § 1114.27(b)(i)(ii) to be filed by FDA as described in section VIII.B, an applicant has some flexibility in determining how to use existing information to support a PMTA for their product and what types of additional investigations it may need to conduct to provide FDA with information that demonstrates that permitting the marketing of its new tobacco product would be APPH. For example, information about known problems and risks related to mouth ulcers in moist tobacco products would be informative and could be used to extrapolate known health risk information for a related type of product that is the subject of the PMTA submitted to FDA. Applicants may want to review the areas of scientific investigation listed in § 1114.31 to determine whether there are gaps in the existing scientific information regarding its product that it may need to fill by conducting a new study regarding its tobacco product. As discussed in the description of § 1114.31 in section VIII.D, acceptance and filing of a PMTA does not mean that it has sufficient scientific information necessary to obtain a marketing granted order.

(Comment 60) Another comment stated that FDA's interpretation of section 910(b)(1)(A) of the FD&C Act set forth in § 1114.7(k) is both unclear and is potentially limitless in scope. The comment noted that the requirements in § 1114.7(k)(1) go far beyond the information that is required to be submitted for other products regulated by FDA, such as the requirements for new drug applications. The comment recommended that rather than requiring information concerning the product under the range of conditions under which the product might be used, FDA should revise the rule to focus on normal, customary, and ordinary conditions of use and permit the use of customary scientific methods, such as bracketing and dose response curves, to provide such information to FDA.

(Response 60) FDA declines to revise § 1114.7(k) in response to the comment and disagrees with the claim that it is potentially limitless in scope. Unlike the premarket approval standard for drugs or devices, which requires the submission of information to show whether a drug or device is safe and effective, section 910(b)(1)(A) of the FD&C Act requires applications to include information regarding the health risk of the tobacco product and whether the product presents less risk than other tobacco products. As discussed in section VIII.B.13.a, FDA interprets the information required under section 910(b)(1)(A) of the FD&C Act, together with its authority under section 910(b)(1)(G) of the FD&C Act, to include the health risk investigations specified in § 1114.7(k)(1). This requirement ensures that FDA understands the full scope of the health risk investigations for a new tobacco product as well as provides FDA with crucial information when determining whether permitting the marketing of the new tobacco product is APPH.

FDA also declines to limit the required submission of information to just what the applicant considers to be normal, customary, and ordinary conditions of use because understanding the full range of conditions under which a product may be used, including the potential for misuse, is important to determining the health risks posed by a new tobacco product. For example, in ENDS products, the heating element configurations and the number of heating elements have been known to be modified. Another misuse that has occurred includes modifying the wicking materials and the amount of wicking materials in the ENDS product. Information such as whether an applicant's product design reduces the possibility that the product will be misused or used outside of ordinary conditions of use are an important part of demonstrating that the new tobacco product would be APPH.

(Comment 61) Another comment requested clarification regarding what constitutes information that is ''known to or which should reasonably be known to an applicant,'' suggesting that documentation of a search of its own files and a survey of its scientific staff should be sufficient. Multiple comments also requested that FDA amend § 1114.7(k)(2) to require that an applicant impose a reasonable time limit on searches of its own files and available literature, such as a limitation to what is currently available or what has recently been published (*e.g.,* within a specified time period).

(Response 61) FDA declines to adopt an interpretation of documents that should reasonably be known to an applicant as part of this rulemaking because it is likely to be a fact specific determination. FDA also declines to set a time limit for the literature search requirement because there is no such limitation in the statutory requirement to submit full reports of published investigations. Under § 1114.7(k)(2), the application must contain a description of the literature search performed, including the databases searched and the date searched, search terms, reasons for inclusion or exclusion of documents, and the strategy for study quality assessment. If, for example, an applicant limits the literature search to a certain time period, the applicant must include the reason for such limitation in their description of the literature search.

ii. General recommendations related to health investigations. The rule does not require an applicant to conduct any of its own studies for the purposes of the application acceptance and filing requirements in § 1114.27, except as necessary to meet the filing requirements of § 1114.27(b)(2)(ii). Should an applicant choose to do so, FDA is providing recommendations for consideration throughout this section of the preamble. In addition to recommendations for specific types of studies that follow, FDA is making recommendations for three general topics related to health risk investigations that may help an applicant prepare a PMTA in some instances: (1) Bridging data from an investigation conducted using a different product to the product that is the subject of the application; (2) choosing appropriate comparison products; and (3) using foreign data.

(Comment 62) One comment stated that because FDA is acknowledging the acceptability of ''bridging,'' ''comparison products,'' and ''foreign data,'' it should define these terms in the final rule, stating that it is not sufficient to just mention these terms in passing.

(Response 62) FDA declines to define the terms in the final rule. We believe the discussion of these topics and the associated recommendations that follow provide sufficient information to be useful to applicants in preparing PMTAs.

- Bridging

FDA recognizes that in preparing the health risk investigations section of a PMTA, an applicant may choose to use data from a study conducted using a different tobacco product in an attempt to demonstrate the health risks of the product that is the subject of the application. The submission of studies using different products is optional. Ideally, a PMTA will contain studies conducted with respect to the new tobacco product itself, but the bridging of data from a different product to the

new tobacco product that is the subject of the application may be feasible for a subset of products or for certain types of studies. If an applicant lacks data on the product from one or more of the types of studies listed in this section, the applicant could bridge data regarding another product, or an earlier version of the product where appropriate. For example, ''X-flavor'' e-liquids with nicotine concentrations ranging from 1 milligram per milliliter (mg/mL) to 24 mg/mL may be able to show the health risks of each of the e-liquids without having to conduct a unique study for each nicotine concentration of the ''X-flavor'' product if data from a subset of nicotine concentrations (*e.g.,* low, middle, high) of ''X-flavor'' products may be bridged to other nicotine concentrations of ''X-flavor'' products. Other examples where data from studies on a smaller number of products could potentially be bridged to a larger number of products include smokeless tobacco products available in various pouch sizes or e-liquids available in various container volumes.

FDA received multiple comments regarding bridging information in a PMTA, as discussed below.

(Comment 63) Multiple comments expressed concerns related to the use of bridging in a PMTA. One comment requested that FDA prohibit the use of bridging information from an investigation conducted using a different tobacco product to the new tobacco product that is the subject of the PMTA. The comment stated that specifically with regard to ENDS, even minor variations in e-liquids and battery outputs affect the production of toxicants. Another comment stated that the health effects of a given product can differ dramatically because of individual differences among consumers. Both comments suggested instead that FDA require applicants to conduct product-specific research. Another comment stated that FDA should issue a marketing granted order for a PMTA based on bridged data only where FDA concludes that there is compelling evidence that the differences between the product studied and the new tobacco product that is the subject of the application are immaterial to FDA's review of the application.

(Response 63) FDA declines to prohibit the use of bridging in a PMTA because it can be used to provide information that is relevant to FDA's review of a PMTA. Where an applicant chooses to bridge to data from a general study or a study conducted using a different tobacco product, it would need to provide a scientific rationale to justify why the study findings apply to its new tobacco product and any study limitations that may be relevant. Failure to provide a sufficient justification that such data can be used to evaluate the new tobacco product would result in FDA being unable to rely upon it in evaluating the PMTA. There may be circumstances when an applicant would need to submit additional substantive information, including bridging studies, as appropriate, to justify that the results of a general study or a study using a different tobacco product is relevant to evaluation of its new tobacco product. Where an applicant seeks to use information from a study conducted using a different tobacco product in the same product category, it may need to provide comparative product information or potentially a bridging study to show the results apply to its specific new tobacco product. For instance, if an applicant wants to use the results of an abuse liability study that was conducted on a different product, an applicant should justify how key similarities between the products (*e.g.,* product design, nicotine formulation and content) demonstrate the results of the study apply to its tobacco product. As another example, national surveys, such as the NYTS, provide information about trends in tobacco product use by youth and typically do so for product categories as a whole, rather than specific products. If an applicant intends to use such survey data to help show the likelihood of youth initiation with its product, it would need to explain why results about a product category in general apply to its specific product.

Another example of when a justification or a bridging study may be needed is when the location or region of a study differs from the intended locations or regions where the product will be used, which is further described in the foreign data section.

- Comparison Products

As part of FDA's consideration under 910(c)(4) of the FD&C Act of the risks and benefits of permitting the marketing of the new tobacco product to the population as a whole, including users and nonusers of tobacco products, FDA reviews the health risks associated with changes in tobacco product use behavior (*e.g.,* initiation, switching, polyuse, cessation) that may occur with the marketing of the new tobacco product. Applicants must compare the health risks of its product to both products within the same category and subcategory, as well as products in different categories as appropriate. Additionally, as likely users of a new tobacco product will vary dependent on the type of product, and product use patterns vary across different populations, the appropriate comparison product(s) may vary. When identifying the likely users of the product and appropriate comparator products, FDA recommends that applicants specifically consider product use patterns, including abuse liability and unintended use, among youth, young adults, and other relevant vulnerable populations. It is helpful for FDA to understand the applicant's rationale and justification for comparators chosen whether within the same category or different categories of tobacco products. This comparative health risk data is an important part of the evaluation of the health effects of product switching. As set forth in § 1114.27(b)(1)(ii), a PMTA must contain substantive information regarding comparative health risks to be filed for review.

Information about tobacco products in the same category or subcategory is important to FDA's evaluation of a tobacco product's potential effect on public health because current users may switch to other products within the same category. When determining an appropriate comparison product within the same category or subcategory of product, FDA recommends applicants consider products consumers are most likely to consider interchangeable with the new tobacco product and other similar products. For example, for a PMTA for an e-liquid, FDA recommends the product be compared to other e-liquids used in a similar manner. This comparison is not meant to be a 1 to 1 comparison as in a SE report under section 905(j); rather, it is meant to demonstrate how the new tobacco product may be evaluated in relation to similar products.

Information about tobacco products in different categories is important to FDA's evaluations because it can help demonstrate the changes in health risks current tobacco users could face if they switched to the new tobacco product or use it in conjunction with their current tobacco product. For tobacco products that are not in the same tobacco product category, but that may be appropriate for examining health risk, FDA recommends determining the likely users of the new tobacco product to justify appropriate comparison products. For example, if an applicant submitting a PMTA for an ENDS believes that current users of cigarettes and ENDS will use its product, it would be appropriate to compare the health risks of the ENDS to both cigarettes and other similar ENDS products.

Polytobacco use risks should also be considered.

FDA received many comments regarding comparison products, as discussed below.

(Comments 64) Multiple comments discussed comparison products. One comment stated that the rule should specifically require PMTAs to compare the health risks of new tobacco products to the health risks of all other tobacco products on the market. Another comment stated that § 1114.7(k)(1)(i) is unclear regarding the tobacco products to which an applicant must compare the new tobacco product that is the subject of an application and stated that requiring a comparison to just cigarettes could disincentivize the development of new, lower risk e-cigarettes, not just to combustible cigarettes.

(Responses 64) As described in the preceding paragraphs, comparative health risk information is an important part of FDA's review of a PMTA because it can demonstrate the potential risks and benefits that current tobacco users could face if they switched to the new tobacco product or used it in conjunction with their current tobacco product. As required by § 1114.27(b)(1)(ii)(B), applicants must compare the health risks of its product to both products within the same category and subcategory, as well as products in at least one different category that are used by the consumers an applicant expects will use its new tobacco product. FDA declines to require comparisons to all other products in every instance because not every application will necessarily require comparisons to all other categories and the determination of which comparison products are necessary to consider in determining the risks and benefits to the health of the population as a whole is more appropriately considered during substantive review. We also disagree with the suggestion that the comparative health risk information requirements in the rule would disincentivize development of lower risk products because FDA requires each PMTA to compare the health risk of its product to other tobacco products in the same product category. Because FDA's APPH determination considers changes in health risks to users of other products in the same category that switch to the new tobacco product, applicants have an incentive to ensure its product does not pose greater health risks than other products in the same category.

(Comment 65) One comment stated that section 910 of the FD&C Act does not permit FDA to require a PMTA to contain a comparison to other products in the same product category and, as a result, FDA should remove the requirement to do so in § 1114.27(b)(2)(ii)(B). The comment stated that interpreting the phrase ''other tobacco products'' in section 910(b)(1)(A) to include products in the same category would defeat the congressional intent of the APPH standard, which the comment, citing a statement from a 1998 Senate committee report, argues is to ensure FDA issues PMTA marketing orders for only those products that do not introduce more risk than conventional tobacco products.

(Response 65) FDA disagrees with this comment. The determination of whether the marketing of a new product would be APPH under section 910(c) of the FD&C Act is required to be based on the risks and benefits to the health of the population as a whole, and not limited to a determination of on whether a new tobacco product presents less risk than conventional tobacco products. As described in this section, information about tobacco products in the same category or subcategory is important to FDA's evaluation of a tobacco product's potential effect on public health because current users may switch to other products within the same category. Not only does this constitute information regarding ''other tobacco product'' that falls under section 910(b)(1)(A), it is relevant to the subject matter under 910(b)(1)(G) of the FD&C Act because it informs FDA's consideration of the risks and benefits of the product to the health of the population as a whole.

- Foreign Data

Foreign clinical studies should be performed by clinical investigators so that the rights, safety, and welfare of human subjects are protected in accordance with ethical principles acceptable to the international community, such as those reflected in the International Council for Harmonisation (ICH) Good Clinical Practice standards.

An application may be required to contain full reports of foreign investigations even if they do not meet these criteria because of the requirements of § 1114.7(k) that an application contain all published studies regarding the health risks of a new tobacco product and other topics. This could include, for example, a published health risk investigation regarding the product conducted outside the United States by someone other than the applicant. Where data do not meet the recommendations described in the preceding paragraph, an application should contain a description of the ways in which the foreign data fails to meet those criteria and, if applicable, describe whether FDA should still consider the data to be valid.

FDA received one comment regarding foreign data, as discussed below.

(Comment 66) One comment stated that FDA should be required to provide its own rationale as to why any foreign data in an application are relevant to the U.S. population and why FDA concluded that specific data from U.S. studies are not required. The comment stated that FDA should not assume that consumers in the U.S. market will respond the same way as consumers in a different country.

(Response 66) FDA declines to make the requested revision. An application may contain health risk investigations conducted outside of the United States. If the study data concern a demographic that is different from the United States, the burden is on the applicant to provide a scientific rationale for why the results of the study can be generalized to other demographic groups that are representative of the U.S. population as whole.[32] This could include a discussion of the factors that would be expected to influence study findings and whether they vary significantly across the U.S. population. The applicant should also clearly describe any reasons why study findings may not be generalized to the broader U.S. population.

iii. Health risks of the product. Section 1114.7(k)(1)(i) requires a PMTA to contain full reports of all investigations, published or known to, or which should reasonably be known to, the applicant regarding the potential health effects of their product. This includes full reports of investigations on the constituents, including HPHCs, in the specific product or formed during use of the product, and at the quantitative levels that would be delivered to both users and nonusers under the range of conditions under which the specific product may be used. FDA includes these investigations under its interpretation of the requirements of section 910(b)(1)(A) of the FD&C Act, because the health effects of constituents at the levels delivered to both users and nonusers help demonstrate the overall health risks of the product. Types of investigations into the health effects of constituents that applicants must submit as part of a PMTA if published or known to, or which should reasonably be known to

[32] For a discussion of both intrinsic and extrinsic factors in foreign data that might need to be addressed, please see the International Council for Harmonisation (ICH) E5 guidance: ''Ethnic Factors in the Acceptability of Foreign Clinical Data.''

an applicant include human exposure studies, in silico computational toxicology techniques, risk assessments, in vitro toxicology studies, published reports of in vivo toxicology studies, and, if necessary, new in vivo toxicology studies.

As set forth in § 1114.27(b)(1)(ii) and described in section VIII.B, an application must contain substantive information regarding the health risks of the new tobacco product as described in either § 1114.7(k)(1)(i)(A), (B), or (C) as well as substantive information regarding the health risks of the new tobacco product compared to the health risks generally presented by products in the same category as described in § 1114.7(1)(i)(D). While the rule does not require an applicant to conduct any particular type of studies regarding the health risks of the constituents for the purposes of application acceptance and filing, the applicant would be required to do so where it is not aware of existing studies that could be used to support the application or where additional information is necessary to ensure the application contains substantive information regarding the health risks of the new tobacco product. Where an applicant chooses to, or must, conduct its own investigations, FDA is providing the following discussion of nonbinding recommendations for consideration. The adequacy of the studies provided and whether they help demonstrate that a product is APPH will be determined during FDA's review of the application. The study recommendations, provided here and throughout this document, are intended to help an applicant develop a more robust application, which would facilitate FDA making a determination as to whether the product is APPH.

The health effect evaluation of tobacco constituents, including HPHCs, in a PMTA should begin with an assessment of human exposure. For tobacco product users, this assessment should include direct measurements of exposure, estimates of exposure from analytical studies of the tobacco product and its smoke or aerosol, or investigations that combine both approaches. For nonusers of the tobacco product, exposure estimates would include analytical studies. One source of this information can be the HPHC data required by § 1114.7(i)(1)(v). FDA recommends that these investigations specifically assess the levels of each HPHC to which users and nonusers could be exposed and that direct measurements or estimates of exposure use the same route of administration (*e.g.,* inhalation, ingestion, dermal contact) as the tobacco product they evaluate. Other aspects of the exposure that FDA recommends applicants define in the tobacco constituent exposure assessment include exposure duration, inhalation rate, consumption rate, body mass, and other similar relevant measures.

Study reports regarding the health effects of product constituents at both the exposure ranges estimated for user and nonuser exposure and higher exposures are important in the toxicological evaluation of a PMTA because it allows for a more thorough dose-response assessment. Higher exposures may provide indication of toxicity potential from lower exposure levels over longer exposure times. FDA recommends including dose-response assessments across a range of exposures. For noncarcinogenic constituents, FDA recommends including study reports that define the threshold of toxicity, especially those that identify the no-observable-adverse effect level and lowest-observable-adverse-effects-level. For carcinogenic constituents, if only high-exposure studies are available, an assumption of linearity should be made for low-dose extrapolation. For both carcinogenic and noncarcinogenic constituents, user and nonuser exposures should be compared to available dose response information.

FDA received several comments regarding this issue, as discussed below.

(Comment 67) One comment stated that because FDA notes that clinical studies would typically be a necessary part of a PMTA, FDA should not allow applicants to conduct animal studies, which the comment states are unethical.

(Response 67) Restrictions on the types of investigations that an applicant is allowed to conduct are outside the scope of this rule. FDA supports reducing the reliance on animal testing where adequate and scientifically valid nonanimal alternatives can be substituted. FDA encourages sponsors to meet with CTP early in the development process to discuss what, if any, animal testing is appropriate and the suitability and acceptability of nonanimal tests for their specific new tobacco product. When animal-based nonclinical laboratory studies are conducted, investigators should use appropriate animal models and adhere to the best practices of refinement, reduction, and replacement of animals in research and to applicable laws, regulations, and policies governing animal testing, such as the Animal Welfare Act (7 U.S.C. 2131 *et seq.*) and the Public Health Service Policy of Humane Care and Use of Laboratory Animals (available at *https://olaw.nih.gov/policies-laws/phs-policy.htm*).

Under § 1114.7(k)(1)(i)(B), a PMTA must contain all investigations, published or known to, or which should reasonably be known to, the applicant regarding the toxicological profile of the new tobacco product related to the route of administration, including, but not limited to, the genotoxicity, carcinogenicity, respiratory toxicity, cardiac toxicity, reproductive and developmental toxicity, and chronic (repeat dose) toxicity of the new tobacco product relative to other tobacco products.

(Comment 68) One comment stated that FDA should revise all of the PMTA requirements to give more prominence to heart and lung disease effects and in particular, § 1114.7(k)(1)(i)(B) should be amended to require applicants to prioritize submission of information regarding the cardiovascular and respiratory effects of the new tobacco product, and additionally include effects on blood and intergenerational health effects caused by epigenetic changes.

(Response 68) FDA agrees that heart and lung disease effects are important considerations, which is why they are part of the information required by § 1114.7(k)(1)(i)(B). However, the rule does not set forth requirements in order of importance and moving a particular item would not affect the importance of any requirements.

The toxicological profile also includes information regarding the ingredients, additives, and HPHCs, relative to the route of administration and the range of the potential levels of exposure resulting from the use of or other exposure to the product. While FDA is aware of the risk of harm posed by HPHCs generally, understanding the toxicological effects of HPHCs in the product is important to FDA's review because the levels and combinations of HPHCs to which a consumer may be exposed can determine whether, and the severity with which, a user may experience harm. For example, some constituents may only cause harm above certain levels of exposure, while others may have no safe level of exposure. Additionally, since there are potential complex interactions between HPHCs and each tobacco product can produce a different mixture of these HPHCs, FDA needs to determine the toxicity of the specific mixture of HPHCs in a tobacco product in order to compare that tobacco product to other similar products on the market and to use this comparison in its determination of whether permitting the marketing of the product would be APPH. The toxicological profile investigations covered by the rule also includes

studies that discuss the toxicological effects of any leachables and extractables from the container closure system and the ingredient mixture, such as additive or synergistic effects.

FDA includes the toxicological profile of the tobacco product as part of its interpretation of the health risk investigations required under section 910(b)(1)(A) of the FD&C Act, where published, known to, or which should reasonably be known to an applicant, because it identifies the hazardous or harmful effects of product constituents and allows for product comparisons that estimate the impact of the assessed tobacco product on the health of both users and nonusers of the tobacco product.

The types of toxicological information or data regarding a tobacco product that a PMTA must contain if published or known to, or should reasonably be known to, an applicant generally include the characterization of toxic effects of HPHCs to which users and nonusers may be exposed. This evaluation can include identification of the organs affected by constituents; the cancer and noncancer effects of the constituents; dose response relationships between exposure to constituents and health effects; and, when appropriate, threshold levels of exposure above which noncancer effects occur. The toxicological assessment of the product that is the subject of a PMTA should focus on the HPHCs reported in § 1114.7(i)(1)(v), the constituent reporting section. The types of studies or information required by the rule, if published or known to, or should reasonably be known to an applicant, include toxicological assessments conducted in terms of both the whole tobacco product and the individual HPHCs that the product contains or delivers to users and nonusers.

Because different tobacco products contain different ingredients and additives, they may also have different HPHC yields. A tobacco product that would result in increased exposure to a potent HPHC or set of HPHCs, for example, may present higher health risks to users. However, important aspects such as dose-response and whether the end organ toxicity is carcinogenic or noncarcinogenic in nature could affect whether this higher exposure results in an estimate of increased risk. The information generated from the toxicological assessment of tobacco products is part of the information that the applicant should use in product comparisons to estimate the impact of the assessed tobacco product on the public health.

The types of toxicological information that the applicant must include in a PMTA if published or known to, or should reasonably be known to, the applicant include information about, or investigations into, the potential for a tobacco product or its constituents to cause toxicity. For the specific toxicological profile of a new tobacco product or constituents in or formed during use of the new tobacco product, the applicant should address known tobacco target organs of toxicity, as appropriate for the product and/or route of administration. The profile should include data and thorough literature reviews of the following health effects known to be caused by tobacco products as applicable such as:

- Genotoxicity (the ability of a chemical agent to damage DNA within a cell, causing mutations that may lead to cancer);
- carcinogenicity (the ability of a chemical agent to directly cause cancer in humans or animals after exposure);
- cardiovascular toxicity (the ability of a chemical agent to cause adverse effects on the cardiovascular system (*i.e.,* heart and blood vessels));
- respiratory toxicity (the ability of a chemical agent to cause adverse effects on the respiratory system, which comprises the nasal passages, pharynx, trachea, bronchi, and lungs);
- reproductive toxicity (the ability of a chemical agent to cause adverse effects on the male or female reproductive systems such that normal reproduction is impaired);
- developmental toxicity (the ability of a chemical agent to interfere with the development of the embryo or fetus); and
- other diseases associated with use.

While not required for application acceptance or filing under § 1114.27, FDA recommends that an application contain a discussion of the toxicological potential for the tobacco product to cause additional chronic toxicities, other than those listed above, such as any end-organ toxicity or route of administration effects. These end-organ toxicities include, but are not limited to, the potential toxicity on the liver, kidneys, immune system, digestive system, and neurological system. An example of route of administration effects that FDA recommends be addressed is the toxic potential of a smokeless tobacco product to the oral cavity, including teeth.

FDA also recommends the application address acute toxicity, which concerns the ability of a chemical agent to cause adverse effects after either a single exposure or multiple exposures in a short period of time (usually less than 24 hours). If there are known acute toxicities for product constituents at the levels to which an individual may be exposed (*e.g.,* carbon monoxide poisoning from waterpipe use, the ingestion of nicotine contained in e-liquids) including through accidental or unintended exposures, an applicant should justify how the product could contain such constituents and how permitting its marketing would be APPH. This could include a description of the design features, such as child-resistant packaging for e-liquids, that would prevent exposures to constituents that could result in acute toxicity as part of § 1114.7(i)(1)(vi)(B). See the discussion in section VII.B.9.a.vi. for more information about protective packaging.

FDA recommends that an applicant compare the toxicity of its product to the toxicity of other products in the same product category or subcategory. Additionally, FDA recommends that applicants consider use exposure in conjunction with the hazards posed by a particular product to determine the most appropriate group of comparator products.

While applicants are not required to conduct toxicological analyses under the rule, if an application does not contain substantive information regarding either the health risks of the new tobacco product or a comparison of the health risks compared to other tobacco product categories, FDA intends to refuse to file a PMTA as set forth in § 1114.27(b)(1)(ii) and described in section VIII.B. Information about the product's toxicity and a comparison of its toxicity to other tobacco products could satisfy this substantive information requirement for filing; however, it should be noted that information from nonclinical studies alone, including a product's toxicological profile, is generally not sufficient to support a determination that permitting the marketing of the product would be APPH. An applicant should also consider the existing valid scientific evidence regarding its new tobacco product to determine whether it would need to conduct and submit a full report of toxicological analyses to demonstrate the potential health risks of the new tobacco product as part of its PMTA. If an application does not contain sufficient information about the health risks of the new tobacco product to allow FDA to make a determination regarding the potential risks and benefits to the population as a whole under section 910(c)(4) of the FD&C Act, FDA will issue a marketing denial order for the new tobacco product.

Under § 1114.7(k)(1)(i)(C), a PMTA must contain all studies concerning the pharmacological profile of the new tobacco product that are published or known to, or which should reasonably be known to, the applicant, including investigations into the pharmacokinetics, pharmacodynamics, metabolism, and elimination profile, of each of the ingredients, additives, and HPHCs for the range of potential levels of exposure resulting from the use of or exposure to the product relative to other tobacco products. The applicant also must specify whether the studies were conducted in vitro, in vivo, ex vivo, or in silico. The pharmacological profile of the product and its constituents are important for FDA to consider when evaluating the relationship between the dose of the product and the body's response. As such, where published or known to, or which should reasonably be known to the applicant, the pharmacological profile of the tobacco product is part of the information required under section 910(b)(1)(A) of the FD&C Act because it provides important information regarding how the product constituents and human body interact with each other, which directly impacts whether and what health impacts the constituents can have on users and nonusers of the product.

The types of pharmacological information that the applicant must include in a PMTA if published or known to, or which should reasonably be known to, the applicant include pharmacokinetics and pharmacodynamics. Pharmacokinetics concern the movement of a constituent into, through, and out of the body. Types of pharmacokinetic information that an application must contain if published or known to, or which should reasonably be known to, the applicant include absorption (the rate and movement of a constituent into the bloodstream after administration), bioavailability (the extent to which the constituent reaches the site of action), distribution (the transfer of a constituent from one location in the body to another), metabolism (the breaking down of a constituent), and excretion (the elimination of a constituent). Pharmacodynamics refers to the effects of the constituent on the body including physiological (*e.g.,* changes in blood pressure and heart rate) and subjective effects (*e.g.,* whether the product is ''liked'' or produces other changes in affect). Types of pharmacodynamic information that an applicant must submit in a PMTA if published or known to, or which should reasonably be known to, the applicant include physiological and subjective effects data and information regarding drug-receptor interactions, chemical interactions, and dose-response relationships.

FDA received several comments regarding toxicological information, as discussed below.

(Comment 69) One comment stated that the pharmacological profile of many of the ingredients or constituents in a tobacco product might not be helpful to FDA's determination of health risks and that FDA should recommend inclusion of this information rather than require it. The comment noted that some constituents, such as nicotine, have already had their pharmacological profile established in literature and that other constituents are delivered at such low levels that they would not permit evaluation of their pharmacological profile.

(Response 69) FDA declines to revise the rule as a result of this comment. The pharmacological profile of the product and its constituents provide important information about the health risks of the product as well as its risk relative to other products. Specifically, this information is important for FDA to consider when evaluating the relationship between the dose of the product and the body's response. While the pharmacological profile of some ingredients and constituents, such as the nicotine pharmacokinetic (PK) profile, is well characterized for some general classes of tobacco products, slight changes in product features (*e.g.,* cigarette ventilation (Ref. 128), tobacco pH and nicotine absorption site (Ref. 68), ENDS voltage (Refs. 129–133)) affect the nicotine PK profile. In general, the abuse potential of nicotine increases when absorption is rapid because the rewarding properties of the compound increase, and suppression of withdrawal symptoms occurs more quickly. Nicotine's pharmacological profile impacts use behavior that can then affect the overall exposure of the user to HPHCs and other constituents in the product. Changes in use behavior may result from the pharmacokinetic properties of the nicotine and can result in increased or decreased exposure to the constituents within a product (Refs. 4 and 132–134). Because this profile directly impacts use behaviors and abuse liability, it remains a critical piece to understanding a tobacco product's impact on public health.

(Comment 70) One comment stated that in addition to describing the health risks of the tobacco products contained within the new tobacco product, FDA should require applicants to present evidence that the product does not interfere with the pharmaceutical drugs that expected users of the new tobacco product may be taking.

(Response 70) As required under § 1114.7(k), a full report of each health risk investigation that is published or known to, or which should reasonably be known to, an applicant concerning the potential for interaction between drugs and the new tobacco product must be included as part of a PMTA in order for it to be filed for review. FDA intends to consider the implications of such health risk information, or a lack thereof, during substantive review, as appropriate.

Under § 1114.7(k)(1)(i)(D), a PMTA must contain full reports of all investigations published or known to, or which should reasonably be known to the applicant concerning the health risks of the tobacco product compared to other tobacco products on the market, never using tobacco products, quitting tobacco product use, and using the tobacco product in conjunction with other tobacco products. Under section 910(b)(1)(A) of the FD&C Act, an applicant must submit investigations that have been made to show whether the tobacco product presents less risks than other tobacco products. Under section 910(b)(1)(G) of the FD&C Act, FDA requires applicants to submit investigations that have been made to show whether the tobacco product has the same or different potential health risks (not just less potential health risks) than other tobacco products to capture investigations that could potentially show a range of risks compared to other tobacco products. FDA requires applicants to include comparisons between the health risks of the tobacco product and never using tobacco product under the authority of section 910(b)(1)(A) and (G) of the FD&C Act because this information is relevant to determining the health risks faced by nonusers who initiate tobacco use with the tobacco product.

FDA also requires that an application contain, if published, known to, or which should be reasonably known to the applicant, comparisons between the health risks of the tobacco product and using the tobacco product in conjunction with other tobacco products because existing data indicates that a significant number (approximately 40 percent or more by some estimates) of both adults and youth who currently use tobacco products use more than one type of tobacco product (Refs. 135 and 136). This information is important in determining the health risks faced by individuals that may use the new tobacco product in conjunction with other tobacco products because research

indicates that individuals who use a tobacco product with lower health risks in conjunction with a tobacco product with potentially higher health risks may continue to face the potentially higher health risks of the more dangerous product above a certain threshold of usage (Refs. 137 and 138).

The types of investigations that a PMTA must contain if published or known to, or which should reasonably be known to the applicant, in this section include, for example:

- Cross-sectional and longitudinal surveys (such as market analyses or publicly available national surveys such as NYTS);
- epidemiologic studies that are descriptive (which describe the occurrence of a prespecified or unknown outcome), such as case reports and case series; and
- analytic studies (which describe the association between exposure and outcome) such as randomized controlled clinical trials, cohort studies, and case control studies.

Additionally, clinical studies that employ surrogate endpoints (*e.g.,* biomarker studies) may be used to draw conclusions regarding the effects of the product on a clinical benefit endpoint and patient reported outcome data (*i.e.,* report of the status of health that comes directly from the subject without interpretation of the subject's response by a clinician) may be used as supportive evidence for health outcomes or effects.

For determining the health risks that are posed to a typical user of a tobacco product for the purposes of comparison, FDA recommends using an average of light, moderate, and heavy users. FDA also recommends including evidence and a description supporting the range of light, moderate, and heavy use an applicant includes in its PMTA, including how they relate to the exposures in the submitted toxicology studies. Where an applicant does not have data regarding light, moderate, or heavy product use because the product has not been commercially marketed, including outside the United States, an applicant could, where applicable, bridge to data regarding a similar tobacco product or conduct clinical studies under ad libitum (*i.e.,* unrestricted use) conditions.

As set forth in § 1114.27(b)(1)(ii) and described in section VIII.B, for an application to be filed it must contain substantive information comparing the new tobacco product's health risks to those generally presented by the same product category and at least one different product category that is used by the consumers an applicant expects to use their new tobacco product.

(Comment 71) One comment stated that § 1114.7(k)(1)(i) is unclear regarding the tobacco products to which an applicant must compare the new tobacco product that is the subject of an application. The comment stated requiring a comparison to just cigarettes could disincentivize the development of new, lower risk e-cigarettes.

(Response 71) FDA disagrees with the suggestion that the rule requires a comparison to cigarettes in each application. Section 1114.27(b)(1)(ii) requires a PMTA to contain substantive information regarding the health risks of the new tobacco product compared to the health risks generally presented by both products in the same product category and products in at least one different category that are used by the consumers an applicant expects will use its new tobacco product. While this could require a comparison to cigarettes for at least some applications, it would not be required in all applications. For the comparison to other products in the same category, this could include, for example, comparing an e-liquid to other e-liquids used in a similar manner. We also disagree with the suggestion that the comparative health risk information requirements in the rule would disincentivize development of lower risk products because FDA also requires each PMTA to compare the health risk of its product to other tobacco products in the same product category. Because FDA's APPH determination considers changes in health risks to users of other products in the same category that switch to the new tobacco product, applicants have an incentive to ensure its product does not pose greater health risks than other products in the same category.

An applicant should consider the appropriate comparative health information a PMTA may need beyond the minimum requirement for substantive information to provide FDA with a full understanding of the potential risk and benefits to current tobacco users. If a PMTA lacks sufficient information to demonstrate the changes in risk to which current users of tobacco products would potentially be exposed if they switched to the new tobacco product or began using it in conjunction with their current product, FDA intends to issue a marketing denial order for the new tobacco product.

For demonstrating the health risks that are posed by the product in comparison to using other tobacco products, a PMTA must contain, under § 1114.27(b)(1)(ii), comparison to both products that are within the same category or subcategory of tobacco product and also to other categories of tobacco products currently on the market, as appropriate. As described in section VII.B.13.a, when determining an appropriate comparison product within the same category or subcategory of product, FDA recommends applicants consider products that consumers are most likely to consider interchangeable with the new tobacco product and other similar products. For example, for a PMTA for an e-liquid, FDA recommends the product be compared to other e-liquids likely to be used in the same manner. When determining appropriate comparator products that are not in the same tobacco product category, FDA recommends, in addition to the requirements of § 1114.27(b)(1)(ii), comparing the health risks of the product to categories of products that users are likely to switch to. Applicants may compare to comparator products that have a substantial market share (*e.g.,* cigarettes, smokeless tobacco, cigars); however, such comparisons may only be appropriate if users are likely to switch to the comparator products. Because it is expected that current consumers of products that are in the same category may switch products and consumers of different categories of tobacco product may also switch products or use a new product in conjunction with their current product, this comparative health risk data is an important part of the evaluation of whether switching could potentially result in a lower or higher population health risks.

iv. Impacts on tobacco use behavior of tobacco product users. FDA interprets the health risk investigations that must be provided under section 910(b)(1)(A) of the FD&C Act (where published or known to, or which should reasonably be known to the applicant) to include the effect of either the product or its label, labeling, or advertising, to the extent that advertising has been studied, on tobacco use behavior and tobacco use topography because use behavior and topography are directly related to levels of exposure to HPHCs, which, in turn, impacts health risks. For example, changes in tobacco product use behavior and topography that result in more frequent or intense use of the product will result in greater exposure to HPHCs and may result in increased health risks. Aspects of a product that could result in more frequent or intense use compared to currently marketed products can include differences in the appeal and design of the product, including ingredients; flavors; alteration in the

amount or delivery of nicotine; physical differences such as changes in the velocity of the inhaled particles, the effort required to inhale, or the density of the smoke, vapor, or aerosol; or other changes which similarly affect user behavior (*e.g.,* ventilation, filter density).

(1). Abuse liability. Section 1114.7(k)(1)(ii)(A) requires a PMTA to contain full reports of investigations into the abuse liability of the new tobacco product that are published or known to, or which should reasonably be known to the applicant. However, as set forth in § 1114.27(b)(1)(ii) and described in section VIII.B, if a PMTA does not contain substantive information regarding the abuse liability of a new tobacco product, FDA may refuse to file the application. This means where there is no published information regarding the abuse liability or information that is otherwise known to the applicant or should reasonably be known to an applicant, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigation and include a full report of the results in its PMTA for filing.

Abuse liability refers to the potential of a substance to result in addiction and be used repeatedly or even sporadically resulting in undesirable effects. The abuse liability of a new tobacco product is important for FDA to evaluate because it indicates the degree to which users of the tobacco product are likely to use and develop an addiction to the product. Abuse liability may result in craving of the product and compulsive and continued use despite harm or risk of harm. FDA requires the submission of abuse liability information under its interpretation of section 910(b)(1)(A) and (G) of the FD&C Act because it indicates the likelihood of users to become addicted to the product and face the health risks posed by product use over the long term, and provides insight into the use and adoption of the product, which is an important part of FDA's assessment of the health risks of the new tobacco product as part of its determination of the risks and benefits to the population as a whole under section 910(c)(4) of the FD&C Act. If FDA lacks sufficient information regarding the potential abuse liability of the new tobacco product, it intends to issue a marketing denial order for the new tobacco product.

The types of investigations that inform an evaluation of a product's abuse liability can be wide ranging and are likely to overlap with data submitted elsewhere as part of the PMTA, including data regarding product chemistry, pharmacology, and pharmacokinetic characteristics. Where the data are included elsewhere in a PMTA, FDA recommends including content in this section by cross-reference to the full reports of relevant investigations in other sections. Applicants should analyze the results of all investigations included in the application that impact the abuse liability of the product and synthesize the findings in this section.

While applications need to contain some amount of substantive information concerning abuse liability under § 1114.27(b)(2)(ii) to be filed, the abuse liability of a tobacco product is an important part of FDA's finding of whether permitting the marketing of the new tobacco product would be APPH and applicants should consider conducting an abuse liability study if they do not believe there is sufficient existing data regarding their product. The ''standard'' abuse liability study is a double-blind, placebo-controlled, within-subject study comparing several doses of a new product to a comparator product with a known abuse liability. Generally, the primary outcome measure is peak ''liking'' (Emax) as reported via a visual analog scale. Applicants that wish to conduct abuse liability studies examining tobacco products may utilize a similar framework with additional assessments, although evaluating multiple doses may not be applicable to some tobacco products. These assessments may include use topography, and pharmacokinetics and pharmacodynamics assessments under both prescribed and ad libitum (*i.e.,* unrestricted) use conditions. Real world, actual use data may also provide outcomes relevant to the products' abuse liability, including misuse. Abuse liability conclusions should be considered as an integral assessment of all outcome measures important to understanding the abuse liability of the new tobacco product both independently and relative to other tobacco products with a known abuse liability. FDA generally expects abuse liability studies to contain a comparison to one or more tobacco products and applicants seeking to market a new tobacco product for which little abuse liability data has been established should ensure FDA has sufficient information to understand how the abuse liability of such a product compares to other relevant categories of tobacco products.

FDA received comments regarding abuse liability, as discussed below.

(Comment 72) One comment objected to the inclusion of a statement in numerous places throughout the preamble to the proposed rule indicating that an applicant would be required to conduct investigations in certain circumstances. The comment stated that the requirement should appear in the codified, rather than the preamble, and requested additional information regarding how a company that does not have a product on the market could meet such requirements.

(Response 72) FDA disagrees with the characterization that it is creating a requirement for the submission of information in the preamble rather than in the codified. The instances identified by the comment in which FDA references the potential need for applicants to conduct their own investigations for submission in a PMTA are each a part of a discussion regarding the substantive information required by § 1114.27(b)(1)(ii) for application filing. These portions of the preamble identified by the comment, make it clear that where there is no existing substantive information regarding these topics that an applicant could include in its PMTA, including published investigations or investigations it could bridge to its new tobacco product, the applicant would need to conduct its own investigation to generate such substantive information for inclusion in its application or have FDA refuse to file its application for failing to meet the requirement of § 1114.27(b)(1)(ii).

(Comment 73) One comment stated that the rule is overly broad in that it requires the submission of information regarding abuse liability and also contains recommendations concerning abuse liability studies that align with how FDA assesses abuse liability for drugs. The comment stated that because tobacco products are legal, there are no defined parameters regarding abuse or misuse. The comment also noted that there are a number of factors concerning individual users that affect whether they will develop dependence and that a number of social factors drive individual's decisions to start using and continue to regularly use tobacco products and these factors cannot be simulated in a premarket setting. The comment recommended that FDA use the term ''dependence potential'' and that FDA should limit the scope of required information only to the product that is the subject of the application and a comparator.

(Response 73) As described in the preceding paragraphs, the abuse liability of a new tobacco product is important for FDA to evaluate because it indicates

the degree to which users of the tobacco product are likely to use or develop an addiction to the product. Despite tobacco products being marketed legally in the United States, nicotine is an addictive drug and there are diagnostic criteria for tobacco use disorder in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. There are a number of factors that contribute to the abuse liability of a substance and there are methodologies widely accepted to evaluate abuse liability in a research setting. These methodologies can be used to inform FDA about the abuse liability of product described in a PMTA. FDA requires the submission of abuse liability information because it indicates the likelihood of users to become addicted to the product and face the health risks posed by product use over the long term and may provide insight into the use and adoption of the product, which is an important part of FDA's assessment of the health risks of the new product. Given the importance of this information in FDA's understanding of the abuse liability of the new product both independently and relative to other products with a known abuse liability, FDA declines to use the term ''dependence potential'' or limit the scope of required information to only the product that is subject of the application and a comparator product. FDA generally expects abuse liability studies to contain a comparison to one or more tobacco products to ensure that FDA has sufficient information to understand how the abuse liability of a product compares to other relevant categories of tobacco products.

(Comment 74) One comment stated that FDA should prioritize evidence about real-world actual use over clinical trials or laboratory studies and proposed revisions that appear to require the submission of actual use data that is relevant to the abuse liability of the new tobacco product.

(Response 74) We agree that information regarding actual use of a product and its abuse liability are important to FDA's review of an application, which is why, under § 1114.27(b)(1)(ii), FDA may refuse to file a PMTA that does not contain substantive information regarding those topics. We decline to require ''real-world actual use data'' concerning abuse liability as part of FDA's acceptance and filing requirements, because a determination of whether the data in an application adequately demonstrate the abuse liability of a product is more appropriately considered during substantive review on a case-by-case basis.

(2). Use Topography, Frequency, and Trends. Section 1114.7(k)(1)(ii)(B) of the rule requires a PMTA to contain investigations published or known to, or which should reasonably be known to the applicant into how consumers actually use the product, including use topography, the product use frequency, use trends over time, and how such use affects the health risks of the product to individual users. FDA requires this information because the ways in which consumers actually use the product, instead of relying only on how manufacturers intend the product to be used, help to demonstrate the levels of constituents to which the users will be exposed.

An actual use study can include the use of actual product in either a simulated use setting or in a real use environment. Actual use studies are important to the evaluation of a PMTA because they provide information regarding whether consumers will use the product as intended. In addition, actual use studies help demonstrate whether consumers are likely to misuse the product, including in ways that may change the health risks that the product poses to users and nonusers. For example, ENDS users have applied e-liquid directly onto an exposed heater coil, a process known as dripping, which can lead to greater exposure to volatile aldehyde and a resulting change in the health risks of using the product (Ref. 83). Actual use studies may be conducted using outpatient protocols so that results are as close to actual use as possible. The format of the study should reflect the goals of the study and how the applicant believes the information will inform FDA's decision.

Use topography measures the way in which users consume a product. Use topography is an important measure to consider in assessing a product's health risk and abuse liability because the volume, frequency, and duration of product use determines the amount of, and manner in which, a user is exposed to HPHCs in a product and, consequently, affects the health risks of the product. For combusted or inhaled products, use topography could include measurements of the number of puffs taken, puff duration, puff volume, duration of use, and other relevant measures. For smokeless tobacco, use topography could include measures such as the number of smokeless tobacco tins used per week, the total dips per day, and the dip duration.

FDA received one comment regarding this issue, as described below.

(Comment 75) One comment requested that FDA clarify what information an applicant would be required to submit under § 1114.7(k)(1)(2)(ii)(B) to demonstrate how consumers actually use the product, including use topography, the product use frequency, use trends over time, and how such use affects the health risks of the product to individual users. The comment noted that the rule seemed to require actual use studies and requested that FDA clarify whether this needs to be real-world studies or they could be in a simulated setting.

(Response 75) Under § 1114.27(b)(1)(ii), FDA may refuse to file a PMTA that does not contain substantive information regarding how consumers actually use the product, including use topography, product use frequency, use trends over time, or how such use affects the health risks of the product to individual users. Thus, where there is no published information regarding actual use or information that is otherwise known to the applicant, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigation and include a full report of the results in its PMTA for filing. However, FDA does not require a particular type of actual use study. For example, applicants may conduct and submit results from an actual use study in a real or simulated setting. The types of studies that may provide this information on current tobacco use behavior can include, but are not limited to, actual use studies and national survey databases that could be used to bridge general data to the specific product. Ideally, the studies would look at the past, present, and likely future behaviors of tobacco product users. As described in the following paragraphs, FDA requires this information because the ways in which consumers actually use the product, instead of relying only on how manufacturers intend the product to be used, helps to demonstrate the levels of constituents to which the users will be exposed.

(3). Polyuse. Section 1114.7(k)(1)(ii)(C) of the rule also requires the PMTA to contain full reports of all investigations, published or known to, or which should reasonably be known to the applicant, regarding the likelihood that users will use the product in conjunction with other tobacco products (*i.e.,* polyuse).

FDA received on comment regarding polyuse, as discussed below.

(Comment 76) One comment stated that to assess the health impacts of dual use, proposed rule § 1114.7(k)(1)(i)(D) should be strengthened to require submission of meaningful estimates of

true levels of dual and polyuse based on research for the proposed product or comparable products.

(Response 76) FDA agrees that consideration of dual and polyuse are important to determining whether permitting the marketing of a new tobacco product would be APPH, which is why FDA is finalizing § 1114.7(k)(1)(ii)(C). Data indicate that a substantial number of tobacco product users are polyusers of tobacco products (Refs. 135 and 136). FDA requires information regarding the likelihood of dual or polyuse because such use may increase or decrease known health risks and may pose risks that are not currently known (Refs. 137 and 138). The likelihood of tobacco product users using the new tobacco product in conjunction with another tobacco product, when considered with the health effects resulting from such polyuse, will help FDA determine the health risks that polyusers may encounter. However, because the main purpose of the rule is to set requirements for application acceptance and filing that ensure that a PMTA contains sufficient information for FDA to conduct substantive review of the application, FDA declines to make the requested revisions. Questions about whether data regarding the potential for polyuse of other tobacco products along with the new tobacco product is meaningful, valid, or applicable are more appropriate to consider during substantive review, rather than at filing review, because it requires an in-depth, scientific evaluation to make such a determination.

(4). Start or continue use of product. Section 1114.7(k)(1)(ii)(D) through (F) of the rule also requires the PMTA to contain full reports of investigations published or known to, or which should reasonably be known to the applicant, regarding the likelihood that current tobacco product users:

- Will start using the product;
- will starting using the product exclusively and then switch to other tobacco products that may present increased risks to individual health; and
- will start or continue to use the product when they otherwise would have quit using tobacco products.

While § 1114.7(k)(1)(ii)(a) through (f) requires a PMTA to contain only information published or known to, or which should reasonably be known to the applicant, as set forth in § 1114.27(b)(1)(ii), if a PMTA does not contain a substantive information regarding likelihood of changes to tobacco use behavior of current tobacco users, FDA intends to refuse to file the application. This means where there is no published information regarding the likelihood of changes in tobacco use behavior by current users of tobacco products or information that is otherwise known to the applicant, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigations and include a full report of the results in its PMTA to meet this requirement for application filing. Although the rule would not require an applicant address each potential change in tobacco product use behavior for the purposes of filing, FDA must be able to determine the potential risks and benefit to the population as a whole, including each of the potential risks and benefits associated with changes in tobacco product use behavior by current tobacco product users in order to issue a marketing granted order. If a PMTA lacks sufficient information needed for FDA to make these determinations, FDA intends to issue a marketing denial order for the new tobacco product.

FDA requires information regarding the tobacco use behavior of current tobacco product users because these behavior patterns affect the health risks posed to those individuals. Current tobacco product users who start using the product may be switching from a product that may present greater, lower, or equal levels of individual health risk. Current tobacco product users that adopt the product may not continue use of the product in the future, so FDA seeks information regarding whether they are likely to switch back or switch to a product that may present higher levels of individual risk. Finally, current tobacco product users who would have otherwise quit using tobacco may use the new tobacco product instead, exposing them to health risks to which they might not have otherwise been exposed.

FDA received one comment regarding this issue, as discussed below.

(Comment 77) A comment stated that FDA should require applicants to submit all marketing research related to the development of any proposed new product, specifically including research considering the positioning of the proposed new product as a competitor to quitting. FDA also requires information regarding current tobacco product user behavior because to determine whether the product is appropriate for the protection of public health, FDA must take into account the increased or decreased likelihood that current tobacco product users will stop using tobacco products under section 910(c)(4)(A). The types of studies that will likely fall into this category can include actual use studies and national survey databases that could be used to bridge general data to the specific product. Ideally, the studies would look at past, present, and likely future behaviors of the tobacco product users.

(Response 77) Each PMTA is required by § 1114.7(k)(1)(ii)(F) to contain full reports of all investigations that are published, known to, or which should reasonably be known to, an applicant concerning the likelihood that current tobacco product users who may have otherwise quit using tobacco products will instead start or continue to use the product. This could include information such as applicant-conducted or sponsored marketing research as part of the development of its marketing plans. The description of marketing plans required under § 1114.7(f)(2) could also provide relevant information concerning how an applicant would target the marketing of its new tobacco product to specific intended audiences.

v. Impacts on tobacco use initiation by nonusers, including youth, young adults, and other relevant vulnerable populations. The rule also requires a PMTA to contain full reports of investigations published or known to, or which should reasonably be known to the applicant, regarding the likelihood that consumers who have never used tobacco products, particularly youth, young adults, and other relevant vulnerable populations, will initiate use of the tobacco product and the likelihood that consumers who have never used tobacco products and adopt use of the tobacco product will switch to other tobacco products that may present higher levels of individual health risk; however, as set forth in § 1114.27(b)(1)(ii), if a PMTA does not contain substantive information regarding the likelihood of initiation of tobacco use by current nonusers of tobacco products, FDA intends to refuse to file the application. This means that where there is no published information or information that is otherwise known to the applicant regarding the likelihood of changes in tobacco use behavior by current nonusers of tobacco products, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigations and include a full report of the results in its PMTA for filing. If FDA lacks sufficient information to determine the potential risks and benefits to the population as a whole, including the potential risks and benefits associated with changes in tobacco product use behavior by current tobacco product users, it may issue a

marketing denial order for the new tobacco product.

The rule also requires a PMTA to contain full reports of investigations published or known to, or which should reasonably be known to the applicant, regarding the likelihood that former users of tobacco products will re-initiate use with the tobacco product. FDA include information regarding likelihood of re-initiation by former users as part of its interpretation of the requirements of section 910(b)(1)(A) and under its authority of section 910(b)(1)(G) of the FD&C Act because it will help FDA determine the health risks to which these former users may be exposed if they begin using the new tobacco product. Survey studies are one type of investigation that is likely to fall into this category.

FDA received several comments on initiation information, as discussed below.

(Comment 78) One comment requested clarity regarding a statement in the preamble regarding the assessment of current nonusers of tobacco products who initiate tobacco product use with the new tobacco product and that begin polyuse of tobacco products or switch completely to another tobacco product. The comment stated that predicting such potential future behaviors that would be made after the potential future initiation of tobacco product use would be challenging both in terms of reliability and precision.

(Response 78) FDA does not generally require applicants to conduct studies regarding the likelihood that nonusers would initiate tobacco product use with the new tobacco product and then transition to polyuse or switch to another tobacco product for the purposes of application acceptance and filing under the rule. Applicants would only be required to submit full reports of such investigations where they are published or known to, or which should reasonably be known to an applicant. However, such information would be helpful to FDA's determination of whether the marketing of the new tobacco product would be APPH, specifically FDA's consideration of the likelihood that nonusers of the tobacco product will start using the product. Where there is no direct information about the new product and its impact on patterns of use among those who initiate, it's possible an applicant could use historical data on patterns of tobacco use (*e.g.,* rates of switching between product categories), to discuss what they anticipate the impact of the new product might be. For example, this could be information about the proportion of new users of a tobacco product or tobacco product category that sustain use for a year and become polyusers of the new product or product category and another tobacco product or switch entirely to another tobacco product. This information may be available from sources such as existing longitudinal and repeated cross-sectional datasets available to the public.

FDA requires information regarding likelihood of tobacco use initiation and switching to potentially more harmful tobacco products, including among youth and young adults, as part of its interpretation of the requirements of section 910(b)(1)(A) of the FD&C Act because it will help FDA determine the number of current nonusers who will likely be exposed to the health risks presented by the tobacco product, as well as the risks posed by potentially more harmful products that individuals may go on to use. The information regarding initiation and switching by current nonusers of tobacco products is also being required under section 910(b)(1)(G) because FDA must take into account the increased or decreased likelihood that those who do not use tobacco products will start using tobacco products under section 910(c)(4)(A) of the FD&C Act. The types of studies that would likely fall into this category include survey studies and focus groups. In order to assess whether permitting the marketing of a new tobacco product would be APPH, FDA will need to understand how individuals below the minimum age of sale may use or intend to use the new tobacco product because individuals below the minimum age of sale are a population of particular concern for initiating tobacco use.

(Comment 79) One comment supported the requirement to submit information regarding the potential health risks of the new product on youth and young adults, but it stated that tobacco companies should not be permitted to conduct research on youth because applicants could use such information to design their marketing campaigns to attract youth. In addition, multiple comments stated that FDA needs to be more explicit about whether it recommends conducting investigations using youth as test subjects. One comment requested explicit direction regarding what falls within the narrow scope of research using youth subjects that could be appropriate and how applicants should assess whether the benefits of the research outweigh its risks. Another comment requested more information regarding bridging methods and information on how it could be used to extrapolate the impact on youth from young adult data in the context of consumer and perception studies.

(Response 79) FDA does not require research to be conducted on individuals below the minimum age of sale and does not anticipate that will be necessary or an applicant to do so because inferences regarding individuals below the minimum age of sale may potentially be extrapolated from young adults, as well as derived from existing sources of data, reviews of published scientific literature, or bridging information obtained from other sources. Providing data from the published literature or marketing information in an application with appropriate bridging information may be one useful approach. If an applicant takes such an approach, FDA recommends a PMTA contain a clear explanation of how such data can be extrapolated to the target population or populations of interest for the product that is the subject of the PMTA. Setting requirements with respect to different types of tobacco product research that an applicant may conduct is outside the scope of this rulemaking, which is why in the following paragraph we highlight some of the laws and ethical considerations applicable to research involving subjects below the minimum age of sale. If an applicant chooses to conduct a study in the United States using minors, it must use appropriate parental consent procedures, as well as follow the requirements of the Children's Online Privacy and Protection Act (15 U.S.C. 6501–6505), the Pupil Rights Amendment (20 U.S.C. 1232h), and their implementing regulations (See 16 CFR part 312 and 34 CFR part 98, respectively). FDA strongly recommends that any studies conducted outside of the United States are designed so that the rights, safety, and welfare of human subjects, including minors, are protected in accordance with ethical principles acceptable to the international community, such as those reflected in the ICH Good Clinical Practice standards.

Regardless of where a study is conducted, any studies using individuals under the minimum age of sale should have a narrow research scope and be as focused as possible given sensitivities around the conduct of research in these populations. Specifically, research priorities for individuals minimum age of sale should be focused on key questions relating to use (*e.g.,* prevalence of use, characteristics of users, and patterns of use), risk perception, and intention to initiate/susceptibility among non-users.

Studies conducted among individuals under the minimum age of sale focusing on issues beyond these key questions (*e.g.,* exposing youth to advertisements or marketing material for tobacco products) would necessitate a very strong justification to demonstrate that the risks of conducting the research are minimal and do not outweigh the potential benefits of collecting such information.

vi. Perceptions and use intentions. The rule requires a PMTA to contain full reports of investigations published or known to, or which should reasonably be known to the applicant, regarding tobacco product perceptions and use intentions, including the effect of either the product or its label, labeling, or advertising, to the extent that advertising has been studied, on individuals' perception of the risks of the product, use intentions, and the ability of individuals to understand the labeling and instructions for use and use the product in accordance with those instructions.

FDA received one comment on this issue, as discussed below.

(Comment 80) One comment stated that FDA should require testing regarding product packaging, labeling, and advertising that shows they will not mislead consumers or otherwise encourage any harm-increasing uses of the product.

(Response 80) FDA agrees that information regarding consumer perception and use intentions is an important part of an APPH determination. Under § 1114.27(b)(1)(ii), FDA intends to refuse to file any PMTA that does not contain any substantive information regarding the potential impact of either the product or its label, labeling, or advertising on individuals' perception of the product, or their use intentions. This means where there is no published information or information that is otherwise known or should reasonably be known to the applicant regarding either the potential impact of the product or its label, labeling, or advertising on individuals' perception of the product, and their use intentions, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigation or testing regarding at least one of the topics and include a full report of the results in its PMTA for filing. If, based upon a fair evaluation of all material facts, FDA determines that the proposed labeling is false or misleading in any particular, FDA must issue a marketing denial order as required by section 910(c)(2)(C) of the FD&C Act. Additionally, as described in section VII.B.6, because the advertising, marketing, and promotion of a tobacco product can have a significant impact on the potential for tobacco product initiation, especially by youth, where FDA is unable to determine the impact that the labeling, advertising, marketing, or promotion of the new tobacco product may have on consumer perceptions and use intentions, FDA intends to issue a marketing denial order for the new tobacco product.

(Comment 81) One comment stated that FDA should make it clear that investigations of perceptions and use intentions are required only for prospectively proposed labels, labeling, and advertising. The comment stated that because FDA is using section 910(b)(1)(G) of the FD&C Act as its authority and that section is limited to information that is relevant to the subject matter of the application, FDA should limit § 1114.7(k)(1)(iv) to investigations for prospectively proposed labels, labeling, and advertising, as this would be the relevant information. The comment added that this approach would avoid potential burdens on applicants and FDA from having to submit and review past materials, especially for products on the market for several years before the requirement took effect.

(Response 81) FDA disagrees with the comment because investigations regarding prior labels, labeling, and advertising can provide information that is relevant to FDA's review. FDA includes perception and use intention studies as part of its interpretation of the requirements of section 910(b)(1)(A), and under its authority of 910(b)(1)(G) of the FD&C Act because perception of the risk of the product may influence decisions to use the product and the resultant exposure to the health risks presented by the product (Ref. 139). If an applicant uses advertising as stimuli in a tobacco product perception and use intention study, the PMTA must indicate, as part of the full report of the study under § 1114.7(k)(3), whether it is representative of advertising that the applicant intends to use in marketing the product that is required by § 1114.7(f)(2). If the advertising is not representative of the advertising an applicant intends to use in marketing the product, the applicant must indicate whether the study results are still relevant to the likely impact of product advertising on tobacco product perceptions and use intentions.

Additionally, information about individuals' understanding regarding the labeling is relevant to determining whether the labeling is misleading, which is a reason for which FDA must deny an application under section 910(c)(2)(C) of the FD&C Act, and also may provide information on the likelihood of individuals using the product. Further, whether consumers understand the instructions for use and use the product in accordance with those instructions can help show whether consumers will be exposed to potentially greater health risks by using the product improperly. Topics that should be examined in tobacco product perception and intention investigations overlap with the topics identified in the human factors section that follows.

vii. Human factors. The rule also requires a PMTA to contain full reports of investigations, published or known to, or which should reasonably be known to, the applicant regarding human factors that influence the health risks of the product, which includes use conditions, use environments, use related hazards, estimated use error risk, potential unintended uses, risk controls to ensure that harms and unintended consequences are minimized, and adverse experiences related to such uses.

FDA received comments regarding human factors, as discussed below.

(Comment 82) One comment stated that the human factors requirements in § 1114.7(k)(1)(v) and the corresponding description in the preamble did not address the complex nature of human factors or the numerous permutations and interactions among subcategories of products. Given the complexity of ''human factors'' and unspecified ''threshold amount of information'' applicants are required to submit for FDA to file an application, the comment requested that FDA clarify how much information regarding human factors is required for filing.

(Response 82) Section 1114.27(b)(2)(ii) requires a PMTA to contain substantive information concerning the ways in which human factors can affect the health risks of the new tobacco product. This rule does not require an applicant to conduct an investigation regarding human factors for an application to be filed unless there is no information that is published or can otherwise be bridged to the new tobacco product that is the subject of the application. As described in section IX.B, FDA considers substantive information to be information that is relevant to the subject it claims to support and has evidentiary support. Any amount of substantive information regarding the ways in which human factors can affect the health risks of the new tobacco product is sufficient to meet the filing requirements of § 1114.27(b)(2)(ii).

Further, although the rule requires an application to contain some amount of substantive information for filing, FDA must be able to determine the potential risks and benefits of the new tobacco product to the population as a whole, which includes youth, young adults, and other vulnerable populations. If FDA lacks sufficient information to make this determination, it intends to issue a marketing denial order for the new tobacco product. FDA requires human factors information as part of its interpretation of the requirements of section 910(b)(1)(A) and (G) of the FD&C Act because it provides an assessment of use-related health hazards for the tobacco product.

In situations where it is critical for the end user to have instructions on how to properly use the product, it is important for applicants to demonstrate that the instructions for use are adequate. FDA recommends that human factors studies focus on the particular aspects of labeling that provide instructions for use. For example, it may be appropriate for a human factors study to evaluate the tobacco product user's:

- Ability to select the appropriate task from a set of instructions that include different options;
- understanding of how to identify a defective or expired product;
- awareness and understanding of the safety information provided in the instructions for use;
- recognition of any potential harms or dangers that would signify the need to seek medical attention, such as shortness of breath, allergic reaction, weakness, increased heart rate; and
- understanding of diagrams, if provided as part of the product labeling (which may overlap with investigations regarding consumer perception and understanding).

Analyzing use-related risks is a critical step in identifying use related hazards associated with the product and in characterizing high-risk hazards so that they can be mitigated or eliminated. FDA recommends that a PMTA contain a use-related risk analysis to help identify critical tasks that should be evaluated in human factors studies and inform the priority of testing the tasks in a human factors study, and determine if there are specific use scenarios to include in testing. If an applicant conducts human factors testing to determine tobacco product use-related risks, FDA recommends that the test considers potential users of the product, use environments, similar products used within the environments, and any associated medical factors or health conditions that may affect whether users may experience serious or unexpected adverse experiences. An applicant may also want to include information on known use related problems with similar products or previous versions of the product.

As part of the risk analysis, FDA recommends that an application first identify all users and use environments for the product, as well as unintended users who are likely to use the product and unintended environments, in which the product is likely to be used. For example, intended users may be characterized within the application according to their respective experience levels, skills, age ranges, and use responsibilities. Use environments are an important factor to consider because they can have diverse characteristics that affect the users' interactions with the product. In some cases, use of the product may be prohibited (*e.g.,* laws prohibiting use of a product in the workplace, public spaces, airplanes).

(Comment 83) One comment stated that actual use studies concerning human factors are costly and time consuming, and in some cases, they are unnecessary. The comment recommended that FDA consider less costly alternatives to actual use studies, such as simulated use studies. The comment stated that data from the actual use of products that are already on the market should also be acceptable. The comment also noted that the preamble references a human factors validation study, which is referenced nowhere else in the rule, and requested this reference be better explained. The comment raised additional concerns with the human factor section's discussion of unintended users and unintended use environments, stating that there is no logical way for manufacturers to address all potential users and environments that fit into those categories.

(Response 83) FDA recommends that human factors investigations be conducted in the form of actual use studies, rather than simulated use studies. Because it may be difficult in some cases to simulate the conditions of use, physical characteristics of the product, or environment of use, actual use studies allow for better assessment of how users interface with the product. However, the rule does not require a specific type of human factors study. As described in this section, the rule requires a PMTA to contain at least some amount of substantive information concerning the ways in which human factors can affect the health risks of the new tobacco product in order for the application to be filed for substantive review.

FDA recommends an applicant conduct human factors validation testing because it can demonstrate that the expected users can understand and follow the device instructions without serious use errors or problems under the expected use conditions. For ENDS, for example, the human factors validation study should demonstrate and provide evidence that an e-cigarette, as designed, can be used as intended by people who are representative of the expected users and under normal use conditions. If errors or failures or new findings are identified in a human factors validation study, then these problems should be evaluated to determine the root cause(s), potential for harm, and additional measures to eliminate or mitigate risk.

b. Literature search. Section 1114.7(k)(2) requires a PMTA to describe, and contain the results of, a literature search for each type of information described in § 1114.7(k)(1). FDA requires that an application contain the bibliography and literature search information because section 910(b)(1)(A) of the FD&C Act requires (in part) that a PMTA contain full reports of all published health risk investigations. FDA is also including these requirements in the rule under authority of sections 701(a) and 910(b)(1)(G) of the FD&C Act because they would help FDA to determine whether the application contains reports of all published investigations in an efficient manner rather than having to follow up with the applicant about the inclusion or exclusion of specific studies.

FDA received multiple comments regarding the literature search requirement, as discussed below.

(Comment 84) One comment stated it was unclear how the literature search requirement would apply and what level of detail the Agency expects to see. The comment noted that in the case of a product not on the market, there would be no or limited scientific literature on the product.

(Response 84) Section 1114.7(k)(2) requires a PMTA to contain a description of the literature search performed, including the databases searched and the date searched, search terms, reasons for inclusion or exclusion of documents, and the strategy for study quality assessment. The PMTA must also contain a bibliography of all published studies and articles referenced in the application. If a literature search was performed and resulted in no information found, the application must contain a statement to that effect. FDA must determine whether the application contains all

published investigations because the Agency needs to ensure it has all relevant health risk data to determine whether permitting the marketing of the product would be APPH. The description of the reasons for inclusion or exclusion of documents, in particular, will facilitate FDA's review of an application because it will explain, if applicable, why some investigations that initially appear relevant were excluded from the application and why some investigations that do not initially appear to be relevant were included in the application. For example, if an applicant limits the literature search to a certain time period, the applicant must include the reason for such limitations in their description of the literature search. For ease of review, FDA recommends that an applicant include internal hyperlinks to, or otherwise reference, the location of published studies that are included in an application. If applicable, it is also recommended that an application explain why an investigation that was conducted using a product other than the one that is the subject of the PMTA is relevant to the application to inform FDA's review of the PMTA.

It is possible that there may be less information captured by the literature search for novel products; however, there may be at least some applicable information, such as investigations on constituents delivered to users and nonusers under the range of conditions under which the product may be used, which may be bridged to the product that is the subject of the application.

c. Study reports. Section 1114.7(k)(3) sets requirements for the full report of each investigation that must be included as part of an application. An application must contain each type of documentation listed in § 1114.7(k)(3) to the extent that it is applicable to the type of investigation and to the extent that it is reasonably available to the applicant. FDA considers a document to be reasonably available unless it does not exist or it would be unduly burdensome to obtain the document due to the effort or expense involved. Where an applicant considers a document required by this section to not be reasonably available, the application must contain an explanation in the full report that describes the actions taken to obtain the document and specifies why the document is not reasonably available. It is important to note that failure to submit documents may affect the extent to which FDA is able to rely upon an investigation's findings during substantive application review. A full report of the investigation must contain:

i. Full copies of any published articles and other reference materials. FDA requires that an application contain full copies of published articles and other reference materials to facilitate the review process.

ii. Documentation of all actions taken to ensure the reliability of the study. The requirements for this item would differ based upon whether the investigation is a clinical investigation or a nonclinical laboratory investigation. For nonclinical laboratory investigations, an application must contain documentation demonstrating all actions taken to ensure the reliability of the study, including whether the investigation was conducted using good laboratory practices (GLPs), such as those specified in part 58 (21 CFR part 58). FDA considers GLPs to be those that support the quality, reliability, and integrity of nonclinical laboratory investigations. This requirement helps FDA determine whether the study's findings are accurate and reliable. While this rule on its own does not require compliance with the GLP regulations found in part 58,[33] FDA would consider a nonclinical laboratory investigation that contains the documentation required by part 58 to be one way to satisfy the requirements of § 1114.7(k)(3)(ii).

FDA recommends that an application contain a final report of each nonclinical laboratory investigation that contains the following items, at minimum, to show that the study was accurate and reliable:

- Name and address of the facility performing the study and the dates on which the study was initiated and completed;
- objectives and procedures stated in the approved protocol, including any changes in the original protocol;
- statistical methods employed for analyzing the data;
- the test and control articles identified by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics;
- stability of the test and control articles under the conditions of administration;
- a description of the methods used;
- a description of the test system used. Where applicable, the final report should include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification;
- a description of the dosage, dosage regimen, route of administration, and duration;
- a description of all circumstances that may have affected the quality or integrity of the data;
- the name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study;
- a description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis;
- the signed and dated reports of each of the individual scientists or other professionals involved in the study;
- the locations where all specimens, raw data, and the final report are stored;
- the statement prepared and signed by the quality assurance unit, if any, a description of the quality control review performed and its results;
- the study director's signature and date upon completion of the final report; and
- any corrections or additions to a final report, clearly identifying the part of the final report that is being added to or corrected and the reasons for the correction or addition, and bearing the dated signature of the person responsible.

The rule requires full reports of investigations (both clinical and nonclinical) to contain, to the extent reasonably available, a certification that the investigators do not have, or documentation fully disclosing, any potential financial conflicts of interest, such as the financial arrangements specified in the financial disclosure by clinical investigators regulation in part 54 (21 CFR part 54). While FDA does not currently require compliance with part 54 for tobacco product investigations, complying with those requirements for both clinical and nonclinical investigators would be one way to satisfy the financial disclosure requirements of the rule. Financial conflicts information is important for FDA to consider because they address a potential source of bias in investigations. Applicants would be able to use these disclosures as well as appropriate procedures in the design and conduct of the study to demonstrate that a potential bias that may affect the results of the investigation has been minimized. FDA would use the information contained in these disclosures, in conjunction with information about the design and purpose of the study, as well as on-site

[33] It is important to note that in the **Federal Register** of August 24, 2016 (81 FR 58341), FDA issued a proposed rule that, when finalized, would require laboratory investigations regarding tobacco products to comply with the requirements of part 58.

inspections (if necessary) in its assessment of the reliability of the data.

The investigator financial arrangements that the applicant should disclose and describe, include:

- Any financial arrangement entered into between the sponsor of the study and the investigator involved in the conduct of a clinical trial, whereby the value of the compensation to the investigator for conducting the study could be influenced by the outcome of the study;
- any significant payments of other sorts from the sponsor of the study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
- any proprietary interest in the tested product held by any investigator involved in a study;
- any significant equity interest in the sponsor of the study held by any investigator involved in any clinical study; and
- any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interests, or payments.

iii. A copy of all protocols and amendments that were used in the study.

iv. Copies of all investigator instructions, if any were produced in addition to the protocol.

v. The statistical analysis plan. The rule requires that the applicant submit a statistical analysis plan, including a detailed description of the statistical analyses used (including all variables, confounders, and subgroup analyses), the scientific rationale for the choice of sample sizes, and any amendments to the plan. FDA requires the protocol, investigator instructions, and statistical analysis plan to be part of the full report of a study because they would enable FDA to understand a study's design, conduct, and analysis in its entirety and to evaluate the validity of a study.

FDA received one comment regarding statistical methods, as discussed below.

(Comment 85) One comment stated that FDA should require that all studies submitted in support of a PMTA be adequately powered, and § 1114.7(k)(3)(v) should be amended to require presentation of power data, including study power and minimum detectable effect size, as part of the statistical methods used.

(Response 85) FDA agrees that having adequately powered data is important to an applicant's prospects of receiving a marketing granted order, but the Agency disagrees with this comment insofar as it proposes to restrict the data companies would be required to submit in a PMTA. An applicant must submit full reports of health risk investigations as described in § 1114.7(k), regardless of whether an applicant considers them to be adequately powered. FDA will review the information and make its own determination as to whether the data are sufficient to support the issuance of a marketing granted order.

vi. Line data. To facilitate FDA's review, the application should contain line data in Statistical Analysis Software (SAS)-transport file in .xpt format, created by a procedure that allows the files to be readily read by the JMP software. FDA also recommends that an application contain data definition files that include the names of the variables, codes, and formats used in each dataset, and copies of SAS programs and necessary macro programs used to create derived datasets and the results reported in the study reports. Such data are important for FDA to replicate applicant findings or conduct alternative statistical analyses. FDA intends to provide technical specifications on its website for submitting information, such as line data, in an electronic format that FDA can review, process, and archive (*e.g.,* method of transmission, media, file formats, preparation, organization of files, accompanying metadata) (*https://www.fda.gov/tobacco-products*).

FDA received one comment regarding line data, as discussed below.

(Comment 86) One comment stated that where an applicant is using a published health risk investigation in its application, FDA should not require the applicant to obtain and submit underlying data from the study sponsor because, in most cases, the source data are unavailable and FDA lacks the resources to review, verify, and audit that data.

(Response 86) Under the rule, the full report of each health risk investigation in a PMTA must contain the items specified in § 1114.7(k)(3) to the extent those items are applicable to the type of investigation and to the extent they are reasonably available. For additional information on what constitutes a document that is reasonably available, please see section VIII.B.13.c. FDA declines to amend the rule such that the underlying data from published investigations would not need to be submitted where reasonably available. Reviewing data from a study can be an important part of FDA's assessment of the reliability of its results and where an application does not contain data, it may affect the extent to which FDA is able to rely upon an investigation's findings during substantive application review.

vii. Sites and clinical investigators. A list of sites and clinical investigators that conducted the study, including contact information and physical address(es).

viii. The location of all source data. If the site that conducted the study has not maintained all of the source data, indicate where the data are located.

ix. Format. The format of the records and data (*e.g.,* electronic or hard copy).

x. Early termination sites. In the proposed rule, § 1114.7(k)(3)(x) would have required a PMTA to a list of all sites that had early termination, the reason for early termination, and audit certificates and inspection results for study sites with early terminations. We have revised this provision in response to this comment, as discussed below.

(Comment 87) One comment objected to the proposal to require audit certificates and inspection results for study sites that had an early termination, stating it contradicts long-standing FDA policy and should not be included in the final rule. The comment cited to FDA documents concerning the regulation of other products, which state that granting FDA access to quality assurance unit inspection reports would tend to weaken the inspection system and that confidentiality is necessary for inspections to be complete and candid. The comment states that FDA does not explain why it would fail to recognize this long-standing practice in the tobacco context and that it should not be changed as a part of this rule.

(Response 87) FDA agrees with the comment that the requirement to submit audit certificates and inspection results should be removed from the rule because of the policy concerns the comment describes and we have revised § 1114.7(k)(3)(x) accordingly to require only a list of all sites that had early termination and the reason for early termination. The rule also now clarifies that FDA may conduct inspections of sites that had early terminations. As part of these inspections, FDA intends, as appropriate, to review a firm's written quality assurance program.

xi. Contractors. A list of contractors who participated in the study, the role of each contractor, and the initiation and termination dates of the participation of each contractor.

xii. Signed report. A signed full report of all findings.

xiii. Study materials and case report forms. For human subject studies, all versions of study materials and case report forms used, and all individual case report forms associated with participant deaths, other serious and unexpected adverse experiences, withdrawals, and discontinuations from

the study. The rule requires the application to contain one blank copy of each version of the study materials (including, but not limited to, consent forms, questionnaires, and stimuli) and case report form, and only those completed individual case report forms regarding deaths, serious and unexpected adverse experiences, withdrawals, and discontinuations for individuals that were exposed to the tobacco product, or for individuals who were exposed to a similar or related product that the applicant is using to help demonstrate the health effects of its product. An example of where such case report forms from a study regarding a similar product are required is where a clinical biomarker study on a product that is similar to the new tobacco product in terms of design, ingredients, and HPHCs is used to provide information about the anticipated health risks of the new tobacco product. As described in § 1114.45, applicants must keep each questionnaire and case report form from the study as part of its own internal records, which FDA may inspect, as described in § 1114.27, or request that the applicant submit to facilitate its review of an application. If an applicant fails to keep such records, FDA may be unable to rely upon an investigation's findings during substantive application review.

Additionally, while clinical investigations for tobacco products are not currently required to be conducted in accordance with the requirements for the protocol and procedures implemented to protect human subjects in the Institutional Review Boards regulation in part 56 (21 CFR part 56) and the Protection of Human Subjects regulation in part 50 (21 CFR part 50), FDA plans to issue regulations requiring compliance with those parts for tobacco products. Until FDA takes such action, FDA strongly encourages applicants to follow the requirements of parts 50 and 56 or take sufficient actions to ensure that the investigation is conducted in a manner that comports with the ethical and moral considerations involved with conducting studies using human subjects. Each clinical investigation included in the PMTA should have been reviewed and approved by an institutional review board (IRB) operating to safeguard the rights, safety, and well-being of all trial subjects, with special attention being paid to potentially vulnerable study subjects including, but not limited to vulnerable populations, such as children, incarcerated persons, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. For more information on some of the laws and ethical considerations applicable to research involving subjects below the minimum age of sale, please see section VIII.B.13.a.(5).

FDA recommends applicants retain documentation concerning efforts related to the protection of human subjects, including documents related to the IRB, such as:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany he proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;
- minutes of IRB meetings in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;
- records of continuing review activities;
- copies of all correspondence between the IRB and the investigators;
- a list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution (*e.g.,* full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant);
- written procedures for the IRB; and
- statements of significant new findings provided to subjects, such as those discussed in § 50.25.

FDA also strongly recommends, but does not currently require, maintaining all documentation of the protocol and procedures implemented to protect human subjects, such as those set forth in the protection of human subjects regulation in part 50. Each clinical investigation included in the PMTA should have been conducted using only human subjects who gave their informed consent to participate in the study. As described in § 50.20, informed consent is consent that is obtained from the subject or the subject's authorized representative under circumstances that provide the prospective subject or representative with sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the subject's representative should be in language understandable to the subject or the representative. The informed consent should not include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

xiv. Perception and use intention studies. For perception and use intention studies that use a label, labeling, advertising, or other materials as stimuli, the rule requires the full report of the study to contain a statement regarding whether the label, labeling, or advertising used is representative of those the applicant intends to use in marketing the product. If the advertising used as stimuli is not representative of the advertising an applicant intends to use in marketing the product, the applicant must indicate whether and how the study findings are still relevant to the likely impact of product advertising on consumer tobacco product perceptions and use intentions. For more information about tobacco product perception and use intention studies, please see the description of § 1114.7(k)(1)(iv) in section VII.B.13.a.iv.

14. The Effect on the Population as a Whole

The rule requires a PMTA to contain an in-depth analysis and discussion of how the data and information contained in the application establish that permitting the marketing of the new tobacco product would be appropriate for the protection of public health. This discussion must include the effect that the new tobacco product may have on the health of the population as a whole, including youth, young adult, and other relevant vulnerable populations with emphasis on the populations disproportionately affected by and most likely to use the new tobacco product by integrating all of the information (both qualitative and quantitative as available) regarding the product, its potential effects on health, as well as tobacco use behavior (including likelihood of both cessation and initiation), to provide an overall assessment of the potential effect that the marketing of the tobacco product may have on overall tobacco-related morbidity and mortality. Relevant outcomes measures could include reductions in serious medical conditions and premature mortality and gains in life-years lived in the population. This requirement directly informs FDA's determination under section 910(c)(2)(A) of the FD&C Act as

to whether permitting the marketing of the new tobacco product would be APPH.

FDA received one comment regarding population health analysis, as discussed below.

(Comment 88) One comment stated that FDA should require PMTAs to provide reasonable estimates of information regarding the future public health impacts from FDA issuing a marketing granted order for the new tobacco product, including comparisons to other products and the likelihood of changes in tobacco product use behavior. The comment suggested that this could include estimates regarding product harmfulness, possible harm-increasing consumer uses, mortality impacts or impacts on quality adjusted life years.

(Response 88) FDA agrees that information regarding the potential risks and benefits related to the tobacco product, including comparisons to other products and the likelihood of changes in tobacco product use behavior, is important to the evaluation of a PMTA. Accordingly, FDA requires a PMTA under § 1114.7(k) to contain full reports of investigations regarding the health risks of the tobacco product and to contain an analysis and discussion of all data and information under § 1114.7(*l*) that integrates the information regarding the likely effects of the new tobacco product on overall health and tobacco use behavior to provide an assessment of the likely effect that the marketing of the new tobacco product would have on overall tobacco-related morbidity and mortality.

15. Certification Statements

Section 1114.7(m) requires that the application contain a specific statement certifying that the applicant will maintain all records to substantiate the accuracy of the application consistent with the record retention requirements in § 1114.45, that the information and accompanying submission are true and correct, that no material fact has been omitted, that the signer is authorized to submit the information on the applicant's behalf, and that the signer understands that anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties under 18 U.S.C. 1001. This certification will help ensure that the applicant understands the responsibilities related to the application (including the potential consequences of submitting false information to the U.S. Government), the applicant intends to submit the PMTA, and the PMTA is ready for review.

C. Amendments (§ 1114.9)

FDA generally expects that when an applicant submits a PMTA, the submission will include all information required by section 910(b)(1) of the FD&C Act and part 1114 to enable FDA to determine whether it should authorize the marketing of a new tobacco product. However, FDA recognizes that additional information may be needed to complete the review of a PMTA and, therefore, allows the submission of amendments to a pending application.

Section 1114.9 provides that FDA may request, and an applicant may submit, an amendment to a pending PMTA together with the appropriate form (Ref. 140). Because FDA tracks PMTAs using the STN, an amendment must specify the STN that is assigned to the PMTA. An amendment must contain the certification statement set forth in § 1114.7(m), with the appropriate information inserted, and signed by an authorized representative of the applicant. FDA may, at any time after it receives and before it acts on an application, request that an applicant submit additional information that is necessary to complete the review of a PMTA. Similarly, an applicant may submit an amendment on its own initiative that is necessary for FDA to complete its review of the pending PMTA. These amendments may include information such as newly completed or published studies that are relevant to the PMTA, clarifications, or a transfer in ownership of the PMTA as described in § 1114.13.

Section 1114.9(b)(2) describes the effect that minor amendments have on the 180-day review period. FDA considers minor amendments to be any amendments that are not major amendments. Minor amendments can be clarifications or other information that FDA needs to complete its review of a PMTA, but they will not require substantial review time. Examples of minor amendments that FDA has requested include a certificate of analysis and administrative information.

FDA received many comments regarding amendments, as discussed below.

(Comment 89) Multiple comments requested that FDA provide additional clarity regarding, and examples of, what constitutes a minor amendment or a major amendment.

(Response 89) Section 1114.9(b) describes how the submission of an amendment may affect the time required for the review (as described in § 1114.27(c)(1)) of the application. FDA intends to notify applicants regarding changes to the review period, including pausing, resuming, and resetting the review period for amendments as described in this section. If the applicant submits a major amendment to an application, either at FDA's request or on its own initiative, FDA will restart the 180-day review period. FDA considers major amendments to be those that will require substantial FDA review time. Examples of major amendments include: Substantial new data from a previously unreported study, detailed new analyses of previously submitted data, or substantial new manufacturing information (*e.g.,* addition of a new manufacturing site for primary and secondary processing, or a change in a manufacturing step or process to address a product quality or safety issue not initially provided in the application). When an applicant submits a major amendment, FDA would consider the applicant to have submitted a new PMTA with the review period beginning on the date FDA receives the amendment. Therefore, under § 1114.9(b)(1), a new 180-day review period would begin on the date FDA receives a major amendment.

(Comment 90) One comment stated that FDA should allow applicants to submit amendments containing the results of studies that were ongoing when the PMTA was submitted and FDA should not automatically restart the 180-day review clock when an applicant does so. The comment suggested that FDA should instead only add the number of review days needed to complete review of the amendment.

(Response 90) FDA declines to take this suggestion because FDA does not expect that it will be able to reliably predict the number of days needed to review a major amendment, such as one containing the results from a new study, which could require FDA to conduct a potential inspection of the study site, at the time when it is received. While FDA will restart the 180-day review period after the receipt of a major amendment, the Agency intends to promptly act on an amended application, which might take fewer than 180 days.

(Comment 91) One comment stated that the rule implies that applicants would be unable to submit minor amendments on their own initiative. The comment requested that FDA amend the rule to allow for the submission of unsolicited minor amendments and give such amendments the same due consideration as solicited amendments.

(Response 91) As set forth in § 1114.9, FDA may request, or an applicant may submit on its own initiative, an amendment to a PMTA containing information that is necessary for FDA complete the review of a pending PMTA. This permits the submission of unsolicited minor amendments, which FDA will consider in the same manner as solicited minor amendments.

If FDA determines that a minor amendment is necessary to complete its review of a pending submission and requests that the applicant submit the amendment, FDA may pause the review period on the date that it issues the amendment request to the applicant. FDA will resume the review period on the date that it receives a written response from the applicant either submitting the requested information or declining to submit the amendment. For example, if FDA requests a minor amendment on day 80 of its review, the date FDA receives the amendment would be day 81, even though weeks or months may have passed from the date of request to receipt. An applicant may notify FDA that it is declining to submit an amendment; however, if an applicant declines to submit an amendment to FDA, and FDA is not be able to determine whether the PMTA meets the requirements to receive a marketing granted order without the amendment, it will issue a marketing denial order.

If FDA requests an amendment, either major or minor, and the applicant neither submits the amendment nor notifies FDA that it is declining to submit the amendment within the time period specified in FDA's request, FDA may, as described in § 1114.9(c), consider the applicant to have submitted a request to voluntarily withdraw its PMTA and issue an acknowledgement letter stating that the application has been withdrawn under § 1114.11. FDA will consider requests for more time to submit an amendment and may grant reasonable requests. Section 1114.9(c) is based on FDA's authority under section 701(a) of the FD&C Act to efficiently enforce section 910 of the FD&C Act because it would allow FDA to dedicate its resources to reviewing PMTAs that are more likely to receive a marketing granted order, rather than continuing to review a PMTA submitted by a nonresponsive applicant that is unlikely to provide FDA with the information it needs to complete its review.

If an application has been closed under § 1114.29 or withdrawn under § 1114.11, § 1114.9(d) does not allow the application to be amended. If an applicant wishes to make changes to an application after it is closed or withdrawn, it would have to do so through submission of a new application.

D. Withdrawal by Applicant (§ 1114.11)

Section 1114.11 discusses the ability of an applicant to withdraw a pending PMTA. At any time prior to FDA acting on the application (*i.e.,* taking one of the actions described in § 1114.29), the applicant may request to withdraw its application by using the appropriate form (Ref. 140) to specify the name of the new tobacco product, the STN of the application, and state whether the withdrawal request is related to a health concern. If the request is related to a health concern, the applicant must describe the concern(s), including the extent, duration, and frequency of the health effects, and identify what gave rise to the concerns, such as adverse experience reports. FDA requires information about health concerns under authority of section 909 of the FD&C Act because the information would help FDA protect the public health (*e.g.,* identifying a problem that could be present in similar currently marketed products) and section 701(a) of the FD&C Act because it allows FDA to efficiently enforce provisions of the FD&C Act (*e.g.,* more quickly ensure an identified health concern was addressed if an application for the same product is submitted again). Once FDA receives and processes the withdrawal request, it will issue an acknowledgment letter to the applicant, at which time the application will be considered withdrawn. Withdrawing an application would not prejudice a future submission.

The application is an Agency record even if withdrawn. Thus, under § 1114.11(c), FDA will retain the withdrawn application consistent with Agency record retention schedules and policies and will provide a copy to the applicant upon request, subject to the Agency's public information regulations in part 20 and under the fee schedule in § 20.45.

E. Change in Ownership of an Application (§ 1114.13)

Section 1114.13 describes the steps that an applicant must take when it transfers ownership of a PMTA. This section is intended to facilitate transfers of ownership and help ensure that FDA has current information regarding the ownership of a PMTA. An applicant may transfer ownership of its PMTA at any time prior to FDA taking one of the actions described in § 1114.29. Under § 1114.13, at the time of the transfer, the new and former applicants (or owners) of the PMTA must use the appropriate form (Ref. 140) and submit certain information to the Agency. First, the former applicant must submit a notice to FDA identifying the new applicant and stating that all rights to the PMTA have been transferred to the new applicant. Second, the new applicant must submit a signed notice to FDA containing the following information:

- To the extent applicable, the new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the PMTA (*e.g.,* certifications, proposed restrictions on the sales and distribution of the tobacco product);
- the date that the change in ownership is effective;
- either a statement that the new applicant has a complete copy of the PMTA (including any amendments, or any records required to be kept under § 1114.45); or a statement of intent to request a copy of the PMTA filed with FDA under the Freedom of Information Act (FOIA) (FDA's implementing regulations are in part 20); and
- a certification that no modifications have been made to the new tobacco product since the PMTA was submitted to FDA.

Although FDA expects that the new applicant will have a copy of the PMTA from the former applicant, if the new applicant requests a copy of the PMTA filed with FDA, FDA will provide a copy to the new applicant, subject to the public information regulations in part 20 and under the fee schedule in § 20.45.

The new applicant also would be required to make available all required records upon inspection by FDA (§ 1114.45 would impose a recordkeeping requirement).

F. Supplemental Application Submission (§ 1114.15)

Section 1114.15 discusses the availability of supplemental PMTAs. Supplemental PMTAs are an alternative format for a PMTA that meets the requirements of § 1114.7, which would reduce the burden associated with the submission and review of an application. Specifically, supplemental PMTAs are a standardized cross-referencing format that FDA is implementing under its authority of section 701(a) of the FD&C Act to efficiently enforce section 910 of the FD&C Act for submissions that are based on a PMTA that FDA has previously reviewed. Applicants that have received a marketing granted order would be able to submit a supplemental PMTA to seek marketing authorization for a new tobacco product that results from a modification or modifications to the

original tobacco product that received the marketing granted order. An applicant can submit a supplemental PMTA only for modifications where the submission of limited info can demonstrate that permitting the marketing of the modified product would be APPH. FDA is restricting the use of supplemental PMTAs to ensure that FDA is able to efficiently review the application. An applicant could also submit a supplemental PMTA for modifications made to comply with a product standard issued under section 907 of the FD&C Act where FDA specifies in that product standard rule that the submission of supplemental PMTAs would be appropriate.

Applicants that have questions about whether it would be appropriate to submit a supplemental PMTA for the modifications they are seeking to implement should contact FDA for more information. To further illustrate when a supplemental PMTA could be submitted, FDA has prepared the following examples of modifications to ENDS products that are likely appropriate to be submitted using the supplemental PMTA format and likely not appropriate to be submitted using the supplemental PMTA format. After review and consideration of comments received in response to the proposed rule, we have added an additional example to provide clarity on the product modifications that are likely appropriate to be submitted using the supplemental PMTA format.

Potentially Appropriate for Supplemental PMTA Format

- Changes in connection type/thread size (e.g., 510);
- minor Software Changes not affecting device functionality; and
  - changes to user interface;
  - changes in recording/data capture properties; and
- certain changes to account for improvements in electronics technology or to improve use and convenience (e.g., use of haptics or simplification of device functions like cleaning cycle).
- Minor changes in e-liquid volume, viscosity or boiling temperature;
- minor changes in draw resistance;
- minor changes in air flow rate;
- changes to coil configuration if number of coils, coil gauge, material, and overall coil resistance remain unchanged; and
- changes to amount of wicking material.

Likely Not Appropriate for Supplemental PMTA Format

- Any modification that might increase risk of harm to individual health from the product;
- modifications that may alter tobacco product use behavior and initiation, such as modifications that have strong youth appeal; and
- design modifications that change the category or subcategory of the product (e.g., modifying a closed e-cigarette to be an open e-cigarette).

Additionally, there are two other specific limitations on the submission of a supplemental PMTA. Under § 1114.15(a), a supplemental PMTA could not be submitted where the marketing granted order for the original tobacco product has been withdrawn or has been temporarily suspended or is the subject of temporary suspension or withdrawal proceedings by FDA, except where authorized by FDA in writing. FDA restricts the submission of supplemental PMTAs in these situations because, for example, withdrawal or suspension may involve consideration of whether the marketing of the original product is no longer appropriate for the protection of the public health, or the application was accompanied by an untrue statement of material fact. If the reason for the temporary suspension or withdrawal is unrelated to the sufficiency or reliability of information contained in a PMTA, an applicant may request, and FDA may grant, authorization to use a supplemental PMTA under these circumstances.

FDA received comments about the use of supplements generally, as discussed below.

(Comment 92) One comment stated that verifying compliance with a product standard under section 907 of the FD&C Act should require only a certification by the applicant and not a new PMTA, Supplemental or otherwise. The comment further stated that in adopting a product standard, FDA will have already determined that the standard ''is appropriate for the protection of the public health'' for the products to which it applies, so product modifications made to comply with an applicable new standard thus will not require the same evaluation as a standard or supplemental PMTA. The comment asserted that any requirement beyond a certification of compliance would be needlessly burdensome and would unnecessarily delay consumer access to products that satisfy the new product standard.

(Response 92) The circumstances that would determine the actions a manufacturer would need to take to legally market a tobacco product after issuance of a product standard are fact-specific and are dependent upon the tobacco product, the modifications made (if any), and the product standard involved; however, FDA disagrees with the suggestion that modifications made to comply with a product standard would never need to be the subject of a PMTA or another premarket submission to seek marketing authorization. The rule for a future product standard would indicate whether an applicant may submit a supplemental PMTA, where applicable.

As discussed in § 1114.15(a), an applicant may not submit a supplemental PMTA where the modifications to the original tobacco product require the submission of new information or revisions to the extent that review of the PMTA for the new tobacco product in the supplemental PMTA format would be confusing, cumbersome, or otherwise inefficient and submitting a standard PMTA under § 1114.7(b) would better facilitate review.

(Comment 93) One comment requested that FDA make supplemental PMTAs available to be submitted for a broader range of modifications to reduce the burden on industry.

(Response 93) FDA declines to allow for broader use of the supplemental format because it would likely not result in a more efficient review process. Because supplemental PMTAs are based on a cross-referencing system that is supposed to reduce the burden of preparing and reviewing a PMTA, FDA has created this limitation to ensure PMTAs are submitted in the format that is the easiest to review, process, and archive. Changes that require multiple, sweeping, or difficult-to-trace changes to the PMTA for the original tobacco product would be more efficient to review in the full text format of § 1114.7.

1. Required Format

Under § 1114.15(b) the supplemental PMTA format is the same as the format for standard PMTAs submitted under § 1114.7(b), except that applicants must include content in a supplemental PMTA by cross-referencing content in the PMTA and postmarket reports for the original tobacco product. FDA believes that including content in an application by cross-referencing to a PMTA for the original tobacco product is appropriate for supplemental applications because the referenced information will be presented in the proper context and format, and will facilitate application review.

2. Required Content

The required content for a supplemental PMTA is divided into two general categories: New content sections and content sections cross-referenced from the PMTA for the original tobacco product. The new content sections required under § 1114.15(c)(1) must contain the full text or a cross-reference to text in a tobacco product master file or postmarket reports for the original tobacco product. These sections may not include information by cross-reference to the PMTA for the original tobacco product. The new content sections that must be included under § 1114.15(c)(1) are:

- General information (as described in § 1114.7(c));
- new product information (as described in § 1114.15(d));
- statement of compliance with part 25 (as described in § 1114.7(g));
- labeling (as described in § 1114.7(f)) if the labeling is not identical to the labeling submitted in the PMTA or postmarket reports for the original tobacco product;
- postmarket information (as described in § 1114.15(e)); and
- certification statement (as described in § 1114.15(f));

A supplemental PMTA must also contain application sections that comprise information included by cross-reference to the PMTA for the original tobacco product and contain any additional information that is necessary to supplement or update the cross-referenced information. It is important to note that these cross-referenced sections must be accompanied by the full text of any updates or supplemental information that are necessary to tailor this information to the new tobacco product. These updates or supplemental information should consist of changes to application content that is not otherwise included as part of the new content sections required under § 1114.15(c)(1). For example, if a new health risk investigation on the product is published and it is not contained in the new content sections, the cross-referenced sections must contain a full report (as described in § 1114.7(k)(3)) of the investigation in full text with a cross-reference to the health risk investigations section in the PMTA for the original tobacco product. The cross-referenced sections that must be included under § 1114.15(c)(2) are:

- Descriptive information (as described in § 1114.7(d));
- product samples (as described in § 1114.7(e)). Please note, however, that FDA may, request the submission of product samples after receipt of a supplemental PMTA;
- labeling (as described in § 1114.7(f)) if the labeling is identical to the labeling submitted in the PMTA or postmarket reports for the original tobacco product;
- summary of all research findings (as described in § 1114.7(h));
- product formulation (as described in § 1114.7(i));
- manufacturing (as described in § 1114.7(j)); and
- health risk investigations (as described in § 1114.7(k)).

3. New Product Information

Under § 1114.15(d), the new product information section required under § 1114.15(c)(1)(ii) must contain the following information concerning modifications to the original tobacco product, including:

- Full descriptions of the modification(s) to the original tobacco product and comparisons of such modification(s) to the unmodified version(s) described in the PMTA for the original tobacco product;
- a statement as to whether the new tobacco product is intended to replace the original tobacco product if the new product receives a marketing granted order, is intended to be a line extension of the original tobacco product, or is intended to be introduced as an additional product by the same manufacturer;
- all data and information relating to the modification(s) that are required in an application under § 1114.7. This is data and information that can span across a number of application sections. A change in the connection type or thread size for an ENDS product, for example, may require a change in the design parameters and the manufacturing sections; and
- a concluding summary of how the new tobacco product meets the requirements to receive a marketing granted order. This summary must describe how the data and information concerning the product modification when viewed together with the information cross-referenced from the previously submitted PMTA demonstrate that the new tobacco product meets the requirements of section 910(c) of the FD&C Act to receive a marketing granted order.

4. Postmarket Information

Under § 1114.15(c)(1)(v), a supplemental PMTA must contain postmarket information as specified in § 1114.15(e). Where an applicant has submitted postmarket reports for the original tobacco product, it must incorporate those reports by cross-reference. Where an applicant has yet to submit a postmarket report for the original tobacco product, it must submit a report as part of the supplemental application that contains all the information for the original tobacco product that would otherwise be required in a report under § 1114.41, covering the period in time from when it received its marketing granted order for the original tobacco product to when it submitted the supplemental PMTA. Because information that is contained in a postmarket report for the original tobacco product would likely be required content of a standard PMTA for the modified tobacco product, FDA is allowing applicants to cross-reference this content to avoid the burden of resubmitting information that FDA has previously reviewed.

5. Certification Statement

Under § 1114.15(f), the certification statement required under § 1114.15(c)(1)(vi) must be signed by an authorized representative and, in addition to the certification required under § 1114.7(m) for a standard PMTA, must certify that the modifications identified in the certification are the only modification(s) to the original tobacco product.

G. Resubmissions (§ 1114.17)

Section 1114.17 describes resubmissions, which are an alternative format for submitting an application that meets the requirements of § 1114.7(b) or § 1114.15 to seek a marketing granted order, by responding to the deficiencies outlined in a marketing denial order. An applicant may submit a resubmission for the same tobacco product that received a marketing denial order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a marketing denial order. This application format allows an applicant to address the deficiencies described in a marketing denial order without having to undertake the effort of submitting a standard PMTA. The resubmission format is available to resubmit an application that received a marketing denial order because FDA has completed its review of the PMTAs subject to the marketing denial order and can rely on the findings of these reviews to save time when reviewing a resubmission. The resubmission format is not available for PMTAs that FDA refused to accept, refused to file, cancelled, or administratively closed, or that the applicant withdrew, because FDA has not previously completed reviews of such applications upon which it can rely, and such applications may need significant changes to be

successfully resubmitted. It is important to note that, as discussed in section VIII.E regarding § 1114.33, while FDA will identify deficiencies that resulted in the marketing denial order, the deficiencies specified in the order might not be an exhaustive listing of all deficiencies contained in the PMTA.

Similar to a supplemental PMTA, an applicant may not submit a resubmission to the extent that review would be confusing, cumbersome, or otherwise inefficient and submitting a standard PMTA under § 1114.7 would better facilitate review. Where responding to the deficiencies outlined in the marketing denial order requires broad or sweeping changes to the original PMTA, an applicant would need to submit a standard PMTA under § 1114.7 to better facilitate review. Where possible, FDA will specify in the marketing denial order if an applicant may not pursue a resubmission to address the identified flaws.

Applicants may request a meeting with FDA prior to submitting a resubmission to determine whether it may utilize the resubmission format and to discuss any issues related to the application, such as application organization and format. For example, applicants that have questions about whether it would be appropriate to pursue a resubmission for the modifications they are seeking to implement to respond to deficiencies identified in a marketing denial order may contact FDA for more information.

1. Format

Under § 1114.17(b) the resubmission format requirements are the same as the format in § 1114.7(b) for standard PMTAs, except that applicants must include content in a resubmission by cross-referencing content in the PMTA. FDA believes that including content in a PMTA by cross-referencing to a PMTA for the original tobacco product is appropriate for resubmissions because the referenced information will be presented in the proper context and format and will facilitate application review. In addition, an applicant may include content in a resubmission by cross-reference to a TPMF.

2. Content

The required content for resubmission is divided into two general categories: New content sections and cross-referenced content sections. The new content sections required under § 1114.17(c)(1) must contain the full text or cross-referenced text from a tobacco product master file. These sections may not include information by cross-reference to the PMTA or postmarket reports for the original tobacco product. The new content sections that must be included under § 1114.17(c)(1) are:

- General information (as described in paragraph § 1114.7(c));
- response to deficiencies (as described in § 1114.17(d)); and
- certification statement (as described in § 1114.17(e)).

A resubmission must also contain application sections that comprise information included by cross-reference to the PMTA for the original tobacco product and all additional information that is necessary to supplement or update the cross-referenced information. It is important to note that these cross-referenced sections must be accompanied by the full text of any updates or additional information that are necessary to tailor this information to the new tobacco product. These updates or additional information should consist of changes to application content that is not otherwise included as part of the response to deficiencies section. This information could include, for example, full reports of health risk investigations published after the applicant submitted the PMTA that received the marketing denial order. The cross-reference-based sections that must be included under § 1114.17(c)(2) are:

- Descriptive information (as described in § 1114.7(d));
- product samples (as described in § 1114.7(e)). Please note that FDA may require the submission of product samples after it has received your application;
- labeling (as described in § 1114.7(f)), together with updates to the labeling made by the time of submission, if any;
- statement of compliance with 21 CFR part 25 (as described in § 1114.7(g));
- summary of all research findings (as described in § 1114.7(h));
- product formulation (as described in § 1114.7(i));
- manufacturing (as described in § 1114.7(j)); and
- health risk investigations (as described in § 1114.7(k)).

3. Response to Deficiencies

As described in § 1114.17(d), the response to deficiencies section required under § 1114.17(c)(1)(ii) must list and provide a separate response to each deficiency described by FDA in the marketing denial order, including all data and information necessary to complete each response, as well as any applicant-identified deficiencies. The deficiencies should be addressed in the order in which they are listed in the marketing denial order, followed by applicant-identified deficiencies. Where an applicant modifies the original tobacco product to address the deficiencies outlined in the marketing denial order, the applicant must also include: (1) A full description of each modification to the product and comparisons of that change to the original version described in the PMTA for the original tobacco product and (2) all data and information relating to each modification to the product that would be required in an application under § 1114.7.

4. Certification Statement

Under § 1114.17(e), the certification statement required under § 1114.17(c)(1)(iii) must be signed by an authorized representative and, in addition to the certification required under § 1114.7(*l*) for standard PMTA, must certify either: (1) That the application addresses all deficiencies specified in the marketing denial order and is being submitted for a tobacco product that is identical to the product for which FDA issued a marketing denial order or (2) the application addresses all deficiencies and the tobacco product is distinct from the original tobacco product, but the only modifications to the original tobacco product are those identified in the certification.

IX. FDA Review (Part 1114, Subpart C)

A. Communications Between FDA and Applicants (§ 1114.25)

Section 1114.25 sets forth general principles for the communications between FDA and applicants and is intended to provide more information to applicants about FDA communications. Section 1114.25 explains that, during the course of FDA's review of an application, FDA may seek to communicate with applicants about relevant matters including scientific, medical, and procedural issues that arise during the review process. Communications regarding human risk issues may arise if adverse experience reports exist for the tobacco product.

FDA received some comments regarding its communications with applicants, as discussed below.

(Comment 94) Some comments mentioned that while FDA states that it encourages applicants to meet with FDA, this is not what often happens. Instead of face-to-face meetings, the comment noted that FDA often provides written responses instead. The comment argued that there is no substitute for face-to-face meetings and encourages FDA to include provisions in the PMTA

rule related to presubmission meetings that includes standards for face-to-face meetings.

(Response 94) FDA may use a variety of methods to communicate with applicants such as telephone conversation, letters, emails, or face-to-face meetings depending on the circumstances and issues. Furthermore, as discussed in the guidance entitled ''Meetings with Industry and Investigators on Research and Development of Tobacco Products,'' while an applicant may request a face-to-face presubmission meeting, FDA may determine that this type of meeting is unnecessary and instead provide a written response to the questions raised in the meeting request. If an applicant feels that the written responses are insufficient, it may submit a subsequent request for a meeting.

FDA documents any communications regarding a PMTA in accordance with 21 CFR 10.65. While applicants may contact FDA with questions, as a general matter, FDA does not provide applicants with predecisional details about an ongoing application review, such as whether an initial submission is sufficient to receive a marketing granted order or the date and time at which FDA will act on an application. For additional information on requesting a face-to-face presubmission meeting, please consult the guidance for industry and investigators entitled ''Meetings with Industry and Investigators on Research and Development of Tobacco Products.'' [34]

B. Review Procedure (§ 1114.27)

Section 1114.27 describes the procedures by which FDA would review a PMTA. When an applicant submits a PMTA, FDA performs an acceptance review of the submission. Currently, FDA performs its acceptance review of all premarket submissions based upon the criteria set forth in § 1105.10. The rule incorporates and builds upon these general criteria to set PMTA-specific acceptance criteria. Under the rule, FDA may refuse to accept an application for further review if, upon initial review, it:

- Does not comply with the applicable format requirements for the type of PMTA (*i.e.,* § 1114.7(b) for a standard PMTA, § 1114.15 for a supplemental PMTA, § 1114.17 for a resubmission);
- is not administratively complete because it does not appear to contain the information required by the applicable application content requirements section. This means that the content required for the type of PMTA must be readily and easily identifiable as part of a cursory review of the application (*i.e.,* a standard PMTA must appear to contain information required by § 1114.7, a supplemental PMTA must appear to contain information required by § 1114.15, and a resubmission must appear to contain information required by § 1114.17). The acceptance review would assess the facial completeness of a submission only, and would not be an in-depth, technical review. Examples of submissions that FDA would refuse to accept under this rule include, but are not limited to, applications that do not appear to contain:
  - Labeling (as required by § 1114.7(f));
  - Design parameter information (as required by § 1114.7(i)(2)(ii));
  - An EA (as required by § 1114.7(g)); or
  - A literature search (as required by § 1114.7(k)(2)).
- does not pertain to a tobacco product that is subject to chapter IX of the FD&C Act, as required by § 1105.10(a)(1). Under this provision FDA would refuse to accept the PMTA if it does not pertain to a product that is subject to the jurisdiction of CTP. CTP has premarket review jurisdiction over products that meet the definition of ''tobacco product'' in section 201(rr) of the FD&C Act and are subject to chapter IX of the FD&C Act either in section 901(b) of the FD&C Act or by regulation. Therefore, FDA will refuse to accept submissions for a product that is a drug under the definition in section 201(g)(1), a device under section 201(h), a combination product as described in section 503(g) of the FD&C Act, or otherwise does not meet the definition of a tobacco product; and
- may otherwise be refused under § 1105.10.

Once FDA has completed its acceptance review under § 1114.29(a)(1), FDA will issue a letter to the applicant informing it of FDA's decision. If FDA accepts the application for further review, it will issue an acceptance letter to the applicant that specifies the STN for the PMTA. If FDA refuses to accept the application, it will issue a letter to the applicant that identifies the reasons, where practicable, that prevented FDA from accepting the application. The applicant may, after FDA has refused to accept a PMTA, correct the deficiencies and submit a new PMTA under § 1114.7. Because FDA is not issuing a marketing denial order under § 1114.33 when it refuses to accept a submission, an applicant may not utilize the resubmission format described in § 1114.17 to address the flaws outlined by FDA.

FDA implements the acceptance review procedures under authority of sections 701(a) and 910 of the FD&C Act. The content, format, and jurisdiction requirements that an application must meet to be accepted for review will ensure that FDA will be able to efficiently review applications and consider only applications that are more complete and better prepared for further review. By refusing to accept submissions that have clear deficiencies, FDA will be able to focus its resources on those submissions that are more likely to be filed for substantive review. After FDA accepts a PMTA for review, FDA may request product samples as described in § 1114.7(e).

FDA will also conduct a filing review to determine whether the application contains sufficient information to permit a full substantive review of the application. FDA may refuse to file a PMTA if:

- The PMTA does not include sufficient information required by section 910(b)(1) of the FD&C Act and by § 1114.7, 1114.15, or 1114.17, as applicable, to permit a substantive review of the application. These requirements include a sufficient EA for each type of PMTA, the absence of which is a reason for which FDA may refuse to file an application under § 25.15. The filing requirements also include product samples if required by FDA after application acceptance. FDA's filing review is an examination of the submission to ensure it contains adequate technical information for FDA's substantive review of the application to proceed. Unlike the acceptance review, which considers whether a submission meets basic content, format, and jurisdiction requirements as described above, the filing review is a more in-depth review to ensure the application contains sufficient information for initiating substantive review. For example, during acceptance review, FDA will check whether the PMTA appears to contain product design parameters, but during filing review, FDA will review to determine whether it contains the correct design parameters for the product category and has a value for each design parameter required by § 1114.7(i)(2)(ii). FDA implements the filing review requirements under authority of section 701 of the FD&C Act to improve the efficiency of the PMTA review process. By determining whether a PMTA contains sufficient information

[34] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-industry-and-investigators-research-and-development-tobacco-products.*

prior to conducting substantive review, FDA can commit the considerable resources necessary to conduct substantive review of a PMTA to only those submissions that are prepared for review;

- the application does not contain substantive information regarding certain specified broad categories of information that must be addressed in every PMTA for FDA to determine whether permitting the marketing of the new tobacco product would be APPH. FDA considers substantive information to be information that is relevant to the subject it claims to support and has evidentiary support. Bare statements that the marketing of the tobacco product is unlikely to result in tobacco product initiation or that it has no abuse liability without supporting information do not constitute the types of substantive information necessary for application filing. This information can come from a variety of sources including investigations conducted by the applicant, investigations conducted using a different product that the applicant can bridge to its new tobacco product (as described in section VII.B.13.a.), or published reports of investigations that apply to, or are bridged to, the new tobacco product (such as those found in the literature search required by § 1114.7(k)(2)). Section 1114.27(b)(1)(ii) requires a PMTA to contain substantive information regarding certain categories of investigations described in § 1114.7(k)(1). While FDA retains discretion to file applications as set forth in § 1114.27(b)(1), we generally intend to refuse to file each application that does not meet the substantive information requirement in paragraph (ii). Where there is no substantive information that is published or known to an applicant regarding any of the categories of information outlined in this section, including information in scientific literature or an investigation that an applicant could bridge to its product, an applicant would be required to conduct its own investigations and include the resulting full report in its PMTA in order to meet the requirements for filing. In general, FDA expects that manufacturers seeking to market a new product in accordance with the requirements of the statute will have access to information to meet these requirements for filing.[35]

FDA is implementing the application filing requirement under its authority in sections 910(b) and 701(a) of the FD&C Act. As described in section VIII.D, FDA needs information regarding the potential health risks of the new tobacco product, the likelihood of changes in tobacco product use behavior, and the potential health consequences associated with those changes in behavior to determine the potential risks and benefits to the health of the population as a whole under section 910(c)(4) of the FD&C Act. Refusing to file PMTAs that contain no information regarding these broad categories of information allows FDA to efficiently enforce the premarket review requirements of section 910 of the FD&C Act by avoiding the significant expenditure of resources it would otherwise commit to the substantive review of applications that clearly lack sufficient information to receive a marketing granted order. FDA expects that this efficiency will significantly benefit those applicants seeking timely consideration of complete, high-quality applications.

Section 1114.27(b)(1)(ii) requires a PMTA to contain at least some amount of substantive information regarding each of the following topics:

- The health risks of the new tobacco product as described in either § 1114.7(k)(1)(i)(A), (B), or (C)). Information regarding the health risks of the new tobacco product is a basic piece of information that FDA needs to determine the potential risks and benefits to the population as a whole associated with changes in tobacco use behavior;
- the health risks of the new tobacco product compared to the health risks that are generally presented by both tobacco products in the same category as well as tobacco products in at least one different category that are used by the consumers an applicant expects to use their new tobacco product (as described in a portion of § 1114.7(k)(1)(i)(D)). To demonstrate the health risks that are generally presented by the same, or a different, product category, applicants may use the health risks generally presented by a product category as a whole, or the health risks that are presented by specific products that are generally representative of the risks of the product category as a whole (*e.g.,* products that represent a significant share of the market for the product category). Comparative health risk information is a required part of FDA's review of an application because, as described in section VII.B.13.a, it can demonstrate the potential risks and benefits that current tobacco users could face if they switched to the new tobacco product or used it in conjunction with their current tobacco product;
- the abuse liability of the new tobacco product (as set forth in § 1114.7(k)(1)(ii)(A)). Information regarding abuse liability indicates the likelihood of users to become addicted to the product and face the health risks posed by product use over the long term, and may provide insight into the use and adoption of the product, which FDA must consider as part of its determination of the risks and the benefits of permitting the marketing of the new tobacco product to the population as a whole under section 910(c)(4) of the FD&C Act;
- how consumers actually use the product, including use topography, product use frequency, use trends over time, and how such use affects the health risks of the product to individual users (as set forth in § 1114.7(k)(1)(ii)(B)). Information regarding how consumers will actually use the new tobacco product is necessary to FDA's review of a PMTA because it helps demonstrate the health risks of the new tobacco product by showing the levels, and frequency, of exposure to HPHCs and other toxic substances contained in and delivered from the new tobacco product;
- the potential impact that the marketing of the new tobacco product would have on the likelihood that current tobacco product users would start using the new tobacco product, use the product in conjunction with other tobacco products, and, after using the product, switch to other tobacco products that may present increased risks to individual health (*i.e.,* any of the information described in either § 1114.7(k)(1)(ii)(C), (D), (E), or (F)). Information regarding potential changes to tobacco product use of current tobacco product users is a required basis for FDA's findings under 910(c)(4)(A);
- the potential impact of the product and its label, labeling, or advertising, to the extent advertising has been studied, on tobacco product use behavior of current nonusers of tobacco products (*i.e.,* any of the information described in § 1114.7(k)(1)(iii)). Information regarding potential impact that the marketing of the new tobacco product would have on tobacco product initiation by current nonusers of tobacco products is a required basis for FDA's findings under 910(c)(4)(B);
- the potential impact of the product and its label, labeling, or advertising (to the extent that advertising has been

[35] Information that is available to applicants includes, for example, the studies FDA has funded, published, and made available to the public, which are consolidated on our website. This database includes many ENDS related studies and can be searched by key terms (*e.g.,* e-cigarettes): *https://www.fda.gov/tobacco-products/research/ctp-supported-tobacco-regulatory-research-projects.*

studied) on individuals' perception of the product, and individuals' use intentions (as described in § 1114.7(k)(1)(iv)). This information is important to FDA's review of a PMTA because perceptions of the health risk of the product can influence decisions to use the product and, as described in section VII.B.6, exposure to advertising can have a significant impact on the likelihood that nonusers of tobacco products, particularly youth, will initiate tobacco product use. Without information regarding perceptions and use intentions, FDA will be unable to complete its required determination under section 910(c)(4)(B) of the FD&C Act of the increased or decreased likelihood that nonusers of tobacco products will initiate tobacco product use. It is important to note that this substantive information requirement does not require an applicant to develop or study advertising for the purpose of filing;

- the ways in which human factors can affect the health risks of the new tobacco product (*i.e.,* any of the information described in § 1114.7(k)(1)(v)). This information is important to FDA's review of a PMTA because it provides an assessment of use-related health hazards for the tobacco product.

FDA may also refuse to file a PMTA if:

- The PMTA contains a false statement of material fact; or
- the PMTA is a supplemental PMTA that does not comply with § 1114.15 or the PMTA is a resubmission that does not comply with § 1114.17. FDA may refuse to file a supplemental PMTA or a resubmission that contains all of the required content but does not meet the criteria for when a supplemental PMTA or a resubmission may be submitted. For both supplemental PMTAs and resubmissions, this could occur when, as discussed in §§ 1114.15(a) and 1114.17(a), the modifications to the original tobacco product are not appropriate to review in these formats. As described in § 1114.15(a), FDA may also refuse to file a supplemental PMTA where the marketing granted order for the original tobacco product has been temporarily suspended (except where authorized in writing by FDA) or has been withdrawn. As described in § 1114.17(a), FDA will refuse to file a resubmission where the marketing denial order for the original tobacco product states that the applicant may not use the resubmission format. If FDA refuses to file an application, it will send a letter to the applicant identifying, where practicable, the deficiencies that prevented FDA from filing the application. FDA received many comments regarding review procedures, as discussed below.

(Comment 95) One comment stated that FDA should include clear deadlines for the completion of acceptance and filing reviews. The comment stated that doing so would allow applicants to schedule the submission of PMTA in a way to ensure that the application is accepted and filed before the end of FDA's enforcement discretion policy. The comment stated that in addition, it is inconsistent with FDA policies for other regulated product types such as the deadline of 60 days for the filing of new drug applications.

(Response 95) To the extent that this comment concerns the compliance policy for the submission of PMTAs as a result of the deeming final rule, it is outside the scope of this rule. As a general process matter, FDA declines to set a deadline for acceptance and filing reviews both because it would not affect the 180-day review period and because FDA wishes to retain some amount of flexibility in its review process as it gains more substantial experience in reviewing PMTAs. Unlike with new drug applications, FDA's decision to file an application does not affect the statutory 180-day review period.[36] As described later in this section of the document, regardless of when in the process FDA files a PMTA, the 180-day review period begins when the last piece of information necessary to complete a PMTA is received by FDA.

(Comment 96) Multiple comments expressed opinions regarding the standards for application acceptance and filing. One comment supported the filing requirements, urging FDA to apply a standard of review that will enable it to distinguish between applications that contain scientific information that is arguably sufficient to address the issues relevant to determining whether the marketing of a product is APPH, and those applications that do not. Another comment requested that FDA clarify what an application must contain to be filed for review under § 1114.27(b), stating that what constitutes ''sufficient information'' under the filing standard is not addressed in the rule. Another comment stated that FDA has failed to make any meaningful distinction between the information that satisfies FDA's ability to review a PMTA and the ''sufficient information'' necessary for industry to obtain a marketing order. In addition, several comments requested that FDA clarify the requirements related to acceptance, filing, and substantive review because it was unclear what threshold of information must be in a PMTA to meet the requirements of each.

(Response 96) As described in the rule, FDA may refuse to accept a PMTA under § 1114.27(a)(1) where it does not appear to have the information required by the rule. This is a cursory check for the presence or absence of information at a very high level (*e.g.,* does the application contain labeling) and is intended to eliminate low-quality submissions. FDA may refuse to file an application where it does not contain sufficient information to permit a substantive review by FDA. Filing review is a limited examination to determine whether the technical elements of the application contain the information required by § 1114.7 (or other section as applicable), which FDA considers ''sufficient information'' at that time that would allow FDA to determine whether the application demonstrates the marketing of the product would be APPH. The ''sufficient information'' necessary to receive a marketing granted order is information that does, in fact, demonstrate the marketing of the product would be APPH and the PMTA meets the other requirements of section 910(c)(1)(A)(i) of the FD&C Act.

(Comment 97) Multiple comments stated that FDA should permit applicants to omit certain required information. One comment referenced the regulations for medical devices, in which FDA states that if an applicant believes that particular information is not applicable, an applicant can identify the omitted information and justify the omission. The comment stated that FDA cannot expect each applicant to provide information that will satisfy every requirement and that justified omissions should not result in marketing denial orders as currently stated in the PMTA proposed rule. Another comment requested flexibility regarding requirements to submit information it does not consider to be dispositive of health risks, such as the pharmacological profile.

(Response 97) FDA declines to make any revisions in response to these comments. As discussed throughout the rule, section 910(b)(1) of the FD&C Act describes the required contents of a PMTA upon which FDA must base its determination under section 910(c)(1)(A) of whether to issue a marketing granted order. FDA has carefully described why the information required by this rule is important to FDA's determination of whether a

[36] Compare section 505(c)(1) of the FD&C Act ''within one hundred and eighty days after filing of an application'' to section 910(c) ''as promptly as possible, but in no event later than 180 days after a receipt of an application under [910(b)(1)].''

marketing granted order should be issued and specifies where certain information would need to be submitted only if applicable to the new tobacco product that is the subject of the PMTA.

(Comment 98) One comment stated that FDA should file PMTAs for substantive review where they contain information about the various topics discussed in the rule, even where they do not include the final results of all referenced studies, so long as the applicant includes the study protocol and the expected date by which the applicant would submit the final study report to FDA. The comment also requested FDA identify application deficiencies before making its filing decision and request an amendment containing the specific information necessary for the application to be filed and do so under a reasonable timeline for the applicants' response before FDA issues a refuse to file decision.

(Response 98) FDA is establishing the filing requirements in order to encourage the submission of applications that contain the information FDA needs to determine whether a PMTA meets the requirements to receive a marketing granted order. FDA intends to refuse to file applications that do not contain the information required by § 1114.27(b), regardless of whether the applicant is conducting or sponsoring ongoing studies at the time of submission. FDA declines to, in every instance, identify application deficiencies before making its filing decision. In some circumstances, where the PMTA meets the information requirements in § 1114.27(b), the fact that a study has not yet been completed might not affect FDA's filing decision; however, this is a fact specific determination based on the content of each PMTA.

FDA generally does not intend to submit requests for amendments before it makes its decision to file the application for substantive review and applicants cannot expect to rely on FDA feedback to complete a PMTA after submission. FDA has provided detailed information regarding what application content is necessary for filing in this rule.

(Comment 99) Another comment stated that the final rule should be amended to clarify that FDA's decisions to refuse to accept (RTA) and refuse to file (RTF) PMTAs are subject to judicial review. The comment requested that FDA amend the rule to state that RTA and RTF letters constitute a denial within the meeting of 910 and 912 of the FD&C Act.

(Response 99) FDA disagrees with the contention that its decision to RTA or RTF constitutes a denial of a PMTA as described in section 910(a)(2)(A) of the FD&C Act; rather, refusing to accept or refusing to file constitutes a determination that the submission is either incomplete or does not conform to basic administrative requirements and, therefore, is not ready for substantive review. FDA makes its determination of whether to grant or deny the applicant a marketing authorization order only after conducting substantive review. Refusing to accept or refusing to file an application is a decision that is made without prejudice to any future submission and, as described in section IX.B, FDA intends to provide information regarding how the applicant can address the specific issues that led FDA to RTA or RTF the submission. It is important to note that section 910(c)(1)(A) requires FDA to grant or deny an order within 180 days after receipt of an application under section 910(b) and where FDA chooses to RTA or RTF an application, it is because it lacks required information and, therefore, does not constitute an application under section 910(b) of the FD&C Act.

After FDA files an application, it will begin its substantive review of the PMTA. Within 180 days after receipt of an application described in section 910(b)(1) of the FD&C Act, FDA intends to complete its review of a PMTA and, as described in § 1114.29, act on the application, except as described in §§ 1114.9 and 1114.27(c)(4) through (5).

(Comment 100) One comment stated that the final rule should be amended to clarify that acceptance and filing reviews do not extend the 180-day review clock.

(Response 100) FDA's acceptance and filing reviews do not extend the 180-day review period. To determine when the 180-day period begins, FDA generally relies on the date the last piece of information necessary to complete the submission is received by CTP's Document Control Center or the FDA laboratory (for product samples), not the date that the applicant sent it. It is important to note the event that starts the 180-day review clock is the receipt of an application that meets the requirements of section 910(b)(1) of the FD&C Act which also includes information required by the rule. Given that product samples are likely to be required after application acceptance, the review period would typically begin, at the earliest, when FDA receives product samples. Similarly, if an application is missing other pieces of required information, the review period would begin only upon receipt of that information. FDA intends to provide applicants with notice of the date on which the 180-day review period began, as well as notice of when it is paused, resumed, or reset.

(Comment 101) Multiple comments suggested that because FDA acknowledges the supplemental PMTA format will improve the efficiency of the review process, FDA should shorten the 180-day review period for supplemental PMTAs accordingly. Some comments pointed to the application supplement framework used by FDA for other products, such as drugs, and urged FDA to adopt a tiered system with different notification requirements and timeframes for review corresponding to the nature of the modification and the evidence needed to support it. In addition, one comment stated that FDA should provide clarity about the product modifications for which an applicant would be able to submit a supplemental PMTA, stating that the list of examples provided is insufficient and the suggestion to request a meeting with FDA to discuss supplemental PMTA submission would lengthen what should be an abbreviated process.

(Response 101) FDA agrees that supplemental PMTAs will improve the efficiency of the PMTA review process; however, FDA declines to create a standard shortened review period because it does not yet have any experience in conducting such reviews. In addition, supplemental PMTAs could contain substantial information that was not included in the original PMTA, such as the addition of Bluetooth capability for ENDS which may affect device functionality and, that may affect the review time. The application supplement notification procedures and timelines for other product types regulated by FDA are not only based on different statutory authorities, they are also the result of decades of experience in conducting such reviews. In addition, while FDA will have a 180-day review period to review a supplemental PMTA application, FDA intends to promptly act on the application, which might take fewer than 180 days.

There are four instances in which the 180-day review period after receipt of a complete PMTA would not be 180 consecutive calendar days. First, as described in § 1114.9, the submission of or request for amendments may result in changes to the number of calendar days in the review period. Where FDA requests a minor amendment, the issuance of this request would result in a pause of the review period and receipt of the amendment would resume the review period. As described in section VIII.C, the submission of a major

amendment is considered to be the submission of a new PMTA, which resets the 180-day review period.

The second instance in which FDA's 180-day review period would not be 180 consecutive calendar days after receipt of a complete PMTA is where a new tobacco product, if introduced or delivered for introduction into interstate commerce, would be adulterated or misbranded due to the domestic manufacturer or importer being in violation of the user fee requirements of part 1150 (21 CFR part 1150).[37] Situations in which a new tobacco product would be adulterated or misbranded for failure to comply with user fee requirements are described in § 1150.17(a) and (b), which include failure to pay user fee assessments and failure to submit required reports. In this situation, FDA intends to pause the 180-day review period until any violation of the user fee requirement of part 1150 is resolved. FDA implements this provision under its section 701(a) authority to issue regulations for the efficient enforcement of the FD&C Act. It would be inefficient for FDA to expend the significant resources necessary to review an application for a product that could not be legally marketed. It would also not be reasonable for FDA to complete its review and issue a marketing granted order for a product that, if it is put into interstate commerce, would immediately be adulterated or misbranded and subject to FDA enforcement action. While FDA will not refuse to accept or refuse to file an application on the basis that the product would be adulterated for failure to pay user fees, FDA will not complete its review of a PMTA until the applicant is in compliance with part 1150. FDA will take this action, rather than refusing to accept or refusing to file an application, because noncompliance with the requirements of part 1150 can often be resolved quickly.

The third instance in which FDA's 180-day review period would not be 180 consecutive calendar days after the receipt of a complete PMTA is where FDA is prevented from scheduling or conducting inspections of the manufacturing sites or the sites or entities involved with the clinical and nonclinical research (including third parties and contract research organizations) prevent FDA from completing its review of the PMTA in a timely manner. Where this occurs, FDA may pause the 180-day review period for the number of days necessary to complete the inspection after a delay occurs. FDA has experienced delays in both scheduling and conducting inspections, which results in FDA not having the information it needs to complete its required review in 180 consecutive calendar days.

The fourth instance in which FDA's 180-day review period may not be 180 consecutive calendar days after the receipt of a complete PMTA is where FDA determines after application filing that the applicant has not submitted an adequate EA. NEPA and regulations issued by the Council on Environmental Quality (CEQ) (42 U.S.C. 4332(2); 40 CFR parts 1500 to 1508) require FDA to assess, as an integral part of its decision-making process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment and to ensure that the interested and affected public is appropriately informed. FDA has implemented the NEPA and CEQ requirements in part 25. Under § 25.15(a), failure to submit an adequate EA is grounds for refusing to authorize an application. Consistent with § 25.15(a), FDA may refuse to authorize the marketing of a new tobacco product where a PMTA contains an inadequate EA.

As described in § 1114.27(c)(4), FDA may conduct inspections of the applicant's manufacturing sites, and sites and entities involved with clinical and nonclinical research (including third parties and contract research organizations) to support FDA's review of the PMTA. Inspecting the facilities and controls described in the application will allow FDA to ensure the applicant can manufacture the product in accordance with the manufacturing practices described in the application and would help FDA determine under section 910(c)(2) of the FD&C Act whether such practices conform to an applicable product standard issued under section 907 of the FD&C Act or tobacco product manufacturing practice requirement issued under section 906(e) of the FD&C Act, when in effect. Inspecting sites and entities involved with clinical and nonclinical research, including their records (such as those required to be kept under § 1114.45), will allow FDA the opportunity to verify the study findings and data that the applicant relies upon in the PMTA to demonstrate that the new tobacco product should receive a marketing granted order. Under § 1114.33, failure to grant FDA access at a reasonable time and in a reasonable manner, an opportunity to inspect these sites and have access to, copy, and verify all records pertinent to the application may result in the issuance of a marketing denial order because FDA would not be able to determine whether permitting the marketing of the new tobacco product would be APPH. During an inspection, an applicant should ensure that:

- All pertinent records can be viewed;
- documents written in a language other than English can be translated into English, if requested. Documents that have been translated from another language into English should be accompanied by a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation; and
- if the tobacco product is in production (domestic or foreign) and is intended for U.S. commercial distribution, FDA can view the product being manufactured.

C. FDA Action on an Application (§ 1114.29)

Section 1114.29 lists six actions that FDA may take after receiving an application:

- First, FDA could refuse to accept the application, as described in § 1114.27(a);
- second, FDA could issue a letter administratively closing the application. This could occur where an applicant fails to respond to a request for an amendment within the time period specified in the amendment request under § 1114.9(b) or requests to withdraw an application under § 1114.11. In the proposed rule, FDA had previously stated that ''this could occur where an applicant fails to response to a request for an amendment within 180 days.'' FDA changed this language in the final rule to be the time period to respond to the amendment request to reflect that fact that the time for response might vary according to the complexity of the amendment request and thus could be a period other than 180 days (*e.g.,* an amendment request for relatively simple information might have a shorter response period).
- third, FDA could issue a letter canceling the application if FDA finds it mistakenly accepted the application (*e.g.,* the application does not pertain to a new tobacco product, or the application was submitted in error);

[37] Currently, only the manufacturers of cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and RYO tobacco are subject to the requirements of part 1150. See the final rule, ''Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco'' (81 FR 28707) (May 10, 2016), for more information.

- fourth, FDA could refuse to file the application as described in § 1114.27(b);
- fifth, FDA could issue a marketing granted order as described in § 1114.31; or
- sixth, FDA could issue a marketing denial order as described in § 1114.33.

D. Issuance of a Marketing Granted Order (§ 1114.31)

1. The Requirements To Receive a Marketing Granted Order

Under section 910(c)(1)(A)(i) of the FD&C Act, FDA will issue a marketing granted order for a new tobacco product after its review of a PMTA if it finds that none of the grounds for denial specified in section 910(c)(2) of the FD&C Act applies to the application. This means that in order for FDA to issue a marketing granted order for a new tobacco product, FDA must be able to determine the following:

a. There is a showing that permitting the marketing of the new tobacco product would be APPH. Under section 910(c)(4) of the FD&C Act, FDA's finding that permitting the marketing of a new tobacco product would be APPH must be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of tobacco products, and taking into account:

- The increased or decreased likelihood that existing users of tobacco products will stop using such products and
- the increased or decreased likelihood that those who do not use tobacco products (including youth and young adults) will start using such products.

Finding that there is a showing that permitting the marketing of a new tobacco product would be APPH is a complex determination that must be made with respect to risks and benefits to the population as a whole, considering the likelihood of changes in tobacco product use behavior (including initiation and cessation) caused by the marketing of the new tobacco product. When determining whether the marketing of a particular new tobacco product would be APPH, FDA will evaluate the factors in light of available information regarding the existing tobacco product market, tobacco use behaviors, and the associated health risks at the time of review. As described in section 910(c)(5) of the FD&C Act, the types of scientific data that FDA will consider in making its determination can include well-controlled investigations and, where appropriate, other valid scientific evidence that FDA determines to be sufficient to evaluate the tobacco product. FDA will consider the information supplied in the application together with any other relevant sources of information, including a report or recommendation from TPSAC, when applicable, in making its determination.

Section 910(c) of the FD&C Act requires FDA to consider an array of potential risks and benefits of each new tobacco product with respect to the population as a whole when determining whether permitting the marketing of a new tobacco product would be APPH. As set forth in the criteria for withdrawing a marketing granted order in section 910(d)(1)(A) of the FD&C Act, FDA must continue to find the product meets the APPH standard over time.

FDA received many comments regarding the requirements to obtain a marketing granted order, as discussed below.

(Comment 102) Several comments stated that FDA has failed to explain or justify how it is interpreting and applying the APPH standard when evaluating PMTAs and must do so to allow a determination of whether its issuance of PMTA marketing orders is arbitrary and capricious. In addition, some comments expressed concern that the lack of articulated definitions and standards regarding the APPH standard would leave applicants guessing at what might satisfy the standard. In addition, another comment stated that failing to provide this essential direction could increase the likelihood of arbitrary and inconsistent decisions.

(Response 102) FDA disagrees with the assertion that is has failed to provide adequate information concerning the APPH standard in section 910(c)(2) of the FD&C Act. Similar to premarket standards for other products, such as medical devices or drugs, FDA does not provide a precise definition of the standard but instead provides information regarding the types of information that can be used to demonstrate the standard has been met. FDA intends to consider the marketing of a new tobacco product to be APPH where a PMTA contains sufficient valid scientific evidence to demonstrate that the potential risks and benefits of the marketing of the new tobacco product would likely have a net positive effect on the health of the population as a whole, which includes youth, young adults, and other relevant vulnerable populations. This could include a variety of different types of evidence that may provide FDA with an overall assessment of the potential effect permitting the product to be marketed may have on tobacco-related morbidity and mortality. For example, FDA may consider scientific evidence such as whether levels of HPHCs and other constituents in the new tobacco product are similar or lower than levels of similar tobacco products currently on the market (see section VIII.B.9.a.v), whether the use of the tobacco product has a lower risk of disease than the use of a similar product (see section VIII.B.13.a.ii), whether consumers are likely to use the product in a manner that will lead to possible lower risks (see section VIII.B.13.a.iv), and whether the marketing of the new tobacco product affects the likelihood of nonuser uptake, ways in which the product may be designed to limit or prevent youth access and use, cessation rates or other significant shifts in user demographics such that it decreases morbidity and mortality from tobacco product use, including youth, young adults, and other vulnerable populations (see section VIII.B.6.b). As described in this section, the APPH standard requires a balancing of product-specific potential risks and benefits. For example, an applicant maybe able to demonstrate that their product is APPH by providing sufficient valid scientific evidence to show, among several key considerations, that the tobacco product reduces morbidity and mortality. This could include showing the potential reductions in disease risk as compared to other tobacco products and weighing that against the potential for nontobacco users to use tobacco product and the accompanying potential changes in disease risk among new tobacco users. As a result, the factors that could help demonstrate that the marketing of a particular new tobacco product would be APPH might not support the marketing of a different new tobacco product. As a general example, if an application demonstrates that using a new tobacco product would present significantly less toxicological risk to individual health than cigarettes in a marketplace where many addicted users currently smoke cigarettes, it could likely, depending on other factors, receive an order where the PMTA demonstrates that the vast majority of individuals who would use the product would be current users of cigarettes who otherwise would not have quit and would switch to using the new product exclusively. This can be seen in FDA's determination to authorize the marketing of a tobacco product that demonstrated, among several key considerations, that the product produced fewer or lower levels of some

toxins than conventional cigarettes.[38] On the other hand, where a PMTA for a different tobacco product shows that individuals that would use the new tobacco product are predominately current users of tobacco products that have less toxicological risk to individual health, including products within the same product category, the application is likely, again depending on other factors, to result in the issuance of a marketing denial order because the product is not likely to have a net benefit to the population as a whole. As discussed in section VIII.B.14, understanding of the effect the new tobacco product may have on the health of the population as a whole, which includes youth, young adults, and other vulnerable populations, such as effects on tobacco use initiation, switching, and cessation, and reductions in premature mortality, or increases in life-years lived, directly informs FDA's determination as to whether permitting the marketing of the new tobacco product would be APPH. The discussion should include all of the information in the PMTA regarding the product and its potential effects on health, including, but not limited to adverse experiences, tobacco use behavior, and tobacco use initiation to provide an overall assessment of the potential effect that permitting the product to be marketed has or may have on overall tobacco-related morbidity and mortality including on youth, young adults, and other vulnerable populations.

In addition to the information provided throughout this document, applicants may obtain information regarding how the APPH standard can be met from marketing granted orders and decision memoranda that FDA posts on its website.

(Comment 103) One comment stated that where an applicant proposes a restriction on the marketing of its product, such as a limitation on sales, FDA should apply that restriction in making its APPH determination.

(Response 103) FDA will consider proposed restrictions on the sales and distribution of a tobacco product as part of its review of a PMTA and may determine that it should impose such restrictions where FDA determines they are APPH. However, FDA's review is not constrained by such proposals and FDA intends to consider a variety of factors in determining whether it should include those restrictions, including, but not limited to, whether it would be feasible or realistic for the applicant to implement such restrictions, or the ease with which the implementation of the restrictions may be monitored or enforced as they pertain to all population groups, including among groups disproportionately affected by tobacco product use. FDA will also consider and may impose restrictions on sales and distribution different from, or in addition to, those proposed by the applicant.

(Comment 104) One comment stated that FDA should focus its evaluation on the population segments most likely to be affected by the marketing of the new tobacco product and require applicants to show a public health benefit for those specific groups.

(Response 104) FDA declines to make changes in response to this comment. FDA is required by section 910(c)(4) of the FD&C Act to determine its APPH finding based upon the risks and the benefits to the population as a whole. This includes consideration of all parts of the population, including those more likely to be affected by the marketing of the new tobacco product, and it is not limited to only the effect on specific population segments.

(Comment 105) One comment requested a clear regulatory definition of the APPH standard, with product category-specific guidance about what is required to meet the target, noting that it is missing from the proposed rule and is crucial for applicants as they develop the data needed to substantiate that a new tobacco product meets the APPH standard and prepare their applications. The comment recommended that FDA provide further clarity in the final rule as to the factors to be considered in an APPH analysis and how the Agency will weigh those factors. The comment requested that FDA provide clarification as to whether a showing of reduced morbidity and mortality is required to receive a marketing order, asserting that the structure of the statute and congressional intent make clear that Congress intended a marketing order under section 910 of the FD&C Act to be a less burdensome standard than the standard for a marketing order for a modified risk product under section 911of the FD&C Act. The comment also requested additional information regarding how FDA will determine whether a product has had a net positive effect on the health of the population as a whole, including whether each factor has a threshold finding.

(Response 105) FDA declines to set static requirements that a new tobacco product could meet and be considered to meet the APPH standard because the tobacco product marketplace and trends in consumer behavior that inform FDA's APPH determination are not static. The factors that could demonstrate that permitting the marketing of a new tobacco product would be APPH at one point in time might not support the same determination with respect to a similar product in the future. For example, FDA may consider, in conjunction with other available data regarding the new tobacco product, information showing that a product has reduced morbidity and mortality to help demonstrate that the potential risks and benefits of marketing the new tobacco product would have a net positive effect on the health of the population as a whole (which includes youth, young adults, and other vulnerable populations).

However, FDA does not make its APPH determination on one static set of requirements. FDA makes its APPH determination in consideration of the existing market (*e.g.,* the products on the market, tobacco product use behaviors) at the time the determination is made. For example, FDA has authorized marketing of a product that would, among other things, potentially reduce nicotine dependence in adult smokers who may also benefit from decreasing nicotine exposure and cigarette consumption. In consideration of the existing market and based on the information provided by the applicant, FDA was able to determine that nonsmokers, including youth, would also be unlikely to start using the product, and those who experiment would be less likely to be become addicted than people who experiment with conventional cigarettes. [39] As the tobacco product market changes over time, the potential risks and benefits of marketing a new tobacco product to the population as a whole might also change. A new tobacco product that receives a marketing granted order under the current market conditions might not receive an order at a future time in which fewer individuals are using products that present higher levels of risk to individual health or such products are no longer on the market. Due to the nature of the Federal rulemaking process, if FDA were to codify what could satisfy the APPH standard under market conditions that are current at the time, FDA may not be able to update such standards in a timely manner.

(Comment 106) Several comments stated that FDA has failed to explain or

[38] *https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders.*

[39] *https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders.*

justify how it is interpreting and applying the APPH standard when evaluating PMTAs and must do so to allow a determination of whether its issuance of PMTA marketing orders is arbitrary and capricious. In addition, some comments were concerned that the lack of articulated definitions and standards regarding the APPH standard would leave applicants guessing at what might satisfy the standard. In addition, another comment stated that failing to provide this essential direction could increase the likelihood of arbitrary and inconsistent decisions.

(Response 106) FDA disagrees with the assertion that is has failed to provide direction concerning the APPH standard in section 910(c)(2) of the FD&C Act. FDA describes its interpretation of the APPH standard in details in this section, including the statement that FDA intends to consider the marketing of a new tobacco product to be APPH where a PMTA contains sufficient valid scientific evidence to demonstrate that the potential risks and benefits of the marketing of the new tobacco product would have a net positive effect on the health of the population as a whole.

(Comment 107) Multiple comments stated that FDA should require that PMTAs contain information demonstrating that all available steps have been taken to make the product as minimally harmful as possible in order for the marketing of a tobacco product to be considered APPH.

(Response 107) As described in section IX.D, FDA interprets the APPH standard in section 910(c)(2)(A) to require a showing that permitting the marketing of a new tobacco product would likely have at least a net benefit to public health based upon the risks and benefits to the population as a whole. Where an applicant meets this standard along with the other criteria in section 910(c)(2) of the FD&C Act, FDA will issue a marketing granted order.

(Comment 108) Multiple comments stated that FDA should impose a number of conditions that products must meet to receive a marketing granted order. One comment stated FDA should apply a more rigorous standard than it did in previous PMTA reviews by requiring an applicant demonstrate, among other things that its product is significantly less harmful than other products current on the market and that any increase in health risks is significantly smaller than the likelihood and size of the benefits it presents. Another comment stated FDA should impose specific requirements that a flavored tobacco product must meet to receive a marketing granted order, including requirements such as having no appeal to youth, being substantially less harmful than smoking, and promoting complete cessation of tobacco products.

(Response 108) FDA declines to create a series of criteria that either all products or a specific subset of products must meet be in order for marketing of such products to be considered APPH as part of this rule. As described elsewhere in this section, FDA intends to consider marketing of a new tobacco product to be APPH where permitting its marketing would likely have at least a net benefit to public health based upon the risks and benefits to the population as a whole, which includes youth, young adults, and other vulnerable populations. While this determination would involve consideration of many factors, including some of the particular concerns cited by the comments, it will be made with respect to the risks and benefits to the health of the population as a whole, rather than whether a product meets each item in a series of specific criteria.

(Comment 109) Multiple comments made suggestions regarding how FDA should consider the risks and benefits that the marketing of the new tobacco product may have on specific groups of the population, with one comment emphasizing social justice concerns and highlighting the effects that the new tobacco product may have on disadvantaged or vulnerable populations. Another comment stated that the FD&C Act does not permit FDA to weigh the risks and benefits a product may have on one group more strongly than another.

(Response 109) Section 910(c)(4) of the FD&C Act requires the finding of whether the marketing of a new tobacco product would be APPH to be determined with respect to the population as a whole. As noted elsewhere in this document, FDA has made edits to ensure the rule addresses the potential effects of permitting the marketing of a new tobacco product to vulnerable populations and FDA will consider the potential effects on such groups as part of its assessment of the effect on the population as a whole.

It is important to note that in order for FDA to issue a marketing granted order for a new tobacco product, section 910(c)(1)(A)(i) of the FD&C Act requires FDA to find there is ''a showing'' that the marketing of the new tobacco product would be APPH. FDA interprets this to mean that an applicant must submit sufficient information in its PMTA for FDA to be able to find whether the marketing of a product would be APPH. While FDA may consider outside sources of information during PMTA review, an applicant cannot rely on FDA to seek out or create additional data to fill information gaps that may exist in a PMTA. As discussed in section VIII.E., failure to submit sufficient information that FDA needs to make its required findings would result in the issuance of a marketing denial order.

This rule focuses primarily on PMTA review procedures and content requirements, particularly with respect to application acceptance and filing. An application may meet the acceptance and filing requirements, but still lack vital information that FDA needs to determine whether it should issue a marketing granted order. The rule creates a requirement to submit full reports of all existing health risk investigations; however, where there is not sufficient existing evidence that an applicant may utilize to demonstrate that the marketing of a new tobacco product would be APPH, an applicant would need to conduct its own investigations to ensure that FDA has sufficient valid scientific evidence it needs to determine whether a marketing granted order should be issued for the new tobacco product.

Although an applicant may submit any type of evidence to FDA in an attempt to substantiate that the new tobacco product should receive a marketing granted order, FDA relies upon only valid scientific evidence to determine whether the marketing of the new tobacco product would be APPH.

(Comment 110) One comment stated that FDA should require the full report of each study to identify the source of funding and give less weight to the results of industry research than to independent scientific research and should explicitly consider bias in industry studies.

(Response 110) FDA declines to make changes as a result of this comment FDA's determination of whether there's a showing that permitting the marketing of a new tobacco product would be APPH must be determined on the basis of valid scientific evidence. FDA assesses all scientific evidence with the same rigor to determine whether it is valid, regardless of the source.

(Comment 111) One comment stated that FDA must require long-term clinical studies because it impossible to determine the risks and benefits of a tobacco product without them.

(Response 111) Long-term clinical studies can provide information that is important to FDA's review; however, the FD&C Act grants FDA the authority to consider other valid scientific evidence in making its APPH determination. Section 910(c)(5) of the

FD&C Act explains that APPH ''shall, when appropriate, be determined on the basis of well-controlled investigations.'' This section also explains that FDA may base its APPH determination on ''valid scientific evidence (other than evidence derived from [well-controlled investigations]) which is sufficient to evaluate the tobacco product.'' As discussed in this section, FDA does not expect that long-term clinical studies will need to be conducted for each PMTA; instead, it expects that it should be able to rely on other valid scientific evidence to evaluate some PMTAs.

FDA will determine whether the evidence submitted or otherwise available to FDA is valid scientific evidence for the purpose of determining the new tobacco product's impact on individual and population health, and whether the available evidence, when taken as a whole, is adequate to support a determination that permitting the new tobacco product to be marketed would be APPH.

Valid scientific evidence includes data from well-controlled investigations, as well as other sources upon which FDA may base its determinations under section 910(c)(5) of the FD&C Act. Other sources may include partially controlled studies, studies and objective trials without matched controls, and well-documented case histories conducted by qualified experts. The other sources of study data may be considered valid scientific evidence if they have been gathered using well-established or standardized methodologies from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the reliability of their findings. The evidence required may vary according to the characteristics of the tobacco product, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of consumer experience with its use. Isolated case reports, anecdotal experiences, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not considered valid scientific evidence.

As part of its determination of whether permitting the marketing of a new tobacco product would be APPH, FDA must be able to determine the likely health risks of the new tobacco product. While this rule does not necessarily require applicants to conduct new studies for the purposes of application acceptance and filing (beyond the requirements of § 1114.27(b)(1)(ii)), FDA expects that it could not issue a marketing granted order unless an application contains data from a variety of sources, including both clinical and nonclinical investigations that give FDA comprehensive information about the product's likely health effects in the U.S. market. Where epidemiological evidence is available and comes from an investigation using a different product or one that was conducted outside the United States, FDA would examine whether the PMTA contains sufficient information, or the applicant has conducted bridging studies when needed, to demonstrate the data is applicable to the product and the U.S. population or provides adequate justification for how the information is relevant. FDA recognizes that this type of long-term epidemiological data is not available for all categories of products and does not expect that long-term clinical studies (*i.e.,* those lasting approximately 6 months or longer) will need to be conducted for each PMTA; however, in the event long-term clinical study data should become available for the new product or similar product while the application is pending, this information should be submitted to FDA in an amendment.

Where a PMTA contains no long-term epidemiological evidence regarding the product or that could be bridged to the product, FDA would consider whether there are other sources of scientific evidence that sufficiently demonstrate the potential health risks of the product, such as actual use studies (*e.g.,* clinical studies that assess real-world use conditions and health outcomes, or clinical studies that use scientifically valid endpoints as a predictor for potential long-term health effects). Where a PMTA lacks human subject study data regarding the product or that can be bridged to the product, FDA will examine how a PMTA attempts to estimate the health effects of the product on the U.S. population from the results of nonclinical investigations; however, it should be noted that information from nonclinical studies alone is generally not sufficient to support a determination that permitting the marketing of the product would be APPH.

As part of FDA's consideration of the changes in tobacco product use behavior that are likely to be caused by the marketing of the new tobacco product, FDA will examine data regarding how the product, its label, labeling, and any available advertising, and description of the applicant's marketing plans will affect the tobacco use behavior of both users and nonusers of tobacco products, including the behaviors described in § 1114.7(k)(1)(ii) and (iii). FDA needs sufficient information to determine the potential changes in tobacco product use behavior and the health risks and benefits associated with the changes in user behavior will allow FDA to make a determination of whether permitting the marketing of the new tobacco product would be APPH. Where a PMTA does not contain sufficient information for FDA to make these determinations, FDA will issue a marketing denial order for the product because the PMTA lacks information necessary to determine the risks and benefits to the population as a whole as required by section 910(c)(4) of the FD&C Act.

(Comment 112) Multiple comments stated that a premarket assessment of a new tobacco product can neither fully nor precisely predict future tobacco use behavior patterns and recommended that FDA modify the rule to acknowledge such limitations on premarket research. Another comment expressed a similar opinion and noted that FDA has postmarket tools, including the ability to withdraw a marketing granted order to address unintended consequences.

(Response 112) FDA disagrees with the implication that it should discount the importance of information concerning the likelihood of changes in tobacco product use behavior during application review and, in essence, shift it to a postmarket determination. As discussed in the following paragraphs, the burden is on the applicant to make a showing that the marketing of its new tobacco product would be APPH. Section 910(c)(4) of the FD&C Act requires FDA to consider the likelihood of changes in tobacco product use behavior in making its APPH determination and if an application lacks sufficient information to make this determination, FDA must issue a marketing denial order.

b. The methods used in and the facilities and controls used for, the manufacture, processing, or packing of such tobacco product conform to the requirements of section 906(e) of the FD&C Act. As discussed in section VII.B.12 regarding § 1114.7(j), FDA has not yet issued a regulation under section 906(e) of the FD&C Act, so demonstrating compliance with such regulations in a PMTA is not currently required; however, FDA plans to issue proposed rulemaking(s) under section 906(e), and once such regulations are effective, applicants must demonstrate that their methods, facilities, and controls are in conformance with applicable requirements to receive a marketing granted order under section 910(a)(1)(i)(A) of the FD&C Act. Until such a final rule issued under section 906(e) of the FD&C Act is effective, FDA

will evaluate the manufacturing process and consider whether the product can be manufactured in a manner consistent with the information submitted within the application as part of its determination of whether the marketing of the new tobacco product is appropriate for the protection of public health. As part of this evaluation, FDA will consider whether the applicant would be able to consistently produce the new tobacco product as described in the PMTA. The potential for an applicant to produce nonconforming tobacco products that have higher levels of HPHCs than intended, have dangerous foreign material, or otherwise potentially presents a higher risk of harm than the product described in the PMTA may affect FDA's determination of whether the marketing of a product would be APPH.

(Comment 113) One comment stated that FDA should amend the rule to address how applicants will be able to address evolving requirements, such as product standard and manufacturing practice requirements, especially if changes become effective during application review.

(Response 113) The regulatory processes that FDA must follow to issue a product standard under section 907 of the FD&C Act or tobacco product manufacturing practices under section 906(e) of the FD&C Act are lengthy and would provide applicants with notice of proposed requirements well in advance of any change becoming effective. FDA generally intends to give applicants the opportunity to amend previously submitted applications to demonstrate conformance with new requirements under sections 906(e) or 907 of the FD&C Act; however, FDA may provide directions regarding how to demonstrate conformance in the text of any such rulemaking.

c. Based on a fair evaluation of all material facts, the proposed labeling is not false or misleading in any particular.

d. The tobacco product is shown to conform in all respects to a tobacco product standard in effect under section 907 of the FD&C Act or there is adequate information to justify a deviation from such standard. A PMTA submitted under the rule is required by § 1114.7(d)(2) to contain a statement identifying all tobacco product standards issued under section 907 of the FD&C Act that are applicable to the new tobacco product and a brief description of how the new tobacco product fully meets the identified tobacco product standard(s) or justifies a deviation from such standards, if applicable. FDA must be able to locate the data regarding the tobacco product's compliance with the product standard and determine that the tobacco product does, in fact, meet the requirements of the applicable product standard(s) or, if applicable, deviates from such standards in a way that is justified. For example, if an applicant submitted a PMTA for a product that is subject to a product standard limiting the amount of an HPHC that may be delivered to product users, FDA must be able to verify though a review of the HPHC testing data contained in the product formulation section that the product complies with that product standard. Under section 910(c)(2)(D) of the FD&C Act, FDA will not issue a marketing granted order for a tobacco product unless a PMTA demonstrates that it meets any applicable product standard(s), or an applicant has justified the deviation from such standard, if applicable.

1. Restriction on the Sale and Distribution of a New Tobacco Product in a Marketing Granted Order

Section 1114.31(b) describes restrictions and additional requirements that FDA may include as part of a marketing granted order. Under section 910(c)(1)(B) of the FD&C Act, FDA may require the sale and distribution of the tobacco product be restricted to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d) of the FD&C Act. Section 1114.31(b)(1) reiterates this authority as part of the rule and § 1114.31(b)(2) allows FDA to include restrictions on sales and distribution proposed by the applicant in its PMTA as part of a marketing granted order.

A number of comments suggested that FDA impose a number of specific restrictions on the sales and distribution of tobacco products under the rule, as discussed below.

(Comment 114) One comment stated that the rule should be amended to require age verification for all websites and social media, and to prohibit the use of partners, sponsors, influencers, bloggers, or brand ambassadors to market or promote the product.

(Response 114) FDA declines to revise the rule in response to this comment because, at this time, FDA intends to consider which restrictions on sales and distribution should be included in a marketing granted order for a new tobacco product on a case-by-case basis.

(Comment 115) One comment stated that FDA should amend the rule to require preauthorization of all advertising and marketing materials during an initial 5-year period that a new tobacco product is permitted on the market.

(Response 115) FDA declines to make this revision because it is in conflict with section 903(b) of the FD&C Act.

(Comment 116) One comment stated that FDA should require each marketing granted order to include all available restrictions on the product packaging, labeling, marketing, sale, including the use of restrictions that require products to be sold with additional labeling and marketing requirements that would reduce the risk of youth exposure to the product or its advertising while also reducing the likelihood of increased tobacco-related harms and risks for current users. For example, FDA could require revisions to an ENDS product nicotine warning statement to include information such as the product is meant only as a complete substitute for traditional smoking and any other use will increase harms or risks to the user's health. The comment further stated that FDA must take advantage of readily accessible means in its issuing of marketing granted orders to avoid or reduce any unnecessary individual or public health harms or risks. The comment stated the belief that FDA's failure to implement or consider these types of restrictions to reduce the risk of harm of these products could lead to FDA being found arbitrary and capricious under the Administrative Procedure Act.

(Response 116) FDA agrees with the comment's general point that restricting the sales and distribution of a new tobacco product is an important way in which FDA can potentially limit the health risks of a new tobacco product. FDA intends to consider whether and which restrictions are appropriate for the marketing of a new tobacco product under section 910(c)(1)(B) on a case-by-case basis during substantive review. FDA disagrees with the comment's broad assertion, which suggests that FDA is required to impose certain restrictions in every marketing order, when the FD&C Act does not so require.

(Comment 117) One comment requested that FDA, in issuing a marketed granted order, explicitly prohibit the marketing of a product in any way that targets vulnerable populations unless it only reaches users of more harmful tobacco products or users of more harmful products who have already switched.

(Response 117) FDA agrees with the general principle that a new tobacco product should be marketed in ways that will not increase the health risks to vulnerable populations. FDA declines to implement a blanket restriction on the scope of permissible advertising as part

of this final rule and instead will consider restrictions on the sales and distribution of a new tobacco product under § 1114.31(b)(2) on a case-by-case basis for each new tobacco product that meets the requirements to receive a marketing granted order.

2. Requirements for Postmarket Records and Reports in a Marketing Granted Order

Section 1114.31(b)(3) allows FDA, using its authority in section 910(f) of the FD&C Act, to require an applicant to submit postmarket reports in addition to those described in § 1114.41, as appropriate. This can include, but is not limited to, requirements that an applicant provide information such as labeling, advertising, marketing, promotional materials, or marketing plans not previously submitted to FDA, and do so at least 30 days prior to the initial publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials. Similar to what is described in section VII.B.6, these items provide information that is important to FDA's determination of whether the continued marketing of the new tobacco product would be APPH or whether FDA must withdraw the marketing granted order under section 910(d)(1)(A) of the FD&C Act because the marketing of the new tobacco product is no longer APPH. Receiving this information in advance of its first use is not for pre-approval but will allow FDA to ensure it can appropriately track and monitor the impact that the use of such information has on tobacco use behavior. In addition, if needed, this information will allow FDA to provide applicants with advisory comments, including any concerns about possible impact on youth appeal and tobacco use initiation and with regard to the finding that the continued marketing of the product is appropriate for the protection of public health. FDA anticipates it will use this authority on a case-by-case basis, especially as it relates to novel tobacco products for which the body of knowledge is still growing.

E. Issuance of a Marketing Denial Order (§ 1114.33)

Section 1114.33 describes the circumstances under which FDA would issue a marketing denial order for a new tobacco product after PMTA review. Section 1114.33(a)(1) specifies that based on the information submitted as part of the application and any other information before FDA with respect to the new tobacco product, FDA will issue a marketing denial order if any of the grounds for denial listed in 910(c)(2) of the FD&C Act apply to the application. Any other information before FDA may include, for example, information received from a TPSAC report, toxicological information regarding a particular ingredient or combination of ingredients (*e.g.,* diacetyl) from peer reviewed research results that were published after the PMTA was submitted, or preliminary results from a study that FDA is aware of (*e.g.,* a Tobacco Centers of Regulatory Science study).

As discussed elsewhere in this document, meeting the requirements for application acceptance and filing does not mean that an application has sufficient information to receive a marketing granted order. For example, while FDA may accept and file an application that contains the information in § 1114.7(k), FDA will not issue a marketing granted order unless that information also makes a showing that permitting the marketing of a new tobacco product would be APPH. While the rule does not necessarily require the applicant to conduct studies on its product, applicants would need to do so for products for which insufficient information exists to demonstrate whether marketing of the product is APPH. Similarly, the information required in the manufacturing section of the application is required for acceptance and filing; however, unless the manufacturing process described ensures a product will be consistently produced as described in a PMTA (*e.g.,* implementing sufficient controls), an applicant would receive a marketing denial order.

Examples of when FDA would be required to issue a marketing denial order for a lack of information necessary to make its required findings and determinations under sections 910(c)(2) and (c)(4) of the FD&C Act are contained throughout this document and include, but are not limited to, a lack of sufficient information regarding:

- The health risks of the new tobacco product;
- a comparison of the new tobacco product to the health risks of other tobacco products used by individuals that the applicant expects to use the new tobacco product, including products both within the same category as the new tobacco product and at least one different product category;
- the abuse liability of the new tobacco product;
- potential changes to tobacco product use behavior of current tobacco product users;
- the increased or decreased likelihood that those who do not use tobacco products will start using tobacco products;
- the impact of the product and its label, labeling, and advertising, to the extent that advertising has been developed and studied, on individuals' perception of the health risks of the product and their use intentions; and
- how human factors can influence the health risks of the new tobacco product.

Section 1114.33(a) also allows FDA to issue a marketing denial order where the applicant does not permit an authorized FDA employee, at a reasonable time and a reasonable manner, an opportunity to: (1) Inspect the facilities and controls, and sites and entities involved with clinical and nonclinical research (including third parties and contract research organizations) described in the application or (2) have access to, copy, and verify all records pertinent to the application, where such refusal prevents FDA from making the required findings in 910(c) necessary to issue a marketing granted order. FDA would issue a marketing denial order where an applicant does not permit these inspections because the ability to access and inspect the facilities and controls and sites and entities involved with clinical and nonclinical research, as well as pertinent records, is important to FDA's ability to determine whether any of the denial criteria specified in section 910(c)(2) of the FD&C Act and § 1114.33(a)(1) apply to the application. Inspecting the facilities and controls described in the application will allow FDA to ensure the applicant can manufacture the product in accordance with the manufacturing practices described in the application. Inspecting records, including those required to be kept under § 1114.45, will allow FDA the opportunity to verify the study findings and data that the applicant relies upon in the PMTA to demonstrate that the new tobacco product should receive a marketing granted order. As stated in § 1114.45, the records would be required to be legible and written in English.

If FDA issues a marketing denial order, it will, where practicable, identify measures to address the reasons for which the application is being denied. While FDA will identify the deficiencies that resulted in the marketing denial order, the deficiencies specified in the order might not be an exhaustive listing of all deficiencies contained in the PMTA.

FDA received several comments regarding issuance of marketing denial order, as discussed below.

(Comment 118) One comment stated that § 1114.33(a) should be amended to provide that FDA will issue a marketing denial order if, after considering outside sources of information during PMTA review, FDA finds that the new tobacco product is not appropriate for the protection of the public health.

(Response 118) We have edited § 1114.33 to make it clear that FDA's issuance of a marketing denial order will be made, as required by section 910(c)(2) of the FD&C Act, on the basis of information submitted as part of an application and any other information before FDA with respect to the new tobacco product. If, during substantive review, FDA considers information outside of a PMTA that leads FDA to find that one or more of the grounds for denial in section 910(c)(2) of the FD&C Act apply, FDA intends to issue a marketing denial order for the new tobacco product.

(Comment 119) One comment stated that FDA should consider any public comments submitted in response to MRTP applications for the same new product that is the subject of the PMTA and FDA's assessment of these public comments should be explicitly addressed in any PMTA marketing order.

(Response 119) Under section 910(c)(2) of the FD&C Act, FDA will determine whether a PMTA should be denied on the basis of the information in a PMTA and any other information before FDA with respect to such tobacco product. Where public comments on an MRTPA for the same product are before FDA during its consideration of a PMTA, FDA generally intends to consider those comments where relevant and clearly applicable to the marketing of the new tobacco product without modified risk information. FDA declines to explicitly address its assessment of public comments in a marketing granted order because it would further delay FDA's action on an application and a marketing granted order is not an appropriate venue to address comments to an MRTPA.

(Comment 120) One comment stated that § 1114.33 should be revised to include dual use and deterrence of complete quitting of all tobacco products as factors that FDA must explicitly consider when deciding whether to issue a marketing denial order.

(Response 120) Section 1114.33 incorporates the grounds for denial set forth in section 910(c)(2) of the FD&C Act, which FDA interprets to require consideration of these tobacco product use behaviors. In determining whether permitting the marketing of the new tobacco product would be APPH, FDA will consider dual use and potential changes to cessation as part of its determination of the risks and benefits to the health of the population as a whole.

(Comment 121) One comment suggested that FDA amend § 1114.33 to specifically state that FDA will issue a marketing denial order where FDA is unable to determine the impact that the labeling, advertising, marketing, and promotion of the new tobacco product may have on consumer perceptions and use intentions.

(Response 121) FDA considers information regarding consumer perceptions and use intentions to be an important part of PMTA review. If a PMTA does not contain sufficient information for FDA to determine that permitting the marketing of the product would be APPH, including impact on tobacco product and use intentions, it cannot authorize the marketing of the new tobacco product. FDA recently issued a draft guidance for public comment regarding scientific issues for applicants to consider as they design and conduct tobacco product perception and use intention studies to support tobacco product applications. For more information, please see the guidance for industry entitled ''Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies.'' [40]

(Comment 122) Several comments requested that FDA issue marketing denial orders for all products that meet certain criteria or in certain product categories, including flavored tobacco products, hookah, cigarillos, and little cigars. The comments asserted that FDA should deny all PMTAs for specific products because there is little or no evidence of health benefits and they are attractive to youth.

(Response 122) FDA declines to make revisions in response to these comments because the FD&C Act requires FDA to make an individualized determination of whether to deny an application based on the risks and benefits of a specific tobacco product to the health of the population as a whole (which includes youth, young adults, and other vulnerable populations).

F. Withdrawal of a Marketing Granted Order (§ 1114.35)

Section 1114.35 describes the grounds and procedures for withdrawing a marketing granted order for a new tobacco product. FDA will move to withdraw an order in the following situations:

1. Any of the Grounds for Withdrawal Under Section 910(d)(1) of the FD&C Act Apply

These grounds include situations in which FDA finds that the continued marketing of the tobacco product is no longer APPH. The marketing of a product may no longer be APPH in several situations, including, for example, where there are changes to tobacco product use behaviors that were not expected in FDA's assessment of the PMTA (*e.g.,* more nonusers of tobacco products are initiating use with the product than expected and/or fewer users of potentially more harmful products are switching to the potentially less harmful new tobacco product). Another example is where studies conducted after the issuance of the marketing granted order show that the product presents greater risks to health than FDA understood during application review and, as a result, the product likely has or will have a net negative impact on the health of the population as a whole (which includes youth, young adults, and other vulnerable populations).

FDA also interprets section 910(d)(1)(A) of the FD&C Act to provide for the withdrawal of a marketing granted order where changes to the tobacco product marketplace result in FDA finding that the marketing of a product is no longer APPH:

- The application contained or was accompanied by an untrue statement of material fact;
- the applicant has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or make reports required by part 1114 or another applicable regulation under section 909 of the FD&C Act;
- the applicant has refused to permit access to, or copying or verification of, records as required by section 704 of the FD&C Act;
- the applicant has not complied with the requirements of section 905 of the FD&C Act;
- on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) of the FD&C Act and were not brought into conformity with such requirements within a reasonable time after receipt of

[40] Available at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

written notice from the Secretary of nonconformity;

- on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or
- on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907 of the FD&C Act, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

FDA received comments regarding grounds for withdrawal, as discussed below.

(Comment 123) Multiple comments requested that FDA provide more clarity with regard to how the APPH standard may change over time with respect to determining whether a marketing granted order should be withdrawn. One comment noted concerns regarding the example FDA provided in section IX.F of the preamble to the proposed rule that appears to contemplate FDA withdrawing marketing orders under section 910(d)(1)(A) of the FD&C Act based on only the issuance of a product standard. The comment also stated that FDA should use the PMTA pathway to further the principles of tobacco product harm reduction and the potential for marketing orders to be withdrawn after an unduly short period of time or on an unpredictable basis may discourage manufacturers from investing the significant resources necessary to bring harm-reducing products to market.

Another comment suggested that FDA develop a more systematized approach to determining whether the marketing of a product is no longer APPH. The comment suggested that because substantial shifts in consumer use of tobacco products are unlikely in the short term, FDA should determine whether marketing of a product is no longer APPH by comparing the product to a single comparator product in the same product class as the new tobacco product and that is used by the majority of likely users of the new tobacco product. The comment also requested that FDA reevaluate its APPH determination no sooner than 5 years after the issuance of a marketing granted order, noting that this approach is consistent with section 911 of the FD&C Act for the marketing of MRTPs and would allow FDA to use its authority to temporarily suspend a marketing order if significant health issues needed to be addressed before the end of the 5-year period.

(Response 123) FDA disagrees with the comment's characterization of the APPH standard as changing over time. As described in this document, FDA interprets the APPH standard in 910(c)(2) of the FD&C Act as requiring the marketing of a new tobacco product to likely present a net benefit to the health of the population as a whole to receive a marketing order. FDA interprets section 910(d)(1)(A) of the FD&C Act consistently to require that FDA withdraw a marketing granted order where FDA is no longer able to find that the marketing of the new tobacco product likely presents a net benefit to public health. Because market conditions will change over time, what might be APPH at one point in time may no longer be APPH in the future. Examples of changes that could affect FDA's determination that the marketing of the product is APPH could include the example from the proposed rule mentioned by the comment: FDA's implementation of a tobacco product standard pursuant to section 907 of the FD&C Act that alters the relative health risks presented by other tobacco products. For instance, if FDA issued a marketing granted order for a new (non-cigarette) tobacco product, in part, because it presented significantly lower risks to individual health than cigarettes, and FDA later implemented a product standard that significantly lowered the health risks of cigarettes, FDA may determine that the continued marketing of the new (non-cigarette) tobacco product is no longer APPH. If FDA were to be unable to consider changing market conditions when evaluating whether the marketing of a new tobacco product continues to be APPH after it is granted a marketing granted order, FDA would potentially be unable to address the continued marketing of products that have higher levels of relative health risks, thus undermining its core statutory mandate to reduce the harm caused by tobacco product use. Accordingly, FDA declines to limit its consideration of whether a product continues to be APPH to just one comparator product in the same product category, as suggested by the comment.

The example regarding the issuance of a product standard that changes the health risks to current tobacco product users is a general example of a circumstance that could affect whether the marketing of a new tobacco product continues to be APPH. This example does not dictate that marketing orders for a different category of tobacco products must be withdrawn should such a product standard be implemented; rather, the determination of whether a marketing order should be withdrawn under section 910(d)(1)(A) of the FD&C Act would be made on a fact-specific basis for each new tobacco product based on whether its marketing continues to be APPH and a change to the health risks presented by a tobacco product category an applicant relied on to demonstrate a likely net benefit to public health may affect this APPH determination.

FDA also notes that marketing granted orders do not come with a guaranteed time duration. Applicants concerned about the effect of tobacco product standards on the PMTA pathway should consider the process required under section 907 of the FD&C Act to issue and implement product standards and make business decisions accordingly. FDA also declines to establish a minimum 5-year period in which applicants may market a new tobacco product without having its APPH determination reassessed. FDA intends to review new information regarding the health risks of tobacco products and changes in tobacco product use behavior, including information submitted as part of periodic and adverse experience reports, on an ongoing basis and consider whether it affects FDA's APPH determination for any new tobacco products that have received marketing granted orders. FDA also notes that, contrary to the assertion in the comment, waiting 5 years before reevaluating the issuance of a marketing granted order is not consistent with section 911 of the FD&C Act because 911(j)(1), like 910(d)(1)(A), provides for withdrawal prior to expiration of the order if standard for authorization is no longer met.

2. Any Postmarket Requirement Imposed by the Marketing Granted Order or By This Part That Has Not Been Met and Results in FDA Finding That One or More of the Grounds for Withdrawal Specified in Section 910(d)(1) of the FD&C Act Apply

This requirement will allow the withdrawal of a marketing granted order where an applicant fails to meet requirements imposed by a marketing granted order or part 1114, including postmarket restrictions on the sales and distribution of the tobacco product as described in section VIII.D and results

in FDA finding one or more of the grounds for withdrawal specified in section 910(d)(1) of the FD&C Act apply.

FDA received multiple comments on this issue, as discussed below.

(Comment 124) Multiple comments stated that FDA should include bright lines or triggers in all marketing orders that would result in the automatic withdrawal of marketing authorization. One comment stated that FDA should withdraw or temporarily suspend a marketing order if it learns from any source that the tobacco product is impacting the health of youth and young adults, including increases in the percentages of youth and young adults who report use of the product. Another comment stated that FDA should set a threshold for problems with nonconforming products in the manufacturing process and require an order to be withdrawn if these thresholds are exceeded.

(Response 124) As set forth in § 1114.35(a)(1), FDA will move to withdraw a marketing granted order if FDA finds, after due notice and opportunity for an informal hearing, that the continued marketing of such tobacco product is no longer APPH. As described throughout the preamble to the final rule, FDA must make its APPH determination with respect to the risks and benefits of the population as a whole. FDA agrees that the potential for nonconforming tobacco products and underage use of tobacco products are an important consideration in making this determination and FDA will give them due consideration as part of its ongoing evaluation of whether the marketing of the tobacco product is APPH.

FDA may seek advice on scientific matters from any appropriate FDA advisory committee in deciding whether to withdraw a marketing granted order and may use information other than that submitted by the applicant in deciding whether to withdraw a marketing granted order. Prior to withdrawing a marketing granted order, FDA will notify the holder of the marketing granted order of the opportunity for an informal hearing under 21 CFR part 16. If the holder of the marketing granted order does not request an informal hearing or if FDA decides to withdraw the marketing granted order after the informal hearing is held, FDA will issue an order withdrawing the marketing granted order. FDA will notify the public that the marketing granted order for the product has been withdrawn and state the basis for the withdrawal.

G. Temporary Suspension of a Marketing Granted Order (§ 1114.37)

Section 1114.37 describes the grounds and procedures by which FDA will temporarily suspend a marketing granted order under section 910(d)(3) of the FD&C Act. FDA is required by section 910(d)(3) to initiate a temporary suspension of a marketing granted order when it determines that there is a reasonable probability that the continued distribution of the product will cause serious, adverse health consequences or death, that is greater than what is ordinarily caused by tobacco products on the market. FDA interprets this language to mean serious, adverse health consequences at a rate or of a severity, or death at a rate, that is greater than what is ordinarily caused by tobacco product currently on the market. Under the rule, FDA will notify the holder of the marketing granted order of the opportunity to hold an informal hearing. If FDA determines after the opportunity for the informal hearing that the marketing granted order for the tobacco product should be temporarily suspended, the Agency will issue an order temporarily suspending the marketing granted order. FDA recommends that the applicant submit a plan demonstrating how it intends to comply with the temporary suspension, including a description of how the applicant will ensure that the tobacco product will not cause or continue to cause the serious, adverse health consequences or death (or reasonable probability of such events) that resulted in the temporary suspension, and the steps the applicant plans to take to ensure that the product is not further distributed, imported, sold, marketed, or promoted in the United States. Once FDA temporarily suspends a marketing granted order, it will proceed expeditiously to withdrawal. Where appropriate, FDA may combine the notices and hearings for temporary suspension of a marketing granted order and withdrawal of a marketing granted order into one notice and hearing. Whether the determinations occur separately or in one combined proceeding, the determination regarding temporary suspension and the determination regarding withdrawal will be made separately by the Agency as the findings are separate and distinct.

X. Postmarket Requirements (Part 1114, Subpart D)

A. Postmarket Changes (§ 1114.39)

Section 1114.39 describes the scope of a marketing granted order. FDA issues marketing granted orders for the specific new tobacco product described in the PMTA.

FDA received several comments regarding this section, as discussed below.

(Comment 125) One comment stated that FDA should issue marketing orders for e-cigarettes that allow for the independent sale of components and parts that are identical to the ones contained in the authorized e-cigarette for use as replacements. The comment stated that because the components and parts would have already been reviewed as part of the complete e-cigarette, it would be redundant and unduly costly to require a company to submit a separate PMTA for an individual component or part.

(Response 125) FDA declines to make the revisions suggested by this comment. Unless an applicant otherwise satisfies the requirements of premarket review in section 910(a)(2) of the FD&C Act, it must submit a PMTA and receive a marketing granted order prior to introducing a new tobacco product, or delivering it for introduction, into interstate commerce. This requirement applies to both an entire e-cigarette and its components and parts where sold separately. Applicants seeking to market an e-cigarette and its components and parts in such a manner should consider whether a bundled submission containing the information required to support multiple PMTAs would be appropriate.

An applicant may not make any modification to the specific product that is the subject of the order, as any modification to the tobacco product results in a new tobacco product under the definition in section 910(a)(1) of the FD&C Act. Changes that do not result in a new tobacco product, such as manufacturing process changes that do not modify the finished tobacco product, must be reported under § 1114.41.

(Comment 126) One comment stated that the proposed requirement in § 1114.39 is redundant and unnecessary because it is no different from the plain meaning of section 910(a)(1)(B) of the FD&C Act and, therefore, should not be included in the final rule.

(Response 126) FDA declines to remove § 1114.39 because it serves to emphasize that the requirements of premarket review apply to modifications to new tobacco products that have already received a marketing granted order.

(Comment 127) One comment stated that FDA should clarify the circumstances in which ''changes'' are considered ''modifications,'' and the

pathways available when modifications are made. The manufacturer stated that based on its interpretation of the rule, FDA would not require reporting of any changes that do not rise to the level of modifications resulting in a new tobacco product, other than the specific types of manufacturing-related and labeling changes described in proposed § 1114.41.

(Response 127) FDA has provided numerous examples throughout this document, and guidance documents,[41] regarding modifications that result in a new tobacco product. Under section 910(a)(1)(B) of the FD&C Act, new tobacco products include those that are new because they have been rendered new through any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. The discussion of the definition of the term ''new tobacco product'' in section VII.B. contains information about what constitutes a new tobacco product, including the description of modifications to cigarette paper, container closure systems (*e.g.,* change from glass to plastic e-liquid vials or from plastic to tin container closures), product quantity, or tobacco cut size as some examples of changes that result in a new tobacco product.

Where an applicant seeks to modify a new tobacco product that has received a PMTA marketing order, it may choose to seek premarket authorization through any of the three premarket pathways described in section VII.B; however, we note that the requirements of the PMTA pathway are distinct from those of the SE pathway. Under the SE pathway, an applicant must rely on a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the FD&C Act; the issuance of a PMTA marketing order would not independently create a valid predicate product for use in the SE pathway. Therefore, an applicant seeking to modify a new tobacco product that has received a PMTA marketing order (and does not have a corresponding SE order), has three options to receive premarket authorization: (1) It could submit a new PMTA for the product with the modifications; (2) depending on the type of modification, it could seek authorization through the SE exemption pathway; or (3) it could seek authorization through the SE pathway relying on a valid predicate, *i.e.,* a product FDA has previously found SE or a product that was commercially marketed in the United States (other than for test marketing) as of February 15, 2007. The modifications for which an SE exemption request may be submitted are set forth in § 1107.1. The circumstances under which an applicant may submit a supplemental PMTA for a new tobacco product that results from a modification or modifications to the original tobacco product that received a marketing granted order are described in section VIII.F.

Marketing a new tobacco product without required premarket authorization would render the product adulterated under section 902(6)(A) of the FD&C Act and misbranded under section 903(a)(6) of the FD&C Act and subject to an FDA enforcement action.

B. Reporting Requirements (§ 1114.41)

Section 1114.41 requires applicants that receive a marketing granted order to submit postmarket reports. FDA is requiring postmarket reports under the authority of section 910(f) of the FD&C Act, which requires applicants to establish and maintain records and make reports that FDA requires as necessary to determine or facilitate a determination of whether there may be grounds to withdraw or temporarily suspend a marketing granted order. In addition, under section 909 of the FD&C Act, FDA is permitted to require the reporting of information to assure that a tobacco product is not adulterated or misbranded and to otherwise protect public health. Section § 1114.41 describes the reports that FDA requires through this regulation; however, FDA may require additional reporting in an individual applicant's marketing granted order.

Applicants are required under § 1114.41 to submit two types of reports after receiving a marketing granted order: Periodic reports and adverse experience reports. Applicants must submit periodic reports within 60 calendar days of the reporting date specified in the marketing granted order (or potentially sooner if they choose to use the application as the basis for a supplemental PMTA under § 1114.15). FDA anticipates that the reports will be required on an annual basis, but FDA may require, by a specific order, that reports be made more or less frequently depending upon a number of factors (*e.g.,* the novelty of the type of product).

C. Requirements for Periodic Reports

Applicants must submit the following information electronically together with the appropriate form (Ref. 140) as part of each periodic report under § 1114.41(a)(1). The materials provided in these reports can provide important information regarding whether the marketing of the product is no longer APPH under section 910(d)(1)(A) of the FD&C Act or whether the marketing granted order should be temporarily suspended under section 910(d)(3) of the FD&C Act:

- A cover letter that includes basic identifying information, such as the product name(s) (including the original product name, if different) and application STN;
- a full description of the changes made to the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product, if any, during the reporting period. This description, which we are requiring under section 909 of the FD&C Act, must include sufficient information for FDA to determine whether a change to methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product results in a new tobacco product or do not conform to the requirements of section 906(e) and potentially be a basis to withdraw or temporarily suspend the marketing granted order. This information includes a comparison to the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product, described in the PMTA, the rationale for making the change, and an explanation of why the change does not result in a new tobacco product and why there are no grounds for FDA to withdraw or temporarily suspend the marketing granted order on the basis of the change (*i.e.,* the marketing of product continues to be APPH, the manufacturing process complies with the requirements of section 906(e) of the FD&C Act, and the product still conforms to any product standards under section 907 of the FD&C Act);
- An inventory of all ongoing and completed studies about the tobacco product conducted by, or on behalf of, the applicant that are within the scope of § 1114.7(k) and were not already submitted as part of the PMTA or

[41] Please see ENDS PMTA Guidance and the guidance for industry entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions,'' both of which are available at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

previous postmarket reports. These reports can provide important information regarding health risks or changes in tobacco product use behavior, including initiation, which helps FDA determine whether the marketing of the product is no longer APPH under section 910(d)(1)(A) of the FD&C Act;

- full reports of information (as described in § 1114.7(k)(3)) published or known to, or which should reasonably be known to, the applicant concerning scientific investigations and literature about the tobacco product that would be required in a PMTA under § 1114.7(k)(1) not previously submitted as part of the PMTA or previous postmarket reports, including significant findings from publications not previously reported;
- a summary and analysis of all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or that the applicant is aware of, accompanied by a statement of any changes to the overall risk associated with the tobacco product, including the nature and frequency of the adverse experience, and potential risk factors;
- a summary of sales and distribution of the tobacco product, to the extent that the applicant collects or receives such data, for the reporting period, including:
  - total U.S. sales reported in dollars, units, and volume with breakdowns by U.S. census region, major retail markets, and channels in which the product is sold. Sales and distribution information may constitute confidential commercial information under § 20.61 that is exempt from public disclosure. See § 1114.47 and part 20 for more information about the confidentiality of information submitted to FDA;
  - the Universal Product Code that corresponds to the product(s) identified in the PMTA; and
  - Demographic characteristics of product purchasers, such as age, gender, race or ethnicity, geographic region, and tobacco use status. After reviewing and considering comments received in response to the proposed rule, FDA has updated this language here and throughout the rule as the consideration of vulnerable populations is an important part of determining whether permitting the continued marketing of a new tobacco product is APPH;
- a summary of the implementation and effectiveness of policies and procedures regarding verification of the age and identity of purchasers of the product;
- a summary of all formative consumer research studies conducted (if any), among any audiences, in the formation of new labeling, advertising, marketing, or promotional materials, not previously submitted, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions and behaviors toward using the products, and including the findings or these studies and copies of the stimuli used in testing;
- a summary of all consumer evaluation research studies conducted (if any), among any audiences, not previously submitted, to determine the effectiveness of labeling, advertising, marketing, or promotional materials and shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including the findings of these studies and copies of the stimuli used in testing;
- a summary of the creation and dissemination of the products' labeling, advertising, marketing, and promotional materials (if any), including a list of all entities involved and a description of their involvement, including a description of contractual agreements with such entities. For example, a list of entities involved in the creation and dissemination of marketing materials might include the names of advertising agencies, media companies, public relations firms, market research companies, partners, sponsors, bloggers and social media influencers;
- specimens of all labeling that has not been previously submitted in the PMTA, prior postmarket reports, or under section 905(i) of the FD&C Act and descriptions of all labeling changes including the date the labeling was first disseminated and the date when dissemination was completely terminated. This labeling information can help FDA determine whether the withdrawal grounds under section 910(d)(1)(E) of the FD&C Act apply;
- full color copies of all advertising, marketing, and promotional materials for the tobacco product that have not been previously submitted, the original date the materials were first disseminated, and the date when their dissemination was completely terminated. FDA is requiring the submission of this information under authority of section 910(f) because as discussed in section VIII.B.6.b., the way in which a tobacco product is advertised, marketed, and promoted can play an important role in FDA's determination of whether the marketing of a tobacco product is APPH. A substantial body of evidence illuminates the powerful impact of tobacco product labeling, advertising, marketing, and promotion on youth perceptions of tobacco products, youth appeal of tobacco products, the likelihood of youth initiation and use of tobacco products, even when said marketing is purportedly targeted or designed to appeal to adults. Youth are a significant population of concern as their current stage of brain development makes them especially susceptible to nicotine addiction. Thus, for FDA to help ensure that the continued marketing of a new tobacco product is appropriate for the protection of public health, it is critical for FDA to conduct ongoing review and evaluation of the product's labeling, advertising, marketing, and promotional materials and activities to assess any possible effects on perceptions, appeal, intentions, and behaviors among intended and unintended audiences, especially youth. The information, together with other postmarket information concerning the marketing of the tobacco product, will facilitate determination of whether there are or may be grounds to withdraw a marketing granted order under section 910(d)(1)(A) of the FD&C Act;
- a description of the implementation of all advertising and marketing plans, not previously submitted to FDA (whether conducted by the applicant, on its behalf, or at its discretion), including strategic creative briefs and paid media plans by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including a description of any of the following activities that an applicant may have engaged in:
  - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;
  - Targeting of specific group(s) by age-range(s), including young adults, ages 21–24, and other demographic or psychographic characteristics that reflect the intended audience including the source of such data;
  - with respect to individuals below the minimum age of sale, actions taken to restrict access to the product and limit exposure to the product labeling, advertising, marketing, promotion, or other consumer-directed activities;
  - use of owned, earned, shared, or paid media to create labeling for, advertise, market, or promote the product;
  - use of partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, or promote the product;
  - consumer engagements—whether conducted by an applicant, on its

behalf, or at its direction—including events at which the product was demonstrated and how access was restricted to individuals at or above minimum age of sale; or

○ use of public relations or other communications outreach to create labeling for, advertise, market, or promote the products;

- a summary of media tracking and optimization (*e.g.,* assessment of marketing campaigns in market, and adjustments to a media buy to improve or correct delivery of advertising to the intended audience) by channel, by product, and by audience demographics (*e.g.,* age, gender, race/ethnicity, geographic region), including a summary of any real-time digital media monitoring (*e.g.,* tracking the use of a specific hashtag, reviewing audience engagement metrics such as ''likes'', ''comments'', and ''shares'') and including a summary of implementation of any corrective and preventive measures to identify, correct, and prevent delivery of advertising to individuals below the minimum age of sale, not previously submitted;
- a report or summary of the actual delivery of advertising impressions (*e.g.,* instances where the intended audience had the opportunity to view or consume the product's advertising and marketing), by channel, by product, and by audience demographics (*e.g.,* age, gender, race/ethnicity, geographic region), not previously submitted. This report or summary must be based on post-launch delivery-verification reports submitted to the tobacco product company from an accredited source, where applicable;
- additional information required to be reported under the terms of a marketing granted order (if applicable); and
- an overall assessment of how the marketing of the tobacco product continues to be APPH.

Postmarket information concerning the marketing of a tobacco product is critical to FDA's evaluation of whether the continued marketing of the product is APPH under section 910(d)(1)(A) of the FD&C Act. Determining whether the continued marketing of the tobacco product is APPH requires FDA to consider the likelihood that those who do not use tobacco products, including youth, will start using the product. As discussed in section VIII.B.6.b., youth exposure to tobacco product advertising, marketing, and promotion has a direct and powerful impact on youth trial and uptake of tobacco product use, making it directly relevant to FDA's determination of the likelihood that nonusers and users of other products switching to the new product, including youth will use the product. Accordingly, section § 1114.41(a)(1) seeks information that directly informs FDA's evaluation of youth exposure to marketing materials for the product and youth access to the product. Information regarding paid media plans for the product, such as the channels used and the dollar amount(s) and flighting of the plans, as well as information regarding the use (or nonuse) of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, allows FDA to estimate the scale and potential reach of advertising, marketing, and promotion for the product and thereby directly informs its determination of the likelihood that youth will be exposed to such marketing materials. For example, the use of social media platforms known to reach youth, such as Twitter, Instagram, and YouTube, without use of methods to restrict and monitor youth access to marketing on those platforms may indicate a higher likelihood of youth exposure to marketing for the tobacco product and youth use of the tobacco product (see, *e.g.,* Refs. 12–14 and 16). Additionally, use of partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, or promote a tobacco product may also indicate a higher likelihood of youth exposure to marketing materials for the product and youth use of the product, given studies demonstrating that such methods, including the use of ''organic'' depictions of tobacco use and endorsements of tobacco products by cultural icons and other influencers, are especially effective among youth who are particularly susceptible to social influences (Ref. 9). Moreover, information regarding actions taken to restrict access to the product and limit exposure to the product labeling, advertising, marketing, promotion, or other consumer-directed activities for individuals below the minimum age of sale directly informs FDA's evaluation of youth access to the product.

D. Serious and Unexpected Adverse Experience Reporting

Applicants must report all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or of which the applicant is aware under § 1114.41(a)(2). The serious and unexpected adverse experience reports must be submitted to CTP's Office of Science through the Health and Human Services (HHS) Safety Reporting Portal or in another manner designated by FDA (if applicable) within 15 calendar days after receiving or becoming aware of a serious or unexpected adverse experience. FDA notes that the submission of a report under this section (and any release by FDA of that report) will not constitute an admission that the tobacco product caused or contributed to an adverse experience.

FDA received several comments regarding the requirements for periodic reports, as discussed below.

(Comment 128) One comment stated that section 910 of the FD&C Act does not authorize FDA to require postmarket reporting for manufacturing changes. The comment stated that if a manufacturing change of the nature described by the proposed rule results in a new product, then there can be no ''postmarket'' information for FDA to evaluate because such a product cannot be placed on the market until a new marketing order has been obtained. The comment further stated that, if the manufacturing change does not result in a new tobacco product, then this change cannot alter FDA's prior determination that the marketing of the product is appropriate for the protection of public health nor would it enable FDA to determine, or facilitate a determination, that there are any other statutory grounds for withdrawing or suspending a marketing order. The comment concluded that in the future, manufacturing changes may result in a withdrawal or suspension but as no manufacturing regulations exist under section 906(e) of the FD&C Act, this does not seem applicable.

(Response 128) FDA declines to make any changes as a result of this comment. As discussed in the rule, whether the applicant can consistently manufacture the new tobacco product described in the PMTA is important to FDA's determination of whether a tobacco product is APPH, and given the dangers associated with nonconforming tobacco products, reviewing manufacturing changes on a postmarket basis is necessary for FDA to determine whether the continued marketing of the product is APPH. Additionally, reviewing manufacturing changes would allow FDA to determine whether they would result in a modification (intended or unintended) to the product and is therefore a different new tobacco product without premarket authorization, which would render that tobacco product adulterated under section 902(6)(A) of the FD&C Act and misbranded under section 903 of the FD&C Act. FDA is requiring such information, in part, under its section 909 of the FD&C Act authority, which

allows FDA to require the reporting of information to assure that a tobacco product is not adulterated or misbranded and to otherwise protect public health.

(Comment 129) One comment stated that section 910 of the FD&C Act does not authorize FDA to require postmarket reporting of sales and marketing information. The comment noted that while FDA states that this information will inform a determination of whether the marketing of the new tobacco product continues to be APPH, it claimed that this statement does not establish that all of the information required in the proposed rule is necessary for FDA to make its determination and, as such, many of the postmarket reporting requirements should be deleted in the final rule.

(Response 129) FDA disagrees with the statement that this reporting is not authorized by the FD&C Act. As discussed throughout this document, this postmarket information is necessary to help inform FDA's determination of whether the continued marketing of the tobacco product is APPH. FDA requires applicants to submit sales data under its authority in section 910(f) of the FD&C Act to help inform its determination of whether the continued marketing of the product is APPH. Sales data in conjunction with other data such as demographics of purchasers and information on retail channels can provide information that can help indicate trends in tobacco use behavior across the United States and potential changes in tobacco use behaviors among certain subsets of the population. For example, if tobacco use of a specific product was previously low among a certain demographic and, through the postmarket reporting, is now being reported at higher levels of tobacco use that also correlates with sales of the new product among the same demographic group, this type of information would be important to FDA's determination of whether the continued marketing of the tobacco product is APPH. In addition, sales of tobacco products by retail channel, combined with other required data, can help FDA understand where products are being sold as well as help FDA better understand the potential for youth access to the products. In particular, the data help FDA to assess whether the information regarding likely tobacco product use behavior described in the PMTA was consistent with actual use after authorization. For example, data that indicate significantly higher rates of youth initiation with the tobacco product than among other nonusers than anticipated in the PMTA could result in FDA finding that continued marketing of the tobacco product is no longer APPH and the marketing granted order should be withdrawn under section 910(d)(1)(A) of the FD&C Act. Furthermore, because youth exposure to tobacco product labeling, advertising, marketing, and promotion has a direct and powerful impact on youth trial and uptake of tobacco product use, information regarding the marketing of the tobacco product and potential youth exposure to marketing directly informs FDA's consideration of the likelihood that youth will use the product, which is relevant to determining whether continued marketing of a product is APPH and consistent with its statutory mandate to protect youth from the dangers of tobacco use. In addition, as discussed below, information regarding the marketing of the product can help FDA determine whether the withdrawal grounds under section 910(d)(1)(E) of the FD&C Act apply.

(Comment 130) One comment requested that the rule require the submission of postmarket information to demonstrate that all labeling, instructions for use, and other communications related to the product have been carefully designed and tested to ensure they will provide accurate, not misleading, information and guidance to all consumers, including those with less education, or weaker or non-existent English literacy, and will not encourage harm-increasing uses of the product among any subpopulations.

(Response 130) FDA intends to consider the labeling, advertising, and marketing, and promotion for a new tobacco product, including labels, instructions for use and other advertising and marketing materials, that an applicant uses after receiving a marketing granted order as part of FDA's evaluation of whether the continued marketing of a new tobacco product is APPH. FDA is not requiring formal testing of advertising and marketing materials. However, when determining whether the continued marketing of a new tobacco product is APPH, under section 910(d)(1)(E) of the FD&C Act, FDA is required to consider whether the labeling of the tobacco product is false or misleading. In addition, FDA will review advertising and marketing materials with consideration of the potential for use among nonusers, including youth, as well as product misuse and dual use among current tobacco product users (see section VII.B.6 regarding § 1114.7(f) for a discussion of the impact of advertising).

(Comment 131) One comment stated that FDA should, similar to language FDA uses for other regulated product categories, make it clear that submission of required postmarket reports, including adverse experience reports, does not reflect a conclusion or admission by the applicant or FDA that the product at issue caused or contributed to the adverse experience.

(Response 131) In section X.B., FDA has amended this document to clarify that reporting an adverse experience will not constitute an admission that the tobacco product caused or contributed to the adverse experience.

E. Submission of Additional Information

As part of its review of a postmarket report, FDA could require the applicant to submit additional information to enable it to determine whether a change results in a new tobacco product, or to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing granted order. FDA may notify an applicant that FDA has determined that a change described in a periodic report made under this section results in a new tobacco product outside the scope of the marketing granted order, requiring the submission of a new PMTA under § 1114.7 or a supplemental PMTA under § 1114.15 and issuance of a marketing granted order if the applicant seeks to market the new tobacco product, unless the new tobacco product can be legally marketed through a different premarket pathway. Failure to obtain marketing authorization for a new tobacco product would render it adulterated under section 902(6) of the FD&C Act and misbranded under section 903(a)(6) of the FD&C Act and could be subject to enforcement action.

FDA received one comment on this issue, as discussed below.

(Comment 132) One comment stated that they expected some e-liquid manufacturers to join controlled distribution networks to show youth access to tobacco products would be limited. The comment recommended that the rule be amended to allow third party entities (*e.g.,* controlled distribution networks or their auditing agents) to submit reports directly to the Agency that reference and link to participants' approved PMTAs. This would allow applicants or their designated distribution networks and auditors to submit to FDA all information required.

(Response 132) We decline to make this change. The rule concerns the postmarket reports that applicants are required to make, rather than the information that third parties or other entities may submit to FDA about a tobacco product; however, note that

where an applicant obtains sales data about its product from a third party, the applicant would need to report it to FDA as required by § 1114.41. As noted in section VIII.B.2, applicants have the ability to cross-reference third-party owned information through TPMFs, including in the submission of postmarket reporting requirements.

XI. Miscellaneous (Part 1114, Subpart E)

Subpart E describes other procedures and requirements related to PMTAs, including record retention, electronic submission requirements, and confidentiality considerations.

A. Record Retention (§ 1114.45)

Consistent with the authority to require recordkeeping under sections 909 and 910(f) of the FD&C Act, § 1114.45 requires applicants receiving a marketing granted order to maintain all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing granted order and ensure that such records remain readily available to the Agency upon request. The records must be legible, written in English, and available for inspection and copying by officers or employees designated by the Secretary.

1. Record Retention by the Applicant

Under § 1114.45(a)(1), an applicant must retain all documents submitted to FDA as part of an application and postmarket reports. An applicant must also retain any additional documentation supporting the application and postmarket reports that was not submitted to FDA. This additional documentation includes information that demonstrates:

- Nonclinical laboratory studies were conducted using laboratory practices that ensure the reliability and validity of the study. This information includes documents that were generated during the performance of nonclinical studies, but were not required to be submitted as part of a full study report under § 1114.7(k)(3). One way that an applicant may satisfy this requirement is to retain all of the documentation described in part 58 and
- whether any investigators had financial conflicts of interest. One approach to satisfying this requirement is to retain all of the documentation described in part 54 for both clinical and nonclinical investigations.

Applicants must also retain all other documents generated during the course of a study that are necessary to substantiate the study results (*e.g.,* certain communications, case reports) including:

- Communications related to the investigation between the investigator and the sponsor, the monitor, or FDA and
- all source data and related summaries, including records regarding each study subject's case history and exposure to tobacco products used in the investigation, which can include, but is not limited to case report forms, progress notes, hospital records, clinical charts, x-rays, lab reports, and subject diaries.

The applicant must also maintain a record of each complaint associated with the tobacco product that has been reported to the applicant as well as a summary and an analysis of all complaints associated with the tobacco product reported to the applicant. The records and analysis of complaints should reflect all reports made about the product, including those made during clinical investigations. FDA is requiring that records and analysis of such complaints be kept to demonstrate whether there are any potential issues with the product that could present health or safety issues.

FDA received comments regarding record retention by applicants, as discussed below.

(Comment 133) One comment suggested that the language of the proposed rule be amended to allow for either applicants or their third-party representatives to retain the records required by § 1114.45. The applicant stated that this could be more efficient and save costs.

(Response 133) FDA has amended the language of the preamble to clarify that an applicant may utilize a third-party entity to store records on their behalf. If an applicant uses a third-party entity to store records, it is important to note that the applicant is still solely responsible for ensuring that all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing granted order are readily available to the Agency upon request. This requirement will ensure that records are available to FDA during an inspection.

Applicants that have stopped marketing a tobacco product may want to retain the records for a longer period if the product might be reintroduced in order to avoid the time and expense of having to generate the information again. FDA may, under the terms of section 910(f) of the FD&C Act, impose additional recordkeeping and reporting requirements as part of a marketing granted order in addition to the requirements in the rule.

(Comment 134) One comment expressed support for the requirement for applicants to retain records but suggested the proposed rule should be amended to include retention requirements for specific information that would enable FDA to track and trace a product from the manufacturing source to the shelf.

(Response 134) FDA declines to make such a change because it is outside the scope of this rulemaking. Consistent with sections 909 and 910(f) of the FD&C Act, the rule (as described in § 1114.45) requires applicants to retain all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing order as well as ensure that the tobacco product that is the subject of the marketing order is not adulterated or misbranded.

2. Record Format and Availability

The rule requires the applicant to maintain records that are legible and in the English language, and make them available for inspection and copying by officers or employees duly designated by the Secretary.

3. Retention Period

Applicants must retain the records as described in § 1114.45(a)(3). Records relating to the PMTA must be retained for a period of no less than 4 years from the date the marketing granted order is issued. Records relating to the postmarket reports, including both periodic reporting and adverse experience reporting must be retained for a period of at least 4 years from the date the postmarket report was submitted or the date FDA inspects the records, whichever occurs sooner. FDA has selected 4 years as a means to help ensure that the records would be available for at least one biennial FDA inspection under sections 704 and 905(g) of the FD&C Act.

B. Confidentiality (§ 1114.47)

Section 1114.47 states that FDA will determine the public availability of any part of any PMTA and other content related to a PMTA, including all data and information submitted with or incorporated by reference in the application, as provided under this section and part 20 (Public Information). FOIA (5 U.S.C. 552), as well as certain provisions of the FD&C Act, (*e.g.,* section 301(j) (21 U.S.C. 331(j)) and section 906(c)), govern the disclosure of the existence of a pending PMTA and the information contained in such a PMTA. Under FOIA, the public has broad access to government documents.

However, FOIA provides certain exemptions from mandatory public disclosure. One such provision, 5 U.S.C. 552(b)(4), exempts records that are ''trade secrets and commercial or financial information obtained from a person and privileged or confidential'' from the requirement of mandatory disclosure. Part 20 of FDA's regulations sets forth FDA's general regulations concerning public availability of FDA records.

FDA received several comments regarding confidentiality, as discussed below.

(Comment 135) One comment suggested that a public database be established that lists the products for which a PMTA has been filed, accepted, or is pending substantive review. The comment stated that this is important because it would allow other state and federal agencies to know whether a product has the ability to remain on the shelves of stores. Similarly, another comment stated that by not making the application process more public, FDA is not permitting adequate participation by stakeholders other than the applicant and is contrary to established FDA practice. The comment expressed concern that this could result in FDA having access only to research conducted by industry or prevent FDA from accessing research not yet published.

(Response 135) FDA agrees that stakeholder engagement, including with federal and state entities as well as members of the public, is important to the effective implementation of the law and the PMTA process generally. However, the Agency disagrees with the assertion that a public database or other measures not included in this rule are necessary to ensure adequate public participation or to ensure that FDA has access to all potentially relevant information, including research not yet published, from sources other than the applicant. As discussed in the preamble of the proposed rule, like with drugs and devices, the intent to market a tobacco product that is not currently marketed is often considered confidential commercial information. This is consistent with the recent Supreme Court decision that addressed the legal standard for determining whether information is confidential. See *Food Mktg. Inst.* v. *Argus Leader Media,* 139 S. Ct. 2356, 2366 (2019). Therefore, § 1114.47(b) addresses the confidentiality of a PMTA prior to the issuance of a marketing granted order. Under the rule, FDA will not publicly disclose the existence of a PMTA unless the applicant has publicly disclosed or acknowledged that it has submitted the application to FDA (as such disclosure is defined in § 20.81), the applicant has authorized FDA in writing to publicly disclose or acknowledge the submission of the PMTA, or FDA has referred the application to TPSAC. Section 1114.47(b)(2) provides that FDA will not disclose the fact or contents of an FDA communication with an applicant or regarding an application or information contained in the application unless the applicant has publicly disclosed, acknowledged, or authorized FDA in writing to publicly disclose or acknowledge the existence of the FDA communication or information contained in the application. However, if the applicant has disclosed information contained in the application or that it received a communication from FDA regarding the application, FDA may disclose the record of the communication after redacting confidential commercial or trade secret information. Section 1114.47(b)(3) provides that if FDA refers the application to TPSAC, the PMTA will be available for public disclosure under part 20 as described in § 14.75 (21 CFR 14.75) (which concerns the public disclosure of advisory committee records), except information that that is exempt from public disclosure under part 20, including trade secrets, confidential commercial information, and personal privacy information. This is consistent with FDA's practice for tobacco product premarket applications, as well as for premarket applications generally.

(Comment 136) One comment stated that section 910 of the FD&C Act does not authorize FDA to make PMTAs publicly available as part of FDA or TPSAC review. The comment argued that if Congress intended FDA to have the authority to divulge the content of a PMTA, it would have stated so in the Tobacco Control Act. Another comment argued that the only information that should be referred to TPSAC is a limited summary of the relevant portions of the application.

(Response 136) As stated above, prior to the issuance of a marketing granted order, FDA will not publicly disclose the existence of a PMTA unless the applicant has publicly disclosed or acknowledged that it has submitted the application to FDA, the applicant has authorized FDA in writing to publicly disclose or acknowledge the submission of the PMTA, or FDA has referred the application to TPSAC. Except as described in § 1114.47(b)(4) regarding referral to TPSAC, FDA will not disclose information contained in an application unless the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence of that particular information.

FDA disagrees with the assertion that it cannot make a PMTA publicly available as part of TPSAC review because it is required to do so under section 10(b) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App) and its implementing regulations. If FDA refers the application to TPSAC, the PMTA will be available for public disclosure under part 20 as described in § 14.75 (which concerns the public disclosure of advisory committee records), except information that is exempt from disclosure under part 20, including trade secrets, confidential commercial information, and personal privacy information

Section 1114.47(c) describes the information that FDA will make available after issuing a marketing granted order. Under § 1114.47(c), FDA can make available data previously disclosed to the public, protocols for a test or study, information and data in the application that demonstrate the new tobacco product is appropriate for the protection of the public health, any correspondence between FDA and the applicant, the EA or request for categorical exclusion, and information and data contained in postmarket reports, so long as the information listed above is not exempted from disclosure under part 20.

Even after receipt of a marketing denial order for an application for a product that is not currently marketed, the intent to market may still constitute confidential commercial information, as the applicant may still have the intent to market the new tobacco product that is the subject of the PMTA and it is the type of information that is customarily and actually treated as private by its owner. Under § 1114.47(d), FDA may also make certain information available after it issues a marketing denial order unless the information is otherwise exempt from disclosure under part 20. The information that FDA may disclose includes product category, subcategory, package size, and the basis for the marketing denial order. FDA notes that where an applicant receives a marketing denial order for, or FDA refuses to accept or file, a PMTA for a new tobacco product that is currently on the market as a result of FDA's compliance policy for deemed tobacco products on the market as of August 8, 2016, FDA may disclose additional identifying information about the product to help ensure that it is taken off of the market. Where a product is marketed, basic identifying information regarding the

product is not a trade secret or confidential commercial information.

(Comment 137) One comment states that the final rule should be amended to state that all aspects of the PMTA, including all data and information submitted with or incorporated by reference into the application, are confidential information under § 1114.47.

(Response 137) As explained elsewhere in this section, FDA will determine the public availability of any information contained in a PMTA under § 1114.47 and part 20. This includes the data and information in the application submitted in both full text and incorporated by cross-reference. FDA has amended the language in this section, to clarify what information would be confidential under the rule and part 20.

(Comment 138) One comment stated that the final rule should be amended to state that all data and information received in an ITP submission prior to a PMTA being filed with the Agency is also confidential. Furthermore, the comment stated that FDA should update part 20 to describe the legal standard for FOIA exemption 4 established by the Supreme Court in *Food Mktg. Inst.* v. *Argus Leader Media.*

(Response 138) This rulemaking addresses the general process by which PMTAs are submitted and reviewed. Any comments concerning the investigational tobacco product submission process or FDA's public information regulations under part 20 are outside the scope of this rule.

(Comment 139) One comment stated that FDA should publicly disclose the existence of PMTAs for which the applicant has previously submitted a MRTPA or submits an MRTPA concurrently with the PMTA.

(Response 139) FDA has amended § 1114.47 to state that it will disclose the existence of a PMTA for a new tobacco product for which an MRTPA has been made available for public comment under section 911(e) of the FD&C Act. Once FDA makes an MRTPA for the new tobacco product publicly available, the intent to market the new tobacco product would no longer be confidential commercial information. Further, as stated previously, the contents of a PMTA that is referred to TPSAC (either as a standalone application or concurrently with an MRTPA) will be available for public disclosure under part 20 as described in § 14.75 (which concerns the public disclosure of advisory committee records), including withholding information that is trade secrets, confidential commercial information, or personal privacy information.

(Comment 140) One comment stated that it is important for FDA to publicly disclose all data and information submitted to demonstrate the marketing of a product would be APPH, marketing plans, and postmarket reporting for each new tobacco product that is authorized by FDA. The comment stated that marketing plans concern the sale and distribution of tobacco products, which under section 916 of the FD&C Act (21 U.S.C. 387p) may also be subject to state and local regulation, even if such regulations are different or stricter than Federal regulations. The comment further stated that the public health interest in disclosure outweighs other interests and should result in marketing plans and postmarket reporting being disclosed to the public.

(Response 140) As described in this section, FDA may make information publicly available after the issuance of a marketing granted order consistent with § 1114.47(c) and part 20. FDA is unable to make any information in an application, including descriptions of marketing plans, publicly available to the extent that it constitutes trade secrets or confidential commercial information unless it is disclosed publicly or authorized to be disclosed publicly by the applicant.

C. Electronic Submission (§ 1114.49)

Consistent with FDA's authority to issue regulations for the efficient enforcement of the FD&C Act, § 1114.49 requires an applicant to submit a PMTA and all supporting and related documents to FDA in electronic format that FDA can process, review, and archive unless an applicant requests, and FDA grants, a waiver from this requirement. Reasons that an applicant might request a waiver would include that the applicant has no access to email or a computer. Under § 1114.49(c), an applicant that has a waiver would submit a paper submission to the address that FDA provides in the letter granting the waiver.

FDA received one comment regarding the proposed electronic submission provision, as discussed below.

(Comment 141) One comment stated that while the submission of electronic documents may be a preferred delivery mechanism, it should not be a requirement that an applicant submit a PMTA and all supporting and related documents in electronic format.

(Response 141) FDA declines to take this recommendation. FDA is implementing § 1114.49 based on FDA's general experience with electronic submissions, which FDA has found help facilitate premarket reviews because electronic submissions typically enable FDA to receive, access, search, and review a submission more efficiently than a paper submission. FDA has provided technical specifications on its website for submitting information in an electronic format that FDA can review, process, and archive (*e.g.,* method of transmission, media, file formats, preparation, organization of files, accompanying metadata) (*https://www.fda.gov/tobacco-products/manufacturing/electronic-submissions-tobacco-products*) and update this information as needed to accommodate changes in technology. As previously discussed, applicants who have limited access to email or a computer may apply for a waiver from the electronic submission requirement, which if granted by FDA, would allow an applicant to submit a paper submission to the address that FDA provides.

XII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Premarket Tobacco Product Applications and Recordkeeping Requirements, OMB Control Number 0910–0879.

Description: This rule interprets and codifies requirements related to the content and format of PMTAs, the procedure by which FDA reviews PMTAs, and the maintenance of records regarding the legal marketing of certain tobacco products without PMTAs. The rule also addresses issues such as the procedures of retention of records related to the PMTA, confidentiality of application information, electronic submission of the PMTA and amendments, and postmarket reporting requirements.

Description of Respondents: This rule applies to tobacco product manufacturers. Manufacturer is defined here as any person, including any repacker or relabeler, who: (1) Manufactures, fabricates, assembles, processes, or labels a tobacco product or (2) imports a finished tobacco product

for sale or distribution in the United States.

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the **Federal Register** of September 25, 2019 (84 FR 50566). In response to this rule FDA received two PRA-related comments:

(Comment 142) One comment made specific comments requesting changes to elements in Form 4057.

(Response 142) FDA has considered these comments and agrees that many updates are necessary. The list below details the updates we have made to the form in response to the comments.

- FDA has harmonized, as appropriate, terms used within the PMTA and other FDA forms.
- FDA has revised the form by adding fields for address and contact information for manufacturer information to provide for the situation where the manufacturer is different from the Applicant.
- FDA agrees that the form does not collect organization information for certain parties. FDA has revised the form by providing fields to enter organization information for certain parties, *e.g.,* the authorized representative. Additionally, FDA has revised the form by providing additional fields to describe the alternate point of contact.
- FDA has revised section III which now contains additional fields to identify cross-referenced submissions (ITP, SE, and MRTPA) and formal meetings held with FDA that pertain to the PMTA. For example, the applicant can now input in the revised form document keywords, document filenames, and submission dates for cross-referenced content. For formal meetings with FDA, the applicant can now input in the revised form the new tobacco product name. These fields would also help ensure FDA identify the cross-referenced content or related submission.
- Section III of the revised form also contains new fields (*e.g.,* ''document keyword'' and ''document filename'') that allow the submitter to adequately describe the content they are cross-referencing. Section III now allows the applicant to indicate if the cross-referenced content is relevant to a specific product or to all bundled products in the application. Across all product categories, the subcategory of ''co-package'' has been removed. However, co-packaged items can be grouped within the same submission and the unique identification of this co-packaged product would include the specific items needed to identify each product within the co-package.
- In section IV, FDA has added a ''Submission Table of Contents'' with fields for ''filename,'' ''title,'' ''table of contents category,'' and ''keyword'' in order that FDA can easily identify the application contents listed in section IV.

(Comment 143) One comment made specific comments requesting changes to elements in Form FDA 4057a.

(Response 143) FDA has considered these comments and agrees that many updates are necessary. The list below details the updates we have made to the form in response to the comments.

- FDA has combined sections I and IV to only ask for current owner's information once. The current owner's information is now only required in section I of the revised form.
- FDA now allows the manufacturer's address and contact information to be provided (if a different entity from the applicant) contact information is to be provided.
- FDA has revised the form to allow the organization's name to be provided (where an organization is an alternate point of contact). Additionally, FDA added a field so that organizational affiliation of the authorized representative information can be provided.
- For a change in authorized representative FDA agrees that ''Replace'' is the appropriate step and has added this as an option in section I, subsection C of the form.
- The form has been edited to allow the submitter to indicate the purpose of the amendment (*i.e.,* whether it was for a single new tobacco product or for a bundled/grouped submission).
- Section III of the form has been revised to allow the submitter to indicate the addition, updating or removal of cross-referenced content, related submissions, and meetings with FDA. Section III now allows the submitter to describe the cross-referenced content, related submissions, and meetings, and to indicate the purpose of the cross-referenced content, related submissions, and meetings. Additionally, section III allows the submitter to indicate whether the submitter intends to ''add,'' ''update'' or ''remove'' referenced content, related submissions, and meetings.
- Section III of the revised form now contains a ''submission summary'' field which allows the applicant to be used to describe the subject of the amendment.
- Section II of the revised form now allows information for ''bundled'' or grouped PMTAs to be submitted. Section II now allows submitters to submit updated tobacco product information for all new tobacco products including co-packaged products. Additionally, section II of the revised form enables submitters to describe the subject of their correspondence and provide a submission summary describing the intended use of the submitted contents.

Where appropriate, FDA has harmonized the terminology in the form with other FDA forms and has harmonized the layout of the Amendment and General Correspondence submission form with the layout of the PMTA submission form. For example, section I of the revised PMTA form is used to describe the applicant, the authorized representative, the alternate point of contact and other applicant information. Correspondingly, section I of the revised Amendment and General Correspondence submission form is used to update applicant information. Similarly, section II of the revised PMTA form is used to set out tobacco product information. Correspondingly, section II of the revised Amendment and General Correspondence submission form is used to update tobacco product information.

FDA received generally supportive comments regarding proposed Form FDA 4057b. Comments agreed the form was a positive step towards streamlining the current PMTA submission process, as well as promoting efficient processing and review of bundled PMTAs.

(Comment 144) One comment noted that Form FDA 4057b failed to include an ''oral tobacco-derived nicotine (OTDN)'' category or subcategory designation. The comment argued that OTDN products are both distinct, being tobacco-free and non-dissolvable, and one of the fastest growing tobacco product segments in the U.S. market. Including an OTDN product subcategory would provide clarity for applicants and streamline FDA review of these products. The comment also noted that Form FDA 4057b requires applicants to include characterizing flavor information but does not define this term in Form FDA 4057b or within the proposed rule.

(Response 144) Providing unique identifying information, such as product category or subcategory, ensures FDA can identify the new tobacco product and distinguish it from other tobacco products, including additional new tobacco products in a bundled submission submitted using Form FDA 4057b, and assists FDA in performing its acceptance and filing reviews. At this

time, FDA does not yet have the experience necessary to create requirements for OTDN as a standalone product category or subcategory. Review of OTDN products will be handled on a case-by-case basis and any future decision to update or change the requirements of the rule and form to include OTDN products will follow appropriate notice and comment procedures. While the rule does not specifically include OTDN as a category or subcategory, where an applicant believes its new tobacco product, such as OTDN, does not fit within a product category set forth in the rule, it should identify the product category as ''other''. Applicants are encouraged to include any properties in addition to those required by the ''other'' category or subcategory to fully identify the tobacco product, if applicable.

In addition, the requirement for applicants to include product-specific information, such as characterizing flavor(s), corresponds to the general information requirements of § 1114.7.(c)(3)(iii) that will allow FDA to quickly check whether the product is within CTP's purview and identify the specific product that is the subject of the submission. For the characterizing flavor item, FDA is looking to see how the applicant identifies the tobacco product as having no characterizing flavor or having a particular characterizing flavor. If applicants do not consider the product to have a characterizing flavor, applicants must state ''none''. As discussed in the proposed rule, applicants that have questions regarding how to describe their product's characterizing flavor are encouraged to contact FDA prior to submission.

(Comment 145) Another comment noted that while the use of Form FDA 4057b would be a positive step, the current PMTA process is prohibitively expensive for most individual manufacturers of nicotine e-liquids.

(Response 145) As discussed in the proposed RIA, FDA has considered the costs and benefits associated with the rule, if finalized. While there are costs associated with the rule, the analysis also noted that the rule, would create cost savings for firms and for FDA by reducing the number of follow-on submission for PMTAs (*i.e.,* additional PMTAs submitted for the same product(s) after FDA refuses to accept or file, or issues a marketing denial order in response to, an initial PMTA). The analysis also noted small manufacturers who submit ENDS PMTA bundles would benefit from the proposed rule, if finalized. Submitted bundles, such as those submitted via Form FDA 4057b, would receive marketing orders through the PMTA pathway earlier with rulemaking than without rulemaking, increasing lifetime profits for the ENDS products included in the submitted ENDS bundles.

FDA is finalizing requirements for the content, format, submission, and review of PMTAs, as well as other requirements related to PMTAs, including recordkeeping requirements, and postmarket reporting. FDA is also finalizing recordkeeping requirements regarding the legal marketing of Pre-Existing Tobacco Products and products that are exempt from the requirements of demonstrating substantial equivalence.

Section 910(a)(2) of the FD&C Act generally requires that a new tobacco product be the subject of a PMTA marketing order unless FDA has issued an order finding it to be substantially equivalent to a predicate product or it is exempt from the requirements of demonstrating substantial equivalence. A manufacturer may choose to submit a PMTA under section 910(b) of the FD&C Act in an attempt to satisfy the requirements of premarket review. Section 910(b)(1) describes the required contents of a PMTA, which in addition to specific items, allows FDA to require applicants to submit other information relevant to the subject matter of the application.

Under § 1114.5 an applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing order. A new tobacco product may not be introduced or delivered for introduction into interstate commerce under this part until FDA has issued a marketing order for the product. Section § 1114.7 describes the required content and format of the PMTA. The PMTA must contain sufficient information for FDA to determine whether any of the grounds for denial specified in section 910(c)(2) of the FD&C Act apply. The application must contain the following sections: general information, descriptive information, product samples as required by FDA, a statement of compliance with part 25, a summary, product formulation, manufacturing, health risk investigations, and a certification statement.

Section § 1114.9 provides that FDA may request, and an applicant may submit, an amendment to a pending PMTA. FDA generally expects that when an applicant submits a PMTA, the submission will include all information required by section 910(b)(1) of the FD&C Act and part 1114 to enable FDA to determine whether it should authorize the marketing of a new tobacco product. However, FDA recognizes that additional information may be needed to complete the review of a PMTA and, therefore, section § 1114.9 allows the submission of amendments to a pending application.

Section § 1114.13 describes the steps that requires an applicant to take when it changes ownership of a PMTA. This section is intended to facilitate transfers of ownership and help ensure that FDA has current information regarding the ownership of a PMTA. An applicant may transfer ownership of its PMTA at any time, including when FDA has yet to act on it.

Section § 1114.15 discusses supplemental PMTAs, which are an alternative format for submitting a PMTA. Specifically, supplemental PMTAs are a standardized cross-referencing format that FDA would implement under its authority of section 701(a) of the FD&C Act to efficiently enforce section 910 for submissions that are based on a PMTA that FDA has previously reviewed. Applicants that have received a marketing order are able to submit a supplemental PMTA to seek marketing authorization for a new tobacco product that results from a modification or modifications to the original tobacco product that received the marketing order. FDA is restricting the use of supplemental PMTAs to only changes that require the submission of limited information or revisions to ensure that FDA is able to efficiently review the application. An applicant is also be able to submit a supplemental PMTA for modifications made to comply with a product standard issued under section 907 of the FD&C Act where FDA specifies that the submission of supplemental PMTAs would be appropriate.

Section § 1114.17 describes resubmissions, which are an alternative format for submitting an application that meets the requirements of § 1114.7(b) or § 1114.15 to seek a marketing order for a tobacco product by responding to the deficiencies outlined in a marketing denial order. An applicant may submit a resubmission for the same tobacco product that received a marketing denial order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a marketing denial order. This application format allows an applicant to address the deficiencies described in a marketing denial order without having to submit a standard PMTA. The resubmission format is not available for PMTAs that FDA refused to accept, refused to file, cancelled, or administratively closed, or that the

applicant withdrew because FDA has not previously completed reviews of such applications upon which it can rely, and such applications may need significant changes to be successfully resubmitted.

Section § 1114.41 requires applicants that receive a marketing order to submit postmarket reports. FDA requires such reports as necessary to determine or facilitate a determination of whether there may be grounds to withdraw or temporarily suspend a marketing order. Section § 1114.41 describes the reports that FDA would require through this regulation; however, FDA may require additional reporting in an individual applicant's marketing order. Applicants would be required under § 1114.41 to submit two types of reports after receiving a marketing order: periodic reports and adverse experience reports.

Applicants need to submit periodic reports within 60 calendar days of the reporting date specified in the marketing order. FDA requires the submission of these reports on an annual basis, but FDA may require in a specific order that reports be made more or less frequently depending upon a number of factors. Applicants are also required to report all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or of which the applicant is aware under section § 1114.41(a)(2). The serious and unexpected adverse experience reports must be submitted to CTP's Office of Science through the HHS Safety Reporting Portal within 15 calendar days after receiving or becoming aware of a serious and unexpected adverse experience.

Section § 1114.45 requires applicants receiving a marketing order to maintain all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing order, including records related to both the application and postmarket reports, and ensure that such records remain readily available to the Agency upon request. Under section § 1114.45(a)(1), an applicant must retain all documents submitted to FDA as part of an application and postmarket reports. An applicant must also retain any additional documentation supporting the application and postmarket reports that was not submitted to FDA.

Section § 1100.200 states that subpart C of part 1100 establishes requirements for the maintenance of records by tobacco product manufacturers who introduce a Pre-Existing Tobacco Product, or deliver it for introduction, into interstate commerce

Section § 1107.3 describes that each applicant who submits an abbreviated report under section 905(j)(1)(A)(ii) of the FD&C Act and receives a letter acknowledging the receipt of an abbreviated report from FDA must maintain all records to support a determination that their exemption request meets the requirements of section 905(j)(3)(A)(i) of the FD&C Act that the modification to a product additive described in the exemption request was a minor modification made to a tobacco product that can be sold under the FD&C Act.

Section § 1114.49 requires an applicant to submit a PMTA and all supporting and related documents to FDA in electronic format. Under section § 1114.49(c), an applicant that has a waiver would submit a paper submission to the address that FDA provides in the letter granting the waiver. FDA's section § 1114.49 is based on FDA's general experience with electronic submissions, which FDA has found help facilitate premarket reviews because electronic submissions typically enable FDA to receive, access, search, and review a submission more quickly than a submission submitted on paper through postal mail.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PMTA Submission (ENDS)	200	3.75	750	1,713	1,284,750 [2]

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This total will not be added to the total burden for this rule as its currently approved under a separate OMB control number 0910–0768.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1114.5—Submission of Standard Bundled PMTAs [2]	1	1	1	1,713	1,713
1114.7—Premarket Tobacco Product Application (PMTA) Submission (Form FDA 4057)	24	1	24	0.75 (45 minutes)	18
Premarket FDA Tobacco Product Application Amendment and General Correspondence Submission (Form FDA 4057a)	24	14	336	0.16 (10 minutes)	54
Premarket Tobacco Product Unique Identifying Information for New Tobacco Products Submission (Form FDA 4057b)	24	1	24	0.75 (45 minutes)	18
1114.41—Reporting Requirements (periodic reports)	3	1	3	50	150
1114.9—Amendments	24	2	48	188	9,024
1114.13—Change in Ownership	1	1	1	1	1
1114.15—Supplemental applications	2	1	2	428	856
1114.17—Resubmissions	3	1	3	565	1,695
1114.41(a)(2)—Adverse Experience Reports	3	6	18	0.6 (36 minutes)	11
1114.49(b) and (c)—Waiver from Electronic Submission	1	1	1	0.25 (15 minutes)	0.25

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					13,540

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] FDA anticipates that applicants will submit bundled PMTAs, which are single submissions containing PMTAs for a number of similar or related products. We estimate that a bundle will contain on average (between 6 and 11) with most submitting 9 distinct products.

FDA has based these estimates on the full analysis of economic impacts and experience with current PMTA submissions. Table 1 describes the current estimates for OMB control number 0910–0768 which covers the burden for ENDS products PMTA submissions. These estimates were originally published in the deeming final rule and recently in the **Federal Register** of April 22, 2019 (84 FR 16673). FDA estimates that it will take each respondent approximately 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. FDA also estimates that it would on average take an additional 213 hours to prepare an EA in accordance with the requirements of § 25.40, for a total of 1,713 hours per PMTA application.

Table 1 describes the estimated annual reporting burden per the requirements that the rule would create beyond what is covered in the existing information collection. For this analysis, FDA assumes that firms will submit all applications as PMTA bundles. We also considered updated data on market consolidation that has occurred since the deeming final rule was published. For originally regulated products we expect to receive one full PMTA submission for a total of 1,713 hours.

FDA conducted a thorough analysis of the current paperwork burden associated with the PMTA program and other similar forms and applied the most accurate burden to the forms; however, upon further review and certain updates made to the form based on comments received and product categorization changes, FDA has revised the burden associated with entering the data into the form (which includes searching existing data sources and gathering and maintaining the data needed) to be 45 minutes per individual product (rather than 30 minutes per product) on Form FDA 4057. For Form FDA 4057a, FDA has revised the burden for this form to 10 minutes (from 5 minutes). This form serves several purposes from changing a point of contact (minimal burden) to providing additional substantive information for the purpose of the review of the PMTA application (more burdensome).

FDA developed Form FDA 4057 for use when submitting PMTA single and bundled submissions. FDA estimates that 24 respondents will submit PMTA bundles using this form at 0.75 (45 minutes) per response. The number 24 is accounting for the bundles of ENDS products and the 1 bundle we expect to receive yearly for originally regulated products. (200 + 1 = 201/8.5 products on average in a bundle) for a total of 12 hours.

FDA developed Form FDA 4057a for use when firms are submitting amendments and other general correspondence. Our estimate is 0.16 (10 minutes) per response to fill out this form. We estimate there will be at least one amendment per application for a total of 28 hours. With most applications being submitted toward the end of our 3-year range, we expect fewer amendments during this period. However, FDA expects correspondence from earlier applications to be submitted during this period.

FDA developed an additional form (Form FDA 4057b) that will assist industry and FDA in identifying the products that are the subject of a submission where an applicant groups multiple PMTAs into a single submission (referred to as a bundled submission or a grouped submission). FDA has previously stated that one approach to submitting PMTAs could be to group applications for products that are both from the same manufacturer or domestic importer and in the same product category and subcategory into a single submission. FDA discussed bundled submissions in the proposed rule (84 FR 50566 at 50578) and noted that FDA intends to consider information on each tobacco product as a separate, individual PMTA. The form will assist applicants in providing the unique identifying information for each product in a grouped submission of PMTAs that are required § 1114.7(c)(3)(iii). By having the identifying information for products contained in a submission be more clearly organized, FDA will be able to more efficiently process and review the applications contained in a grouped submission.

Based on the Form FDA 4057 for use when submitting PMTA single and bundled submissions, a respondent would utilize Form FDA 4057b once for each submission containing more than one PMTA. We assume the submitter could include from 2 to 2,000 products in each Form FDA 4057b. Entering data for up to 2,000 rows can take approximately 4 hours on average per Form FDA 4057b for manual data entry. However, FDA's original estimate that Form 4057b would estimate 4 hours per response was a high-end estimate and not an average. We now reflect the average time of 45 minutes per response based on the assumption that we expect to receive an average of nine bundled products per submission. Assuming 45 minutes per Form FDA 4057b for 24 applications, we estimate a total burden of 18 hours for this activity.

FDA estimates under § 1114.41 that three respondents will submit a periodic report. This number is based on the average number of periodic report submissions expected between 2020–2022. The RIA estimates that periodic reports will take between 20 and 80 hours per submission. For this estimate, we use the average of 50 per response for a total of 150 hours.

Under § 1114.9 firms will prepare amendments to PMTA bundles in response to deficiency letters. These amendments contain additional information that we need to complete substantive review. In the RIA we state in our limited history reviewing PMTAs, we on average issue two deficiency letters. Based on this, we would anticipate two responses back per bundle. Therefore, we estimate that 24 respondents will submit 48 amendments (24×2). Assuming 1,500 hours as the time to prepare and submit a full PMTA and amendments may on average take 10 percent to 15 percent of that time (150–225). We averaged this time out (12.5 percent of a full submission preparation time) and arrived at 188 hours per response. FDA estimates the total burden hours for preparing amendments is 9,024 hours.

Section § 1114.13 would allow an applicant to transfer ownership of a PMTA to a new owner. FDA believes this will be infrequent, so we have assigned 1 token hour acknowledging the requirement.

Section § 1114.15 is an alternative format of submitting a PMTA that meets the requirements of § 1114.7 that would reduce the burden associated with the submission and review of an application. Our estimated number of 2 respondents is based on the number estimated for postmarket reports, which is 3 bundles (which is approximately 26 products). Not all applicants will resubmit modifications to previously authorized products, so we estimate 2 bundles (which is approximately 17 products). FDA estimates further that a supplemental PMTA will take 25 percent of the time it takes to do an original submission (including EA hours) for 428 hours per response. We estimate a total of 856 burden hours for this activity.

Under § 1114.17 an applicant may submit a resubmission for the same tobacco product that received a marketing denial order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a marketing denial order. Based on the preliminary RIA, we are estimating that out of all bundles received in 2020, 2021, and 2022, that an average of three bundles are authorized. If we receive 24 bundles yearly, and based on historical data, 58 percent fail at acceptance (down to 8 bundles remaining), 17 percent fail at filing (down to 7 bundles remaining), and 25 percent receive marketing orders (5 left). We estimate that 50 percent will try to resubmit in a year. Thus, this number of respondents is three (rounded up). FDA estimates that a resubmission will take 33 percent of the time it takes to complete an original submission (including EA hours) at 565 hours per response for a total of 1,695 hours.

Under § 1114.41(a)(2), firms would also submit adverse experience reports for tobacco products with marketing orders. We assume the same number of firms submitting periodic reports will submit adverse experience reports. Currently, firms may voluntarily submit adverse experience reports using Form FDA 3800 under OMB control number 0910–0645. We have based our estimates on this information collection which estimates that it takes 1 hour (for mandatory reporting) to complete this form for tobacco products for a total of 18 hours.

Section § 1114.49 would require an applicant to submit a PMTA and all supporting and related documents to FDA in electronic format that FDA can process, review, and archive unless an applicant requests, and FDA grants, a waiver from this requirement. FDA does not believe we will receive many waivers, so we have assigned one respondent to acknowledge the option to submit a waiver. Consistent with our other application estimates for waivers, we believe it would take .25 hours (15 minutes) per waiver for a total of .25 hours.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1114.45—PMTA Records	24	1	24	2	48
1100.204—Pre-Existing Tobacco Product Records	1	1	1	2	2
1107.3—Exemptions from Substantial Equivalence Records	1	1	1	2	2
Total					52

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3 describes the annual recordkeeping burden per the requirements in this rule. FDA estimates that 26 recordkeepers will maintain records at 2 hours per record. Additionally, the rule requires that firms establish and maintain records related to SE Exemption Requests and Pre-Existing Tobacco Products. We expect the burden hours of this rule to be negligible for SE Exemption Requests. Firms would have already established the required records when submitting the SE Exemption Request. Similarly, we expect the hours of this rule to be negligible for any Pre-Existing Tobacco Products that have already submitted Standalone Pre-Existing Tobacco Product Submissions, because firms would have established the required records when submitting the Standalone Pre-Existing Tobacco Product Submissions. We believe this time is usual and customary for these firms. We estimate that it would take 2 hours per record to establish the required records for a total of 4 hours. Therefore, the total recordkeeping burden hours is estimated to be 52 hours.

The total burden for these new collections of information in this rulemaking is 13,540 reporting hours and 52 recordkeeping hours for a total of 13,592 hours.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XIII. Federalism: Executive Order 13132

We have analyzed this rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 916(a)(2) of the FD&C Act is an express preemption provision. Section 916(a)(2) provides that ''no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to . . . premarket review.'' Thus, the final

rule creates requirements that fall within the scope of section 916(a)(2) of the FD&C Act.

XIV. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

XV. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XVI. Analysis of Environmental Impact

The Agency has determined under § 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No extraordinary circumstances exist to indicate that the specific proposed action may significantly affect the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XVII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We expect that the final rule will generate net benefits or negligible net costs for most affected small entities. Therefore, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The final rule will require manufacturers of Pre-Existing Tobacco Products and manufacturers of products that are exempt from the requirements of demonstrating SE to maintain records to demonstrate that they can legally market their products. For products that receive a PMTA marketing granted order, the final rule will require certain postmarket reporting, including periodic reporting and adverse experience reporting. The final rule will also implement and set forth requirements for the content and format of PMTAs and the general procedures we intend to follow in reviewing and communicating with applicants.

The final rule will make the review of PMTAs more efficient. As a result, the final rule will create cost savings for FDA related to the review of some PMTAs. The final rule will also create cost savings for FDA and for PMTA applicants by reducing the number of PMTAs submitted. In table 4, we present the annualized benefits of the final rule. We estimate that annualized benefits over 20 years will equal $2.04 million at a 7 percent discount rate, with a low estimate of $1.36 million and a high estimate of $2.85 million. We estimate that annualized benefits over 20 years will equal $2.08 million at a 3 percent discount rate, with a low estimate of $1.43 million and a high estimate of $2.84 million.

This is the first regulation to address the costs of PMTA requirements for new, originally regulated tobacco products. While we already included the costs to submit and review PMTAs for deemed tobacco products in the final RIA for the deeming final rule, no RIA includes the costs to submit and review PMTAs for originally regulated tobacco products. Therefore, we include the costs to prepare and review PMTAs for these tobacco products in this analysis.

The final rule will increase the cost for applicants to prepare a PMTA. As a result, the final rule will generate incremental costs related to the preparation of PMTAs for ENDS products. Firms will incur costs to maintain and submit postmarket reports and we will incur costs to review these reports. Finally, firms will incur costs to read and understand the rule and costs to maintain records for some Pre-Existing Tobacco Products. In table 4, we present the annualized costs of the final rule. We estimate that annualized costs over 20 years will equal $4.73 million at a 7 percent discount rate, with a low estimate of $2.63 million and a high estimate of $7.45 million. We estimate that annualized costs over 20 years will equal $4.86 million at a 3 percent discount rate, with a low estimate of $2.50 million and a high estimate of $7.95 million.

TABLE 4—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE FINAL RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate %	Period covered (years)	
Benefits:							
Annualized Monetized ($m/year)	$2.04	$1.36	$2.85	2019	7	20	All quantified benefits are cost savings.
	2.08	1.43	2.84	2019	3	20	

TABLE 4—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE FINAL RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate %	Period covered (years)	
Annualized Quantified.							
Qualitative	Benefits from postmarket surveillance.						
Costs:							
Annualized Monetized ($m/year)	4.73	2.63	7.45	2019	7	20	
	4.86	2.50	7.95	2019	3	20	
Annualized Quantified.							
Qualitative.							
Transfers:							
Federal Annualized Monetized ($m/year).	From:			To:			
Other Annualized Monetized ($m/year).	From: Currently marketed tobacco products.			To: New tobacco products with PMTA marketing orders.			
Effects:							
State, Local, or Tribal Government: None.							
Small Business: None.							
Wages: None.							
Growth: None.							

XVIII. Effective Date

This rule will become effective 30 days after it publishes in the **Federal Register**.

(Comment 146) One comment stated that FDA must not apply any requirements from the final rule retroactively to applications that have already been submitted because doing so would be fundamentally unfair. The comment further stated, for instance, that FDA should not discount the results of a study on the basis that it does not contain the newly required statements or documentation regarding financial conflicts of interest.

(Response 146) FDA agrees with this comment insofar as it applies to the acceptance and filing criteria. FDA does not intend to retroactively apply any new acceptance and filing criteria added by § 1114.27 to applications that have been submitted before the final rule is effective. If an applicant has submitted an application before this rule is effective, FDA will not refuse to accept or refuse to file the PMTA unless the FD&C Act or other existing regulations require information that the application is missing. It is important to note that while FDA will not apply acceptance and filing criteria required by this rule retroactively, the information required for acceptance and filing under this rule remains important to FDA's substantive review of an application. The comment's example of information regarding financial conflicts of interest is particularly relevant because determining the reliability of a study's results is an important part of FDA's substantive review of an application, regardless of whether it's applied as a filing criteria. Other provisions in this rule, such as those regarding application amendments, temporary suspension and withdrawal, postmarket changes, postmarket reporting, and recordkeeping, will take effect for all PMTAs, as applicable, once the rule is effective. In addition, all the requirements in section 910 of FD&C Act are in effect.

XIX. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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List of Subjects

21 CFR Part 1100

Administrative practice and procedure, Smoke, Smoking, Tobacco, Tobacco products.

21 CFR Part 1107

Administrative practice and procedure, Smoke, Smoking, Tobacco, Tobacco products.

21 CFR Part 1114

Administrative practice and procedure, Smoke, Smoking, Tobacco, Tobacco products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations will be amended as follows:

PART 1100—GENERAL

■ 1. The authority citation for part 1100 is revised to read as follows:

Authority: 21 U.S.C. 371, 374, 387a(b), 387e, and 387i; Pub. L. 111–31.

■ 2. Revise the part heading to read as set forth above.

Subpart A—Tobacco Products Subject to FDA Authority

■ 3. Add subpart A consisting of §§ 1100.1, 1100.2, 1100.3, and 1100.5 to read as set forth above:

Subpart B [Reserved]

■ 4. Add and reserve subpart B.

■ 5. Add subpart C, consisting of §§ 1100.200, 1100.202, and 1100.204, to read as follows:

Subpart C—Maintenance of Records Demonstrating That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

Sec.

Subpart C—Maintenance of Records Demonstrating That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.

§ 1100.200 Purpose and scope.

This subpart sets out requirements under the Federal Food, Drug, and Cosmetic Act for the maintenance of records by tobacco product manufacturers that introduce a Pre-Existing Tobacco Product, or deliver it for introduction, into interstate commerce.

§ 1100.202 Definitions.

For the purposes of this subpart:

Commercially marketed means selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States.

Pre-Existing Tobacco Product means a tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007. A Pre-Existing Tobacco Product is not subject to the premarket requirements of section 910 of the Federal Food, Drug, and Cosmetic Act.

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the Federal Food, Drug, and Cosmetic Act is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g)).

Tobacco product manufacturer means any person, including any repacker or relabeler, who—

(1) Manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(2) Imports a finished tobacco product for sale or distribution in the United States.

§ 1100.204 Recordkeeping requirements.

(i) Any tobacco product manufacturer that introduces a Pre-Existing Tobacco Product, or delivers it for introduction, into interstate commerce must maintain records that demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007, as described in this subpart. These records may include items such as:

(A) Dated copies of advertisements;
(B) Dated catalog pages;
(C) Dated promotional material;
(D) Dated trade publications;
(E) Dated bills of lading;
(F) Dated freight bills;
(G) Dated waybills;
(H) Dated invoices;
(I) Dated purchase orders;
(J) Dated customer receipts;
(K) Dated manufacturing documents;
(L) Dated distributor or retailer inventory lists; or

(M) Any other dated document that demonstrates that the tobacco product was commercially marketed in the United States as of February 15, 2007.

(ii) All records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. Documents that have been translated from another language into English (*e.g.,* advertisements written in a language other than English) must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation.

(iii) All records required by this subpart must be retained for a period of not less than 4 years after the date either FDA makes a determination that the product is a Pre-Existing Tobacco Product, or the tobacco product manufacturer permanently ceases the introduction or delivery for introduction into interstate commerce of the tobacco product, whichever occurs sooner.

PART 1107—EXEMPTION REQUESTS AND SUBSTANTIAL EQUIVALENCE REPORTS

■ 6. The authority citation for part 1107 is revised to read as follows:

Authority: 21 U.S.C. 371, 374, 387e(j), 387i, 387j.

■ 7. Revise the part heading as set forth above.

■ 8. Add § 1107.3 to subpart A to read as follows:

§ 1107.3 Recordkeeping.

(a) *Definition.* The term ''Pre-Existing Tobacco Product'' means a tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007. A Pre-Existing Tobacco Product is not subject to the premarket requirements of section 910 of the Federal Food, Drug, and Cosmetic Act.

(b) *Record maintenance.* (1) Each applicant who submits an abbreviated report under section 905(j)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act and receives a letter acknowledging the receipt of an abbreviated report from FDA must maintain all records (including those created by third parties on the applicant's behalf) that support the submission. Such records may include, but are not limited to:

(i) A copy of the abbreviated report and, if applicable, the exemption request and all amendments thereto.

(ii) A copy of the acknowledgement letter issued in response to an abbreviated report and, if applicable, the exemption order issued by FDA.

(iii) Documents related to formulation of product, design specifications, packaging, and related items.

(iv) Documents showing design specifications are consistently met.

(v) Documents related to product packing and storage conditions.

(vi) Analytical test method records, including:

(A) Performance criteria.

(B) Validation or verification documentation; and

(C) Reports/results from these test methods.

(vii) Source data and related summaries.

(2) An applicant that submits an abbreviated report for a modification to a Pre-Existing Tobacco Product must also maintain records demonstrating that the Pre-Existing Tobacco Product was commercially marketed in the United States as of February 15, 2007, such as the records described in § 1100.204 of this chapter.

(3) An applicant that submits an abbreviated report for a modification to a tobacco product that previously received premarket authorization (*i.e.,* an exemption (and for which the applicant has submitted an abbreviated report under section 905(j)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act, a substantially equivalent order under section 910(a), or a marketing granted order under section 910(c)) must maintain a copy of the exemption order, substantially equivalent order, or marketing granted order.

(4) An applicant that submits an abbreviated report for a modification to a tobacco product that is the subject of a pending SE report and is marketed pursuant to section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act must maintain all communications to and from FDA relating to the pending SE Report (*e.g.,* acknowledgement letter, deficiency letters), including the SE Report.

(c) *Record quality.* All records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. Documents that have been translated from another language into English (*e.g.,* advertisements written in a language other than English) must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation.

(d) *Record retention.* All records required by this subpart must be retained for a period of 4 years from the date that an acknowledgement letter is issued by FDA.

■ 9. Add part 1114 to subchapter K to read as follows:

PART 1114—PREMARKET TOBACCO PRODUCT APPLICATIONS

Subpart A—General Provisions

Sec.
1114.1 Scope.
1114.3 Definitions.

Subpart B—Premarket Tobacco Product Applications

1114.5 Application submission.
1114.7 Required content and format.
1114.9 Amendments.
1114.11 Withdrawal by applicant.
1114.13 Change in ownership of an application.
1114.15 Supplemental applications.
1114.17 Resubmissions.

Subpart C—FDA Review

1114.25 Communication between FDA and applicants.
1114.27 Review procedure.
1114.29 FDA action on an application.
1114.31 Issuance of a marketing granted order.
1114.33 Issuance of a marketing denial order.
1114.35 Withdrawal of a marketing granted order.
1114.37 Temporary suspension of a marketing granted order.

Subpart D—Postmarket Requirements

1114.39 Postmarket changes.
1114.41 Reporting requirements.

Subpart E—Miscellaneous

1114.45 Record retention.
1114.47 Confidentiality.
1114.49 Electronic submission.

Authority: 21 U.S.C. 371, 374, 387a, 387i, and 387j.

Subpart A—General Provisions

§ 1114.1 Scope.

(a) This part sets forth the procedures and requirements for submitting a premarket tobacco product application (PMTA), the general procedures FDA will follow when evaluating a PMTA, and postmarket reporting requirements.

(b) This part does not apply to modified risk tobacco product applications, except that single applications seeking both a marketing granted order under section 910(c) of the Federal Food, Drug, and Cosmetic Act and an order under section 911(g) of the Federal Food, Drug, and Cosmetic Act must satisfy the requirements of this part in addition to the requirements of section 911 of the Federal Food, Drug, and Cosmetic Act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(d) This part does not apply to ''premium'' cigars as defined in § 1114.3.

§ 1114.3 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product, but:

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco, or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

Adverse experience means any unfavorable physical or psychological effect in a person that is temporally associated with the use of or exposure to a tobacco product, whether or not the person uses the tobacco product, and whether or not the effect is considered to be related to the use of or exposure to the tobacco product.

Applicant means any person that submits a premarket tobacco product application to receive a marketing granted order for a new tobacco product.

Brand means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes.

Characteristics means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

Commercially marketed means selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Composition means the materials in a tobacco product, including ingredients, additives, and biological organisms. The term includes the manner in which the materials, for example, ingredients, additives, and biological organisms, are arranged and integrated to produce a tobacco product.

Constituent means any chemical or chemical compound in a tobacco product that is or potentially is inhaled, ingested, or absorbed into the body, any chemical or chemical compound in an emission (*e.g.,* smoke, aerosol, droplets) from a tobacco product, that either transfers from any component or part of the tobacco product to the emission or that is formed by the product, including through combustion or heating of tobacco, additives, or other components of the tobacco product.

Container closure system means any packaging materials that are a component or part of a tobacco product.

Design means the form and structure concerning, and the manner in which components or parts, ingredients, software, and materials are integrated to produce a tobacco product.

Finished tobacco product means a tobacco product, including all components and parts, sealed in final packaging (*e.g.,* filters or filter tubes sold to consumers separately or as part of kits, or e-liquids sealed in final packaging sold to consumers either separately or as part of kits) or in the final form in which it is intended to be sold to consumers.

Harmful or potentially harmful constituent or *HPHC* means any chemical or chemical compound in a tobacco product or tobacco smoke or emission that:

(1) Is or potentially is inhaled, ingested, or absorbed into the body, including as an aerosol or any other emission; and

(2) Causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products.

Heating source means the source of energy used to burn or heat the tobacco product.

Ingredient means tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing.

Label means a display of written, printed, or graphic matter upon the immediate container of any article.

Labeling means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

Line data means an analyzable dataset of observations for each individual study participant, laboratory animal, or test replicate.

Marketing denial order means the order described in section 910(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act stating that the product may not be introduced or delivered for introduction into interstate commerce.

Marketing granted order means the order described in section 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act stating that the new tobacco product may be introduced or delivered for introduction into interstate commerce.

Material means an assembly of ingredients. Materials are assembled to form a tobacco product or components or parts of a tobacco product.

New tobacco product means:

(1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(2) Any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Other features means any distinguishing qualities of a tobacco product similar to those specifically enumerated in section 910(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. Such other features include harmful and potentially harmful constituents and any other product characteristics that relate to the chemical, biological, and physical properties of the tobacco product.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Premarket tobacco product application or *PMTA* means the application described in section 910(b) of the Federal Food, Drug, and Cosmetic Act. This term includes the initial premarket tobacco product application and all subsequent amendments.

''*Premium*'' *cigar* means a type of cigar that:

(1) Is wrapped in whole tobacco leaf;

(2) Contains a 100 percent leaf tobacco binder;

(3) Contains at least 50 percent (of the filler by weight) long filler tobacco (*i.e.,* whole tobacco leaves that run the length of the cigar);

(4) Is handmade or hand rolled (*i.e.,* no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling);

(5) Has no filter, nontobacco tip, or nontobacco mouthpiece;

(6) Does not have a characterizing flavor other than tobacco;

(7) Contains only tobacco, water, and vegetable gum with no other ingredients or additives; and

(8) Weighs more than 6 pounds per 1,000 units.

Serious adverse experience means an adverse experience that results in any of the following outcomes:

(1) Death;

(2) A life-threatening condition or illness;

(3) Inpatient hospitalization or prolongation of existing hospitalization;

(4) A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;

(5) A congenital anomaly/birth defect; or

(6) Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Submission tracking number or *STN* means the number that FDA assigns to submissions that are received from an applicant, such as a PMTA and a supplemental PMTA.

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the Federal Food, Drug, and Cosmetic Act is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g)).

Tobacco product manufacturer means any person, including a repacker or relabeler, who:

(1) Manufactures, fabricates, assembles, processes, or labels a tobacco product, or

(2) Imports a finished tobacco product for sale or distribution in the United States.

Unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

(1) The known or foreseeable risks of adverse experiences associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as the product labeling and postmarket reports;

(2) The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or

(3) The results of nonclinical investigations.

Vulnerable populations means groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation. Vulnerable populations can include, but are not limited to, youth and young adults, those with lower socioeconomic status, certain races or ethnicities, sexual or gender minorities, underserved rural populations, those pregnant or trying to become pregnant, those in the military or veterans, and those with mental health conditions or substance use disorders.

Subpart B—Premarket Tobacco Product Applications

§ 1114.5 Application submission.

An applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing granted order. A new tobacco product may not be introduced or delivered for introduction into interstate commerce under this part until FDA has issued a marketing granted order for the product.

§ 1114.7 Required content and format.

(a) *General.* The PMTA must contain sufficient information for FDA to determine whether any of the grounds for marketing denial order specified in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply. The application must contain the following sections:

(1) General information (as described in paragraph (c) of this section);

(2) Descriptive information (as described in paragraph (d) of this section);

(3) Product samples (as described in paragraph (e) of this section);

(4) Labeling and description of marketing plans (as described in paragraph (f) of this section);

(5) Statement of compliance with 21 CFR part 25 (as described in paragraph (g) of this section);

(6) Summary (as described in paragraph (h) of this section);

(7) Product formulation (as described in paragraph (i) of this section);

(8) Manufacturing (as described in paragraph (j) of this section);

(9) Health risk investigations (as described in paragraph (k) of this section); and

(10) The effect on the population as a whole (as described in paragraph (l) of this section);

(11) Certification statement (as described in paragraph (m) of this section).

(b) *Format.* (1) The application must be submitted using the form(s) that FDA provides, contain a comprehensive index (*i.e.,* a listing of files and data associated with those files) and table of contents, be well-organized and legible, and be written in English. Documents that have been translated from another language into English (*e.g.,* original study documents written in a language other than English) must be accompanied by: The original language version of the document, signed a statement by an authorized representative of the manufacturer

certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation. As described in § 1114.49, the applicant must submit the application and all information supporting the application in an electronic format that FDA can process, read, review, and archive, unless FDA has granted a waiver.

(2) An applicant may include content in a submission by cross-reference to a tobacco product master file or a pending modified risk tobacco product application for the same tobacco product. Applicants using a master file must provide documentation of their right of reference for the master file and clearly identify the specific content being incorporated into the PMTA submission. Except as provided for in §§ 1114.15 and 1114.17, FDA will not consider content included by cross-reference to other sources of information outside of the submission.

(c) *General information.* The applicant must, by using the form(s) FDA provides, specify the following general information:

(1) Applicant name, address, and contact information;

(2) Authorized representative or U.S. agent (for a foreign applicant), including the name, address, and contact information;

(3) The following information to uniquely identify the product:

(i) Manufacturer;

(ii) Product name(s), including brand and subbrand (or other commercial name(s) used in commercial distribution); and

(iii) The product category, product subcategory, and product properties as provided in the following table. If the product does not have a listed product property, such as ventilation or characterizing flavor, the application must state ''none'' for that property.

TABLE 1 TO PARAGRAPH (c)(3)(iii)

Tobacco product category	Tobacco product subcategory	Product properties
(A) Cigarettes	(*1*) Filtered	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89.1 millimeters (mm), 100.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Ventilation (e.g., none, 10.0%, 25.0%). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Non-filtered	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89.1 mm, 100.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Characterizing flavor(s) (e.g., none, menthol). — Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Other	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89.1 mm, 100.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Ventilation (e.g., none, 10.0%, 25.0%). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
(B) Roll-Your-Own Tobacco Products.	(*1*) Roll-Your-Own Tobacco Filler.	—Package type (e.g., bag, pouch). —Product quantity (e.g., 20.1 grams [g], 16.0 ounces [oz.]). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Rolling Paper	—Package type (e.g., box, booklet). —Product quantity (e.g., 50 sheets, 200 papers). —Length (e.g., 79.1 mm, 100.0 mm, 110.2 mm). —Width (e.g., 28.1 mm, 33.0 mm, 45.2 mm). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Cigarette Tube, Filtered.	—Package type (e.g., bag, box). —Product quantity (e.g., 100 tubes, 200 tubes). —Length (e.g., 89.1 mm, 100.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Ventilation (e.g., none, 10.0%, 25.0%). —Characterizing flavor(s) (e.g., none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Cigarette Tube, Non-filtered.	—Package type (e.g., bag, box). —Product quantity (e.g., 100 tubes, 200 tubes). —Length (e.g., 89.1 mm, 100.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Characterizing flavor(s) (e.g., none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Filter	—Package type (e.g., bag, box). —Product quantity (e.g., 100 filters, 200 filters). —Length (e.g., 8.0 mm, 12.1 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Characterizing flavor(s) (e.g., none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).

TABLE 1 TO PARAGRAPH (c)(3)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	(*6*) Paper Tip	—Package type (e.g., bag, box). —Product quantity (e.g., 200 tips, 275 tips). —Length (e.g., 12.0 mm, 15.1 mm). —Width (e.g., 27.1 mm). —Characterizing flavor(s) (e.g., none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*7*) Other	—Package type (e.g., bag, box). —Product quantity (e.g., 200 tips, 100 filters, 200 tubes. —Characterizing flavor(s) (e.g., none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product.
(C) Smokeless Tobacco Products.	(*1*) Moist Snuff, Loose	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20.0 g, 2.1 oz.). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable, e.g., fine cut, long cut, straight cut).
	(*2*) Moist Snuff, Portioned.	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 22.5 g, 20.0 g). —Portion count (e.g., 15 pouches, 20 pieces). —Portion mass (e.g., 1.5 g/pouch, 1.0 g/piece). —Portion length (e.g., 15.0 mm, 20.1 mm). —Portion width (e.g., 10.0 mm, 15.1 mm). —Portion thickness (e.g., 5.0 mm, 7.1 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Snus, Loose	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20.0 g, 2.1 oz.). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Snus, Portioned	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 22.5 g, 20.0 g). —Portion count (e.g., 15 pouches, 20 pieces). —Portion mass (e.g., 1.5 g/pouch, 1.0 g/piece). —Portion length (e.g., 15.0 mm, 20.1 mm). —Portion width (e.g., 10.0 mm, 15.1 mm). —Portion thickness (e.g., 5.0 mm, 7.1 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Dry Snuff, Loose ...	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20.0 g, 2.1 oz.). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Dissolvable	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 22.5 g, 20.0 g) —Portion count (e.g., 15 sticks, 20 pieces). —Portion mass (e.g., 1.5 g/strip, 1.0 g/piece). —Portion length (e.g., 10.0 mm, 15.1 mm). —Portion width (e.g., 5.0 mm, 8.1 mm). —Portion thickness (e.g., 3.0 mm, 4.1 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*7*) Chewing Tobacco, Loose.	—Package type (e.g., bag, pouch, wrapped). —Product quantity (e.g., 20.0 g, 3.1 oz). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*8*) Chewing Tobacco, Portioned.	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 22.5 g, 20.0 g) —Portion count (e.g., 10 bits). —Portion mass (e.g., 2.1 g/bit). —Portion length (e.g., 8.0 mm, 10.1 mm). —Portion width (e.g., 6.0 mm, 8.1 mm). —Portion thickness (e.g., 5.1 mm, 7.0 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*9*) Other	—Package type (e.g., bag, box, can). —Product quantity (e.g., 20.1 g, 22.5 g, 3.0 oz.). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen, tobacco). —Additional properties needed to uniquely identify the tobacco product.

TABLE 1 TO PARAGRAPH (c)(3)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
(D) Electronic Nicotine Delivery System (ENDS) (Also referred to as vapes).	(*1*) E-Liquid, Open	—Package type (e.g., bottle, box, pod). —Product quantity (e.g., 1 bottle, 5 bottles). —E-liquid volume (e.g., 0.5 milliliters [ml]), 2.0 ml, 5.1 ml). —Nicotine concentration (e.g., 0 milligrams/milliliter [mg/ml], 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/bottle). —Propylene glycol (PG)/vegetable glycerin (VG) ratio (e.g., not applicable [N/A], 0/100, 50/50, 100/0). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) E-Liquid, Closed	—Package type (e.g., cartridge, pod). —Product quantity (e.g., 1 cartridge, 5 cartridges). —E-liquid volume (e.g., 0.5 ml, 2.0 ml, 5.1 ml). —Nicotine concentration (e.g., 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 2.0 mg/bottle). —PG/VG ratio (e.g., N/A, 0/100, 50/50, 100/0). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) E-Cigarette, Closed	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes). —Length (e.g., 100.0 mm, 120.0 mm). —Diameter (e.g., 6.0 mm, 8.0 mm). —Wattage (e.g., 100 watts [W], 200 W). —Battery capacity (e.g., 100 milliampere hours [mAh], 200 mAh). —E-liquid volume (e.g., 0.5 ml, 2.0 ml, 5.1 ml). —Nicotine concentration (e.g., 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/e-cigarette). —PG/VG ratio (e.g., N/A, 0/100, 50/50, 100/0). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product.
	(*4*) E-Cigarette, Open	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes). —Length (e.g., 100.0 mm, 120.0 mm). —Diameter (e.g., 6.0 mm, 8.0 mm). —E-liquid volume (e.g., 0.5 ml, 2.0 ml, 5.1 ml). —Wattage (e.g., 100 W, 200 W). —Battery capacity (e.g., 100 mAh, 200 mAh). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) ENDS Component	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g.,1 coil). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) ENDS Other	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 e-cigarette, 5 bottles). —Characterizing flavor(s) (e.g., none, cherry, wintergreen, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product.
(E) Cigars	(*1*) Cigar, Filtered Sheet-Wrapped.	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 filtered cigars, 25 filtered cigars). —Length (e.g., 89.1 mm, 100.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Ventilation (e.g., none, 0%, 10.0%, 25.0%). —Characterizing flavor (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Cigar, Unfiltered Sheet-Wrapped.	—Package type (e.g., box, film sleeve). —Product quantity (e.g., 1 cigar, 5 cigarillos). —Length (e.g., 100.1 mm, 140.0 mm). —Diameter (e.g., 8.0 mm, 10.1 mm). —Tip (e.g., none, wood tips, plastic tips). —Characterizing flavor (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Cigar, Unfiltered Leaf-Wrapped.	—Package type (e.g., box, film, sleeve, none). —Product quantity (e.g., 1 cigar, 5 cigars). —Length (e.g., 150.1 mm, 200.0 mm). —Diameter (e.g., 8.0 mm, 10.1 mm). —Wrapper material (e.g., burley tobacco leaf, Connecticut shade grown tobacco leaf). —Characterizing flavor (e.g., none, whiskey). —Additional properties needed to uniquely identify the tobacco product (if applicable).

TABLE 1 TO PARAGRAPH (c)(3)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	(*4*) Cigar Component ..	—Package type (e.g., box, booklet). —Product quantity (e.g., 10 wrappers, 20 leaves). —Characterizing flavor (e.g., none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Cigar Tobacco Filler.	—Package type (e.g., bag, pouch). —Product quantity (e.g., 20.0 g, 16.1 oz.). —Characterizing flavor (e.g., none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Other	—Package type (e.g., box, booklet). —Product quantity (e.g., 1 cigar, 5 cigars, 20 leaves, 16 g). —Characterizing flavor(s) (e.g., none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product.
(F) Pipe Tobacco Products.	(*1*) Pipe	—Package type (e.g., box, none). —Product quantity (e.g., 1 pipe). —Length (e.g., 200.0 mm, 300.1 mm). —Diameter (e.g., 25.1 mm). —Characterizing flavor(s) (e.g., none, menthol, cavendish, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Pipe Tobacco Filler	—Package type (e.g., bag, none). —Product quantity (e.g., 20.0 g, 16.1 oz). —Tobacco cut style (e.g., standard cut, such as shag cut, bugler cut, loose cut, etc., or a pressed cut, such as flake, cube cut, roll cake, etc., or a mixture). —Characterizing flavor(s) (e.g., none, menthol, cavendish, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Pipe Component ...	—Package type (e.g., box, bag, none). —Product quantity (e.g., 1 bowl, 1 stem, 100 filters). —Characterizing flavor(s) (e.g., none, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Other	—Package type (e.g., bag, box, none). —Product quantity (e.g., 1 pipe, 1 bowl, 1 stem, 100 filters). —Characterizing flavor(s) (e.g., none, cherry). —Additional properties needed to uniquely identify the tobacco product.
(G) Waterpipe Tobacco Products.	(*1*) Waterpipe	—Package type (e.g., box, none). —Product quantity (e.g., 1 waterpipe). —Height (e.g., 200.0 mm, 500.1 mm). —Width (e.g., 100.1 mm, 300.0 mm). —Diameter (e.g., 100.1 mm, 300.0 mm)—Number of hoses (e.g., 1, 2, 4). —Characterizing flavor(s) (e.g., none). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Waterpipe Tobacco Filler.	—Package type (e.g., bag, pouch). —Product quantity (e.g., 20.0 g, 16.1 oz.). —Characterizing flavor(s) (e.g., none, tobacco, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Waterpipe Heat Source.	—Package type (e.g., box, film sleeve, bag, none). —Product quantity (e.g., 150.0 g, 680.0 g). —Portion count (e.g., 20 fingers, 10 discs, 1 base). —Portion mass (e.g., 15.0 g/finger, 10.0g/brick). —Portion length (e.g., 40.0 mm, 100.0 mm). —Portion width (e.g., 10.0 mm, 40.0 mm). —Portion thickness (e.g., 10.0 mm, 40.0 mm). —Source of energy (e.g., charcoal, battery, electrical). —Characterizing flavor(s) (e.g., none, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Waterpipe Component.	—Package type (e.g., bag, box, none). —Product quantity (e.g., 1 base, 1 bowl, 1 hose, 10 mouthpieces). —Characterizing flavor(s) (e.g., none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Waterpipe Other	—Package type (e.g., bag, box, none). —Product quantity (e.g., 1 base, 1 bowl, 1 hose, 10 mouthpieces). —Characterizing flavor(s) (e.g., none, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
(H) Heated Tobacco Products (HTP).	(*1*) Closed HTP	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 device, 1 HTP). —Length (e.g., 100.0 mm, 120.0 mm).

TABLE 1 TO PARAGRAPH (c)(3)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Diameter (e.g., 6.0 mm, 8.1 mm). —Wattage (e.g., 100 W, 200 W). —Battery capacity (e.g., 100 mAh, 200 mAh). —Characterizing flavor(s) (e.g., none). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Open HTP	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 device, 1 HTP). —Length (e.g., 100.0 mm, 120.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Wattage (e.g., 100 W, 200 W). —Battery capacity (e.g., 100 mAh, 200 mAh). —Characterizing flavor(s) (e.g., none). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) HTP Consumable	—Package type (e.g., hard pack, soft pack, plastic clamshell). —Product quantity (e.g., 20 sticks, 25 cartridges). —Length (e.g., 60.0 mm, 82.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Ventilation (e.g., none, 10.0%, 25.0%). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) HTP Component	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 mouthpiece, 1 spacer). —Characterizing flavor(s) (e.g., none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Other	—Package type (e.g., box, bag, plastic clamshell, none). —Product quantity (e.g., 1 base, 5 capsules). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
(I) Other	(*1*) Other	—Package type (e.g., box, bag, plastic clamshell, none). —Product quantity (e.g., 1 base, 5 capsules). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).

(4) The type of PMTA (*i.e.,* PMTA, supplemental PMTA, or resubmission);

(5) Whether the applicant requests that FDA refer the PMTA to the Tobacco Products Scientific Advisory Committee (TPSAC);

(6) Identifying information regarding any prior submissions regarding the tobacco product (*e.g.,* submissions related to investigational tobacco products, substantial equivalence reports, PMTAs), including submission tracking numbers (STNs) where applicable;

(7) Dates and purpose of any prior meetings with FDA regarding the new tobacco product;

(8) If applicable, the dates when the tobacco product was commercially marketed in the United States;

(9) Address and the Facility Establishment Identifier (FEI) number(s), if available, of the establishment(s) involved in the manufacture of the new tobacco product;

(10) A brief statement regarding how the PMTA satisfies the content requirements of section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act;

(11) A brief description of how marketing of the new tobacco product would be appropriate for the protection of the public health; and

(12) A list identifying all enclosures, labels, and labeling being submitted with the application.

(d) *Descriptive information.* The application must contain descriptive information in this section that outlines the major aspects of the new tobacco product, including the following items:

(1) A concise description of the new tobacco product;

(2) A statement identifying all tobacco product standards issued under section 907 of the Federal Food, Drug, and Cosmetic Act that are applicable to the new tobacco product and a brief description of how the new tobacco product fully meets any identified tobacco product standard, or if the new tobacco product deviates from a product standard, if applicable, the application must include adequate information to identify and justify those deviations;

(3) The name(s) of the product as designated on the product's label;

(4) A description of problems that were identified in prototypes that are the subject of studies in the application and previous or similar versions of the new tobacco product that were marketed, if any. If there are previous or similar versions that are the subject of studies in the application or were marketed, the application must contain a bibliography of all reports regarding the previous or similar version of the product, whether adverse or supportive; and

(5) Any restrictions on the sale, distribution, advertising, or promotion of the new tobacco product that the applicant proposes to be included as part of a marketing granted order under section 910(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act to help support a showing that the marketing of the product is appropriate for the protection of the public health. If there are no proposed restrictions, the application must contain a statement to that effect.

(e) *Samples of new tobacco products.* After FDA accepts a PMTA for review, it may require the submission of samples of the new tobacco product, including its components and parts. If required, the applicant must submit samples of the finished tobacco product or its components or parts in accordance with instructions provided by FDA. FDA may also require the submission of additional samples to further aid in its review.

(f) *Labeling and description of marketing plans*—(1) *Labeling.* The application must contain specimens of

all proposed labeling for the new tobacco product, including labels, inserts, onserts, instructions, and other accompanying information. The specimens of labeling must include all panels, reflect the actual size and color proposed to be used for the tobacco product, and include any warning label statements and other information required by regulation or statute, as applicable.

(2) *Description of Marketing Plans.* A PMTA must contain a description of the applicant's plans to market the new tobacco product, for at least the first year the product would be marketed after receiving a marketing granted order, in way that is both consistent with the applicant's discussion of the increased or decreased likelihood of changes in tobacco product use behavior, including switching, initiation, cessation, and polyuse, under § 1114.7(l), and permits FDA to determine permitting the new tobacco product to be marketed would be appropriate for the protection of public health. The description must include actions to market the product that would be taken by the applicant, on behalf of the applicant, or at the applicant's direction, and also discuss any restrictions on the sales and distribution the applicant proposes to be included in a marketing order under section 910(c)(1)(B) of the Federal Food Drug and Cosmetic Act. The description of marketing plans must contain, at minimum:

(i) A description of the specific group(s) to which the labeling, advertising, marketing, promotion, and other consumer-directed activities for the new tobacco product would be targeted (*i.e.,* the intended audience(s));

(ii) A discussion of how the labeling, advertising, marketing, promotion, and other consumer-directed activities for the new tobacco product would be targeted to reach the intended audience(s) identified in paragraph (i) and what other group(s) would foreseeably be exposed to those materials and activities as a result;

(iii) A discussion of, for individuals below the minimum age of sale, how access to the new tobacco product would be restricted and exposure to the labeling, advertising, marketing, promotion, and other consumer-directed activities would be limited; and

(iv) A concluding summary describing how the applicant's plans for marketing the new tobacco product are consistent with the applicant's discussion of the increased or decreased likelihood of changes in tobacco product use behavior, including switching, initiation, cessation, and polyuse, under § 1114.7(l) and permits FDA to determine permitting the new tobacco product to be marketed would be appropriate for the protection of public health.

(g) *Statement of compliance with 21 CFR part 25.* (1) The application must contain an environmental assessment prepared in accordance with § 25.40 of this chapter, or a valid claim of categorical exclusion, if applicable. If the applicant believes that the action qualifies for an available categorical exclusion, the applicant must state under § 25.15(a) and (d) of this chapter that the action requested qualifies for a categorical exclusion, citing the particular exclusion that is claimed, and that to the applicant's knowledge, no extraordinary circumstances exist under § 25.21 of this chapter.

(h) *Summary.* The application must include a summary of all information contained in the application. The summary must include the following items, highlighting the effects on youth, young adults, and other relevant vulnerable populations:

(1) A summary of the product formulation section of the application;

(2) A summary of the manufacturing section of the application;

(3) A summary of the health risk investigations section of the application, including all information regarding the following items, and identify areas in which there is a lack of information, where applicable:

(i) The health risks of the tobacco product to both users and nonusers of the product and whether the tobacco product may present less health risk than other tobacco products;

(ii) The impact the product and its marketing will have on the likelihood of changes in tobacco use behavior, including cessation, switching, and polyuse, of tobacco product users;

(iii) The impact the product and its marketing will have on the likelihood of tobacco use initiation by tobacco product nonusers;

(iv) How users and nonusers perceive the risk of the tobacco product based upon its label, labeling, and advertising, to the extent that advertising has been studied;

(v) Whether users are able to understand the labeling and instructions for use, and use the product in accordance with those instructions; and

(vi) The impact of human factors on the health risks to product users and nonusers (as described in paragraph (k)(1)(v) of this section);

(4) A concluding discussion describing how the data and information contained in the PMTA both constitute valid scientific evidence and establish that permitting marketing of the new tobacco product is appropriate for the protection of the public health, as determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product. This discussion must specifically describe the effects on youth, young adults, and other relevant vulnerable populations with an emphasis on populations that are most likely to use the new tobacco product. The summary must also identify any key or pivotal studies on which an applicant is relying to establish that permitting the marketing of the new tobacco product would be APPH.

(i) *Product formulation.* The application must contain a full statement of the components or parts, materials, ingredients, additives, constituents, properties, and the principle or principles of operation, of the tobacco product, including the following information:

(1) *Components or parts, materials, ingredients, additives, and constituents.* The applicant must provide a full statement of:

(i) *Components or parts.* The quantity, function, and purpose of, and, where applicable, target specification(s) of, each component or part in the product. Where the tobacco product contains software components, the applicant must provide:

(A) A description of the software or technology (*e.g.,* Bluetooth);

(B) The purpose of the software or technology, such as monitoring where tobacco products are located, activated, or used;

(C) A description of the data collected by the software and how it will be used.

(ii) *Materials.* For each material in the product, include:

(A) The material name and common name(s), if applicable;

(B) The component or part of the tobacco product where the material is located;

(C) The subcomponent or subpart where the material is located, if applicable;

(D) The function of the material;

(E) The quantities (including ranges or means and acceptance limits) of the material(s) in the new tobacco product (with any specification variation, if applicable);

(F) The specification(s) (including quality/grades and suppliers) used for the new tobacco product (including any specification variations, if applicable); and

(G) Any other material properties to fully characterize the new tobacco product.

(iii) *Ingredients other than tobacco.* For ingredients other than tobacco in each component or part of the product, include:

(A) The International Union of Pure and Applied Chemistry (IUPAC) chemical name and common name, if applicable;

(B) The Chemical Abstracts Service (CAS) number or FDA Unique Ingredient Identifier (UNII), if applicable;

(C) The function of the ingredient;

(D) The quantity of the ingredient in the tobacco product, with the unit of measure (including ranges or means and acceptance limits) reported as mass per gram of tobacco for nonportioned tobacco products and as mass per portion for portioned tobacco products (with any specification variation, if applicable);

(E) The specification(s) (including purity or grade and supplier); and

(F) For complex purchased ingredients, each single chemical substance reported separately.

(iv) *Tobacco ingredients.* For tobacco ingredients in each component or part, include the following information or, if applicable, a statement that the product does not contain tobacco ingredients:

(A) The type(s) (*e.g.,* Bright, Burley, reconstituted);

(B) The quantity with the unit of measure (including ranges or means, acceptance limits) of each tobacco ingredient in the tobacco product reported as mass per gram of tobacco for nonportioned tobacco products and as mass per portion for portioned tobacco products (with any specification variation, if applicable);

(C) The specification of tobacco used for the new tobacco product (with any specification variation, if applicable); and

(D) A description of any genetic engineering of the tobacco that impacts product characteristics.

(v) *Constituents.* Constituents, including HPHCs and other constituents, contained within, or emitted from (including its smoke or aerosol), the product, including any reaction product from leaching or aging, by providing:

(A) The constituent names in alphabetical order;

(B) The common name(s);

(C) The Chemical Abstract Services number;

(D) The mean quantity and variance with unit of measure;

(E) The number of samples and measurement replicates for each sample;

(F) A description of method procedure, method validation information and rationale for selecting each test method;

(G) The name and location of the testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(H) Length of time between dates of manufacture and date(s) of testing;

(I) Storage conditions of the tobacco product before it was tested;

(J) Test data including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria, and line data for all testing performed. Test data for combusted or inhaled products must reflect testing conducted using both intense and nonintense smoking or aerosol-generating regimens, where established; and

(K) Complete descriptions of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable.

(vi) *Container closure system.* A description of the container closure system, including:

(A) Information describing how the container closure system protects and preserves the product from damage during transport, environmental contaminants, and potential leaching and migration of packaging constituents into the new tobacco product; and

(B) Information describing design features developed to prevent the risk of accidental exposure, if any.

(vii) *Statement of tobacco blending, reconstitution, or manipulation.* Information regarding tobacco blending, reconstitution, or manipulation, where applicable.

(2) *Other properties.* The applicant must provide a full description of the additional properties of the tobacco product that includes:

(i) *Product dimensions and construction.* The product dimensions and the overall construction of the product using a diagram or schematic drawing that clearly depicts the finished tobacco product and its components with dimensions, operating parameters, and materials.

(ii) *Design parameters and test data.* (A) All final design parameters of the product, specifying nominal values or the explicit range of values as well as the design tolerance (where appropriate), including, but not limited to, the parameters specified in tables 1 to 22 of this paragraph as applicable. If a design parameter specified in tables 1 to 22 does not apply to the tobacco product, applicants must explain why the required design parameter does not apply or how an alternative design parameter would satisfy the required design parameter. If the product has additional design parameters that are not specified in tables 1 to 22, the application must contain a description of the design specifications as well as test data and processes to demonstrate that the design parameters and their associated processes are adequately controlled; and

(B) A quantitative description of the performance criteria, including test protocols, line data, and a summary of the results, for each applicable intermediate and final design parameter and manufacturing step, that includes, but is not limited to the test data specified in tables 1 to 22 of this paragraph for the product category as applicable. If the test data specified in the applicable table does not apply to the tobacco product, applicants must explain why the test data does not apply or how alternative test data would satisfy this requirement. Where tobacco cut size or particle size is a required design parameter for a product category or subcategory and the target specifications and range limits are not available, the following alternative information may be submitted in place of this information: a description of the tobacco cutting process (including a complete description of the milling, cutting, and sifting process; the control parameters of the miller or cutter; and any sift specifications), or the measured particle size distribution;

TABLE 2 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGARETTES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigarette length (mm). • Cigarette circumference or diameter (mm). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3).	• Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (mm or CPI). • Tobacco moisture or oven volatiles (%).

TABLE 2 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGARETTES—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (mm or CPI). • Tobacco moisture or oven volatiles (%). • Cigarette paper length (mm). • Cigarette paper base paper porosity (permeability) (CU). • Cigarette paper band porosity (permeability) (CU) [alternatively, band diffusivity (cm^2/s)] (if applicable). • Cigarette paper band width (mm). • Cigarette paper band space (mm). • Filter length (mm). • Filter pressure drop (mm H_2O). • Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)). • Tipping paper length (mm). • Filter ventilation (%).	• Cigarette paper base paper porosity (permeability) (CU). • Cigarette paper band porosity or permeability (CU) or Cigarette paper band diffusivity (cm^2/s). • Filter pressure drop (mm H_2O). • Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)). • Filter ventilation (%).

TABLE 3 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PORTIONED AND NONPORTIONED SMOKELESS TOBACCO PRODUCTS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
Portioned Smokeless Tobacco Products	
• Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron). • Tobacco moisture (%). • Portion length (mm). • Portion width (mm). • Portion mass (mg). • Portion material thickness (mm) (if applicable). • Pouch material basis weight (g/m^2) (if applicable). • Pouch material porosity (permeability) (CU or $L/m^2/s$) (if applicable). • Nicotine dissolution rate (%/min).	• Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron). • Tobacco moisture (%). • Portion mass (mg). • Pouch material basis weight (g/m^2) (if applicable). • Pouch material porosity (CU) (permeability) ($L/m^2/s$). • Nicotine dissolution rate (%/min).
Nonportioned Smokeless Tobacco Products	
• Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron) • Tobacco moisture (%)	• Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron). • Tobacco moisture (%).

TABLE 4 TO PARAGRAPH (I)(2)(II)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO ROLLING PAPERS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Roll-your-own (RYO) paper length (mm). • RYO paper width (mm). • RYO mass per paper (mg). • RYO paper base paper basis weight (g/m^2). • RYO paper base paper porosity (permeability) (CU). • RYO paper band porosity (permeability) (CU) or [alternatively, RYO paper band diffusivity (cm^2/s)] (if applicable). • RYO paper band width (mm) (if applicable). • RYO paper band space (mm) (if applicable).	• RYO mass per paper (mg). • RYO paper base paper basis weight (g/m^2). • RYO paper base paper porosity (permeability) (CU). • RYO paper band porosity (permeability) (CU) or [alternatively, RYO paper band diffusivity (cm^2/s)] (if applicable).

TABLE 5 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO TUBES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tube mass (mg). • Tube length (mm). • Tube circumference or diameter (mm).	• Tube mass (mg). • Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (permeability) (CU).

TABLE 5 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO TUBES—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tube paper width (mm). • Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (permeability) (CU). • Tube paper band porosity (permeability) (CU) (if applicable) or Tube paper band diffusivity (cm^2/s) (if applicable). • Tube paper band width (mm) (if applicable). • Tube paper band space (mm) (if applicable).	• Tube paper band porosity (permeability) (CU) (if applicable) or Tube paper band diffusivity (cm^2/s) (if applicable).

TABLE 6 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO FILTERED TUBES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tube mass (mg). • Tube length (mm). • Tube circumference or diameter (mm). • Tube paper length (mm). • Nonfilter tube length (mm). • Tube paper width (mm). • Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (permeability) (CU). • Tube paper band porosity (permeability) (CU) (if applicable) or Tube paper band diffusivity (cm^2/s) (if applicable). • Tube paper band width (mm) (if applicable). • Tube paper band space (mm) (if applicable). • Filter length (mm). • Filter pressure drop (mm H_2O). • Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament (DPF), total denier (g/9000m), and filter density (g/cm^3))). • Tipping paper length (mm). • Filter ventilation (%).	• Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (permeability) (CU). • Tube mass (mg). • Tube paper band porosity (permeability) (CU) (if applicable) or Tube paper band diffusivity (cm^2/s) (if applicable). • Filter pressure drop (mm H_2O). • Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament (DPF), total denier (g/9000m), and filter density (g/cm^3))). • Filter ventilation (%).

TABLE 7 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (mm or CPI). • Tobacco moisture or oven volatiles (%).	• Tobacco cut size (mm or CPI). • Tobacco moisture or oven volatiles (%).

TABLE 8 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO PAPER TIPS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• RYO paper tip length (mm). • RYO paper tip width (mm). • RYO paper tip mass (mg). • RYO paper base paper basis weight (g/m^2). • RYO paper porosity (permeability) (CU). • RYO paper tip ventilation (%).	• RYO paper base paper basis weight (g/m^2). • RYO paper porosity (permeability) (CU). • RYO paper tip ventilation (%).

TABLE 9 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR FILTERED SHEET-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar mass (mg). • Cigar wrapper basis weight (g/m^2). • Cigar binder length (mm). • Cigar binder width (mm).	• Cigar mass (mg). • Puff count. • Cigar wrapper basis weight (g/m^2). • Cigar wrapper porosity (permeability) (CU).

TABLE 9 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR FILTERED SHEET-WRAPPED CIGARS—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar binder basis weight (g/m^2) • Cigar length (mm). • Cigar overall diameter (mm). • Cigar minimum diameter (mm) if applicable. • Cigar maximum diameter (mm) if applicable. • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%). • Cigar wrapper porosity (permeability) (CU). • Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper band porosity (permeability) (CU) (if applicable). • Cigar wrapper band width (mm) (if applicable). • Cigar wrapper band space (mm) (if applicable). • Cigar binder porosity (permeability) (CU). • Cigar binder band porosity (permeability) (CU) (if applicable). • Cigar binder band width (mm) (if applicable). • Cigar binder band space (mm) (if applicable). • Filter length (mm). • Filter diameter (mm). • Filter pressure drop (mm H_2O). • Filter efficiency (%) {If no filter efficiency data is available for the products, include information sufficient to show that the cigar filter is unchanged [e.g., denier per filament (DPF), total denier (g/9000m), and filter density(g/cm^3)]}. • Tipping paper length (mm). • Filter ventilation (%).	• Cigar binder porosity (permeability) (CU). • Cigar binder basis weight (g/m^2). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%). • Cigar wrapper band porosity (permeability) (CU) [alternatively, band diffusivity (cm^2/s)](if applicable). • Cigar binder band porosity (permeability) (CU) [alternatively, band diffusivity (cm^2/s)] (if applicable). • Cigar minimum diameter (mm) (if applicable). • Cigar maximum diameter (mm) (if applicable). • Filter pressure drop (mm H_2O). • Filter efficiency (%) (if no filter efficiency data is available for the products, include information sufficient to show that the cigar filter is unchanged [e.g., denier per filament (DPF), total denier (g/9000m), and filter density (g/cm^3)]}. • Filter ventilation (%).

TABLE 10 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR UNFILTERED SHEET-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar mass (mg). • Cigar length (mm). • Cigar overall diameter (mm). • Cigar minimum diameter (mm) (if applicable). • Cigar maximum diameter (mm) (if applicable). • Tobacco rod density (g/cm^3). • Tobacco moisture or oven volatiles (%). • Tobacco cut size (CPI or mm). • Tobacco filler mass (mg). • Cigar wrapper porosity (permeability) (CU). • Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/m^2). • Cigar binder porosity (permeability) (CU). • Cigar binder width (mm) • Cigar binder basis weight (g/m^2). • Cigar tip length (mm) (if applicable). • Cigar tip inner diameter (mm) (if applicable). • Cigar tip mass (mg) (if applicable). • Cigar wrapper band space (mm) (if applicable). • Cigar wrapper band width (mm) (if applicable). • Cigar binder band width (mm) (if applicable). • Cigar binder band space (mm) (if applicable). • Cigar wrapper band porosity or permeability (CU) [alternately, band diffusivity (cm2/s)] (if applicable).	• Puff count. • Cigar mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%). • Tobacco filler mass (mg). • Cigar minimum diameter (mm) (if applicable). • Cigar maximum diameter (mm) (if applicable). • Cigar wrapper porosity (permeability) (CU). • Cigar wrapper basis weight (g/m^2). • Cigar binder basis weight (g/m^2). • Cigar binder porosity (permeability) (CU). • Cigar tip mass (mg) (if applicable). • Cigar wrapper band porosity (permeability) (CU) [alternately, band diffusivity (cm2/s)] (if applicable). • Cigar binder band porosity (permeability) (CU) [alternately, band diffusivity (cm2/s)] (if applicable).

TABLE 10 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR UNFILTERED SHEET-WRAPPED CIGARS—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar binder band porosity (permeability) (CU) [alternately, band diffusivity (cm2/s)] (if applicable).	

TABLE 11 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR LEAF-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar mass (mg). • Cigar length (mm). • Overall diameter (mm). • Cigar minimum diameter (mm). • Cigar maximum diameter (mm). • Tobacco moisture or oven volatiles (%). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%). • Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/m^2). • Cigar binder width (mm). • Cigar binder basis weight (g/m^2).	• Puff count. • Cigar mass (mg). • Cigar minimum diameter (mm). • Cigar maximum diameter (mm). • Cigar wrapper basis weight (g/m^2). • Cigar binder basis weight (g/m^2). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).

TABLE 12 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGAR TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (CPI or mm) • Tobacco moisture or oven volatiles (%)	• Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).

TABLE 13 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGAR WRAPPERS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/cm^2).	• Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/cm^2).

TABLE 14 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Hose length (mm). • Hose materials. • Hose internal diameter (mm). • Stem length (mm). • Stem internal diameter (mm). • Base diameter (mm). • Base volume (cm^3). • Base shape. • Pressure drop (mm H_2O). • Water filter efficiency (%). • Hose air permeability (CU). • Head height (mm). • Head top diameter (mm). • Head bottom diameter (mm). • Number of holes. • Head volume (mm^3). • Heating source type. • Head materials.	• Hose length (mm). • Hose internal diameter (mm). • Stem length (mm). • Stem internal diameter (mm). • Base diameter (mm). • Base volume (cm^3). • Pressure drop (mm H_2O). • Water filter efficiency (%). • Head height (mm). • Head top diameter (mm). • Head bottom diameter (mm). • Head volume (mm^3).

TABLE 15 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).	• Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).

TABLE 16 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE HEATING SOURCES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Heating element temperature range (°C). • Heating element mass (mg). • Heating element density (g/cm^3). • Heating element resistance (ohms) (if applicable). • Number of heating elements. • Heating element configuration. • Heating element diameter (gauge) (if applicable). • Battery current rating (mA) (if applicable). • Battery capacity (mAh) (if applicable) • Battery voltage operating range (volts) (if applicable). • Battery current operating range (amps) (if applicable). • Power delivery unit (PDU) temperature cut-off (°C) (if applicable). • Power delivery unit (PDU) voltage operating range (volts) (if applicable). • PDU current operating range (amps) (if applicable). • PDU wattage operating range (watts) (if applicable).	• Heating element temperature range (°C). • Heating element mass (mg). • Heating element density (g/cm^3). • Heating element resistance (ohms) (if applicable). • Heating element diameter (gauge). • Battery current rating (mA) (if applicable). • Battery capacity (mAh) (if applicable). • Battery voltage operating range (volts) (if applicable). • Battery current operating range (amps) (if applicable). • Power delivery unit (PDU) temperature cut-off (°C) (if applicable). • Power delivery unit (PDU) voltage operating range (volts) (if applicable). • PDU current operating range (amps) (if applicable). • PDU wattage operating range (watts) (if applicable).

TABLE 17 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE FOIL

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Foil length (mm) (for square or rectangular shape foil). • Foil width (mm) (for square or rectangular shape foil). • Diameter (mm) (for circular shape foil). • Foil thickness (mm). • Number of holes. • Diameter of the holes (mm).	• Foil length (mm) (for square or rectangular shape foil). • Foil width (mm) (for square or rectangular shape foil). • Diameter (mm) (for circular shape foil). • Foil thickness (mm). • Diameter of the holes (mm).

TABLE 18 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE HEAD

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Head height (mm), • Head top diameter (mm), • Head bottom diameter (mm), • Number of holes, • Head volume (mm^3), • Head materials,	• Head height (mm). • Head top diameter (mm). • Head bottom diameter (mm). • Head volume (mm^3).

TABLE 19 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PIPES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Bowl chamber cover outer diameter (mm). • Bowl chamber cover inner diameter (mm). • Draught hole diameter (mm). • Screen (if applicable). • Draught hole shape. • Draught hole location. • Bowl chamber hole shape. • Bowl chamber volume (cm^3) • Airway volume (cm^3) • Stem length (mm).	• Bowl chamber volume (cm^3). • Pipe pressure drop (mm H_2O). • Air flow through air valve (cc/min). • Airway volume (cm^3). • Filter pressure drop (mm H_2O). • Filter efficiency (%) {If no filter efficiency data is available for the products, include information sufficient to show that the cigar filter is unchanged [e.g., denier per filament (DPF), total denier (g/9000m), and filter density(g/cm^3)]}.

TABLE 19 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PIPES—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Stem diameter (mm). • Shank length (mm). • Shank diameter (mm). • Draught hole dimension. • Pressure drop through air valve (mm H_2O). • Air flow through air valve (cc/min). • Filter efficiency (%) {If no filter efficiency data is available for the products, include information sufficient to show that the cigar filter is unchanged [e.g., denier per filament (DPF), total denier (g/9000m), and filter density(g/cm^3)]}. • Filter pressure drop (mm H_2O). • Filter length (mm).	

TABLE 20 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PIPE TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).	• Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).

TABLE 21 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR ENDS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Draw resistance (mm H_2O). • Puff count (for full tank/cartridge). • Atomizer tank/cartridge volume (mL). • Number of heating elements (e.g., coil). • Heating Element diameter (gauge). • Heating Element length (mm). • Heating Element resistance (Ohms). • Heating Element temperature range (°C). • Heating Element configuration (target only). • Battery voltage operating range (V). • Battery current operating range (mA). • Battery Capacity (mAh). • Battery Nominal Voltage (V). • Battery Current rating (mA). • Battery charging temperature limits (°C). • Battery discharge temperature limits (°C). • Battery end of discharge voltage (V). • Battery maximum charging current (mA). • Battery maximum discharging current (mA). • Battery upper limits charging voltage (V). • Power Delivery Unit (PDU) voltage operating range (V). • PDU current operating range (mA). • PDU wattage operating range (watts). • PDU temperature cut-off (°C) (if applicable). • Airflow rate (L/min) (if applicable). • PDU Current cut-off (mA) (if applicable). • PDU Temperature cut-off (°C) (if applicable). • Inhaled aerosol temperature (°C). • Ventilation (%).	• Draw resistance (mm H_2O). • Puff count (for full tank/cartridge). • Atomizer tank/cartridge volume (mL). • Heating Element diameter (gauge). • Heating Element resistance (Ohms). • Heating Element temperature range (°C). • Battery voltage operating range (V). • Battery current operating range (mA). • PDU voltage operating range (V). • PDU current operating range (mA). • PDU wattage operating range (watts). • PDU Current cut-off (mA) (if applicable). • PDU temperature cut-off (°C) (if applicable). • Battery Capacity (mAh). • Battery Nominal Voltage (V). • Battery Current rating (mA). • Battery charging temperature limits (°C). • Battery discharge temperature limits (°C). • Battery maximum charging current (mA). • Battery maximum discharging current (mA). • Battery upper limits charging voltage (V). • Inhaled aerosol temperature (°C). • Airflow rate (L/min) (if applicable). • Ventilation (%).

TABLE 22 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR E-LIQUIDS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• E-liquid viscosity (at 20°C). • E-liquid volume (ml). • Particle number concentration (#/cm^3). • Count median diameter (nm). • $PM_{2.5}$ (µg/m^3).	• E-liquid viscosity (at 20°C). • E-liquid volume (ml). • Particle number concentration (#/cm^3). • Count median diameter (nm). • $PM_{2.5}$ (µg/m^3).

TABLE 23 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR HEATED TOBACCO PRODUCTS (HTP)

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Overall Product. ○ Mass (mg). ○ Length (mm). ○ Width (mm). ○ Height (mm). ○ Diameter (mm). ○ Draw resistance (mm H_20). ○ Puff Count (for full tank/cartridge). ○ Puff volume (mL). ○ Product volume (mL). ○ Airflow rate (L/min) (if applicable). ○ Ventilation (%). ○ Operational Temperature (°C). ○ Temperature sensor (if applicable). ○ Material wrapper length (mm) (if applicable). ○ Material wrapper width (mm) (if applicable). ○ Material wrapper basis weight (g/m^2) (if applicable). ○ Material porosity (permeability) (CU) (if applicable). • Heating element. ○ Heating element source/type/approach (electrical, carbon, aerosol, etc.). ○ Heating element temperature range (°C). ○ Heating element operational temperature (°C). ○ Heating element maximum temperature (boost temperature) (°C). ○ Heating element material. ○ Heating element Configuration (i.e., the shape and design of the heating element. If the heating element is a coil, it is the shape and arrangement of the coil. If the heating element is a novel design, provide the configuration and its design targets.). ○ Heating element length (mm). ○ Heating element mass (mg). ○ Heating element location. ○ Number of heating elements (e.g., coil) (dimensionless). ○ Heating Element diameter (gauge) (if applicable). ○ Heating Element resistance (Ohms) (if applicable). • Tobacco/E-liquid. ○ Tobacco mass (mg) (if applicable). ○ Tobacco density (g/cm^3) (if applicable). ○ Tobacco moisture or oven volatiles (%) (if applicable). ○ Tobacco cut size (CPI or mm) (if applicable). ○ E-liquid volume (mL) (if applicable). ○ E-liquid viscosity (at 20°C) (if applicable). • Battery (if applicable). ○ Battery capacity (mA). ○ Battery Voltage Operating Range (V) or Wattage (W). ○ Battery Current Charging range (amps). ○ Battery Nominal Voltage (V). ○ Battery Current rating (mA). ○ Battery charging temperature limits (°C). ○ Battery discharge temperature limits (°C). ○ Battery end of discharge voltage (V). ○ Battery maximum charging current (mA). ○ Battery maximum discharging current (mA). ○ Battery upper limits charging voltage (V). ○ Power Delivery Unit (PDU) voltage operating range (V). ○ PDU current operating range (mA). ○ PDU wattage operating range (watts). ○ PDU temperature cut-off (°C) (if applicable) ○ PDU Current cut-off (mA) (if applicable). • Aerosol. ○ Inhaled aerosol temperature (°C). ○ Aerosol Particle number concentration (#/cm^3). ○ Count median diameter (nm). ○ $PM_{2.5}$ ($\mu g/m^3$). • Filter (if applicable).	• Overall Product. ○ Draw resistance (mm H_2O). ○ Puff count (for full tank/cartridge). ○ Product volume (mL). ○ Airflow rate (L/min) (if applicable). ○ Ventilation (%). ○ Operational Temperature (°C). ○ Temperature sensor (if applicable). ○ Material wrapper length (mm) (if applicable). ○ Material wrapper width (mm) (if applicable). ○ Material wrapper basis weight (g/m^2) (if applicable). ○ Material porosity (permeability) (CU) (if applicable). • Heating element. ○ Heating Element diameter (gauge). ○ Heating Element resistance (Ohms). ○ Heating Element temperature range (°C). • E-liquid. ○ E-liquid viscosity (at 20°C). ○ E-liquid volume (ml). • Tobacco (if applicable). ○ Tobacco moisture (%). ○ Tobacco cut size (CPI or mm). ○ Tobacco density (g/cm^3) • Battery. ○ Battery voltage operating range (V). ○ Battery current operating range (mA). ○ PDU voltage operating range (V). ○ PDU current operating range (mA) PCO wattage operating range (W). ○ PDU Current cut-off (mA) (if applicable). ○ PDU temperature cut-off (°C). ○ Battery Capacity (mAh). ○ Battery Nominal Voltage (V). ○ Battery Current rating (mA). ○ Battery charging temperature limits (°C). ○ Battery discharge temperature limits (°C). ○ Battery maximum charging current (mA). ○ Battery maximum discharging current (mA). ○ Battery upper limits charging voltage (V). • Aerosol. ○ Inhaled aerosol temperature (°C). ○ Aerosol Particle number concentration (#/cm^3). ○ Count median diameter (nm). ○ $PM_{2.5}$ ($\mu g/m^3$). • Filter (if applicable). ○ Filter efficiency (%) {If no filter efficiency data is available for the products, include information sufficient to show that the cigar filter is unchanged [e.g., denier per filament (DPF), total denier (g/9000m), and filter density(g/cm^3)]}. ○ Filter ventilation (%). ○ Filter pressure drop (mm H_2O).

TABLE 23 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR HEATED TOBACCO PRODUCTS (HTP)—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
○ Filter efficiency (%) {If no filter efficiency data is available for the products, include information sufficient to show that the cigar filter is unchanged [e.g., denier per filament (DPF), total denier (g/9000m), and filter density(g/cm^3)]}. ○ Filter pressure drop (mm H_2O). ○ Filter length (mm). ○ Filter diameter (mm). ○ Filter ventilation (%).	

(iii) *Function.* How the product is intended to function.

(iv) *Product pH and nicotine formulation.* The pH of the product and the formulation of nicotine in the product, if applicable, including the form (*e.g.,* unprotonated nicotine, nicotine salts) and quantity.

(v) *Fermentation process.* For smokeless tobacco products and tobacco products that contain fermented tobacco (including naturally fermented tobacco), information on the fermentation process, including the following:

(A) Description of the fermentation process;

(B) Composition of the inoculum (starter culture) with genus and species name(s) and concentration(s) (if applicable);

(C) Any step(s) taken to reduce endogenous microbes (*e.g.,* cleaning of product contact surfaces);

(D) Specifications and test data for pH, temperature, moisture content, and water activity;

(E) Frequency of aeration or turning (if applicable);

(F) Duration of fermentation;

(G) Added ingredients;

(H) Method used to stabilize or stop fermentation (*e.g.,* heat treatment) (if applicable), including parameters of the method (*e.g.,* length of treatment, temperature) and method validation data; and

(I) Storage conditions of the fermented tobacco prior to further processing or packaging and duration of storage (if applicable).

(vi) *Heat treatment process.* For tobacco products that are heat treated, the application must contain the following information regarding the heat treatment process:

(A) Description of the heat treatment process;

(B) Type of heat treatment;

(C) Conditions of heat treatment, including time, temperature, and moisture; and

(D) Method validation data, including microbial loads (including bacteria, spores, yeast, and fungi) and TSNAs before and after heat treatment.

(vii) *Shelf life and stability information.* With the exception of applications for roll-your-own tobacco products and cigarettes that are not HTPs, the application must contain information on the stability of the tobacco product over the shelf life and including the following:

(A) The length of the shelf life, a description of how the shelf life is determined, and a description of how shelf life is indicated on the tobacco product, if applicable;

(B) Stability data assessed at the beginning (zero time), middle, and end of the expected shelf life. If a tobacco product does not have a defined shelf life, provide stability data over a specified amount of time and a justification for why that time period is appropriate. Stability testing must be performed for the microbial and chemical endpoints as follows: Microbial content data, including total aerobic microbial count and total yeast and mold count; water activity; tobacco-specific nitrosamines (TSNAs) yields (total TSNAs, N′-nitrosonor-nicotine (NNN), 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone) (NNK)); and preservatives content.

(C) Stability testing details for each microbial and chemical endpoint, including: The mean quantity and variance with unit of measures; the number of samples and measurement replicates for each sample; the methods used, including any deviation(s) from the methods, associated reference(s), and full validations reports for each method; the testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization; length of time between date of tobacco product manufacture and date(s) of testing; storage conditions of the tobacco product before it was tested; a statement that the testing was performed on a tobacco product in the same container closure system in which the tobacco product is intended to be marketed; and full test data (including quantitative acceptance (pass/fail) criteria, complete data sets, and a summary for the results) for all stability testing performed.

(viii) *Product and packaging design risks and misuse hazards.* A review and assessment of reasonably foreseeable risks associated with the design of the tobacco product and its package that may occur during normal use of the tobacco product or during any foreseeable misuse of the product, including user error, which may cause illness, injury, or death not normally associated with the use of the tobacco product. The review and assessment must identify the measures taken to reduce or eliminate each risk associated with the design of the tobacco product and package.

(3) *Principles of operation.* The applicant must provide a full statement of the principle or principles of operation of the tobacco product, including full narrative descriptions of:

(i) The way in which a typical consumer will use the new tobacco product, including a description of how a consumer operates the product, how long a single unit of product is expected to last (*e.g.,* total length of time of use to consume a unit, number of use sessions expected per unit), and, where applicable, how a consumer can change the product design and add or subtract ingredients;

(ii) A justification for an applicant's determination of what constitutes a single unit of product as described in the PMTA; and

(iii) Whether the product incorporates a heating source, and if so, a description of the heating source.

(4) *Product testing and analysis information.* Each analysis required in this paragraph must be performed on test samples that reflect the finished tobacco product composition and design, and must be conducted using a sufficient sample size and number of

replicates to substantiate the results of the type of testing conducted. Additionally, the applicant must provide the following information:

(i) The name and location of the testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(ii) The length of time between dates of manufacture and date(s) of testing;

(iii) The storage conditions of the tobacco product before it was tested;

(iv) The number of samples and measurement replicates for each sample;

(v) A description of method procedure, method validation information and rationale for selecting each test method, including relevant voluntary testing standards, test protocols, quantitative acceptance criteria, line data, and a summary of the results;

(vi) Reports of product formulation testing that include test protocols, quantitative acceptance criteria, line data, and a summary of the results, for each applicable design parameter; and

(vii) Complete descriptions of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable.

(j) *Manufacturing.* The application must contain a full description of the methods used in, and the facilities and controls used for, the design (including design validation and design verification, to assess whether the tobacco product, as manufactured, performs in accordance with design specifications), manufacture, packing, and storage of the tobacco product in sufficient detail to demonstrate whether the product meets manufacturing specifications, can be manufactured in a manner consistent with the information submitted in the application, and conforms to the requirements of any regulations issued under section 906(e) of the Federal Food, Drug, and Cosmetic Act, including:

(1) A list of all manufacturing, packaging, storage, and control facilities for the product, including the facility name, address, and FEI number, if applicable, and a contact name and telephone number for a representative from each facility;

(2) A narrative description, accompanied by a list and summary, of all standard operating procedures (SOPs) and examples of relevant forms and records for the following categories of information for all manufacturing, design controls, packing, and storage for the tobacco product:

(i) Manufacturing and production process activities at each establishment, including a description of each establishment, all production steps, and process controls, process specifications with relevant acceptance criteria, and monitoring and acceptance activities;

(ii) Managerial oversight and employee training related to the manufacture, processing, packing, and installation of the tobacco product, as applicable;

(iii) Monitoring procedures and manufacturing controls for product design, product characteristics, and changes in products, specifications, methods, processes, or procedures, including a hazard analysis that details the correlation of the product design attributes with public health risk, as well as any mitigation strategies implemented;

(iv) Activities related to identifying and monitoring suppliers and the products supplied (including, for example, purchase controls and product acceptance activities);

(v) Handling of complaints, nonconforming products and processes, and corrective and preventative actions;

(vi) Testing procedures carried out before the product is released to market, including:

(A) A list and summary of any standards used for all testing methods;

(B) Validation and verification activities for all test methods used to ensure that the tobacco product meets specifications;

(C) Documentation of accreditation information for all testing laboratories;

(D) Complete description of smoking or aerosol-generating regimes used for analytical testing, if any; and

(E) Tobacco product specifications (including any physical, chemical, and biological specifications) and acceptance criteria for those specifications;

(F) Reports of release testing performed on finished products to demonstrate conformity with established specifications, including test protocols, line data, and a summary of the results for each applicable testing.

(k) *Health risk investigations*—(1) *Study types.* The application must contain full reports of all information, both favorable and unfavorable, published or known to, or which should reasonably be known to, the applicant concerning investigations, including nonclinical and human subject studies regarding the following topics. If no substantive information exists regarding the topics specified in § 1114.27(b)(1)(ii), including information from published literature or that may be bridged from an investigation of another tobacco product, an applicant may need to conduct its own investigation(s) to ensure substantive information is included in the PMTA to meet the application filing requirements.

(i) *Health risks of the product.* The potential health risks of the tobacco product to users and nonusers, including potential exposures and information regarding risks to youth, young adults, and other relevant vulnerable populations, and whether the product may present different risks than other tobacco products, including:

(A) The health effects of the constituents, including HPHCs, at the quantitative levels delivered to both users and nonusers under the range of conditions under which the product might be used;

(B) The toxicological profile of the new tobacco product related to the route of administration, including the genotoxicity, carcinogenicity, reproductive toxicity, immunotoxicity, acute toxicity, and repeat dose (chronic) toxicity of the new tobacco product relative to other tobacco products. The toxicological profile also includes information on the toxicity of the ingredients, additives, and HPHCs, relative to the route of administration and the range of potential levels of exposure resulting from the use of, or exposure to, the new tobacco product, including studies which discuss the toxicological effects of any leachables and extractables that can appear from the container closure system and the ingredient mixture, such as additive or synergistic effects;

(C) The pharmacological profile of the new tobacco product, including the pharmacokinetics, pharamacodynamics, metabolism, and elimination profile, of any of the ingredients, additives, and HPHCs for the range of potential levels of exposure resulting from the use of, or exposure to, the new tobacco product relative to other tobacco products. The applicant must specify whether the studies were conducted in vitro, in vivo, ex vivo, or in silico; and

(D) The health risks of the tobacco product compared to other tobacco products on the market, never using tobacco products, quitting tobacco product use, and using the tobacco product in conjunction with other tobacco products.

(ii) *Impacts on tobacco use behavior of tobacco product users.* How the product and its label, labeling, and advertising, to the extent that advertising has been studied, will affect the tobacco use behavior of tobacco product users, specifically considering

youth, young adults, and other relevant vulnerable populations, including:

(A) The abuse liability of the tobacco product;

(B) How users actually use the product, including use topography, product use frequency, use trends over time, and how such use affects the health risks of the product to individual users;

(C) The likelihood that users will use the product in conjunction with other tobacco products;

(D) The likelihood that current tobacco product users will start using the product;

(E) The likelihood that current tobacco users who adopt the product will switch to or switch back to other tobacco products that may present increased risks to individual health; and

(F) The likelihood that current tobacco users who may have otherwise quit using tobacco products will instead start or continue to use the product.

(iii) *Impacts on tobacco use initiation by nonusers, including youth, young adults, and other relevant vulnerable populations.* The impact of the tobacco product and its label, labeling, or advertising, to the extent that advertising has been studied, on tobacco use initiation by nonusers, including:

(A) The likelihood that consumers who have never used tobacco products, particularly youth, young adults, and other relevant vulnerable populations, will initiate use of the tobacco product;

(B) The likelihood that nonusers of tobacco products who adopt the tobacco product will switch to other tobacco products that may present higher levels of individual health risk; and

(C) The likelihood that former users of tobacco products will re-initiate use with the tobacco product.

(iv) *Perceptions and use intentions.* The impact of the product and its label, labeling, and advertising, to the extent that advertising has been studied, on individuals:

(A) Perception of the product;

(B) Use intentions; and

(C) Ability to understand the labeling and instructions for use and use the product in accordance with those instructions.

(v) *Human factors.* The impact of human factors on product risk, including discussion of use conditions, use environments, use related hazards, estimated use error risk, potential unintended uses, risk controls to ensure that harms and unintended consequences are minimized, and adverse experiences related to such uses.

(2) *Literature search.* The applicant must conduct a literature search for each type of information described in paragraph (k)(1) of this section, and the application must contain a description of the literature search performed, including the databases searched and the date searched, search terms, reasons for inclusion or exclusion of documents, and the strategy for study quality assessment. The application must also contain a bibliography of all published studies and articles referenced in the application. If a literature search was performed and resulted in no information found, the application must contain a statement to that effect.

(3) *Study reports.* The full report of each study included in the application must describe the specific product studied and include the following items, where applicable and to the extent reasonably available. For applicable items not contained in the full report of an investigation, the applicant must contain a description of the actions taken to obtain the information and why the document is not reasonably available.

(i) Full copies of any published articles and other reference materials;

(ii) Documentation of all actions taken to ensure the reliability of the study. For all studies, to the extent reasonably available or obtainable, the application must contain a certification that investigators do not have, or documentation fully disclosing, any financial conflicts of interest, such as the financial arrangements specified in the Financial Disclosure by Clinical Investigators regulation in part 54 of this chapter. Additionally, for nonclinical laboratory studies, the application must contain, for each study, documentation of all actions taken to ensure the reliability of the study, *e.g.,* documentation of whether the study was conducted in accordance with good laboratory practices, such as those specified in part 58 of this chapter;

(iii) Copies of all versions of protocols and amendments that were used in the study;

(iv) Copies of all versions of investigator instructions, if any were produced in addition to the protocol;

(v) The statistical analysis plan, including a detailed description of the statistical analyses used (including all variables, confounders, and subgroup analyses), the scientific rationale for the choice of sample sizes, and any amendments to the plan;

(vi) Line data, including data definition files that include the names of the variables, codes, and formats in each dataset, and copies of programs and any necessary macro-programs used to create derived datasets, and the results included in the study reports;

(vii) A list of sites and clinical investigators that conducted the study, including contact information and physical address(es);

(viii) The location of all source data. If the site where the study was conducted has not maintained all of the source data, indicate where the data are located;

(ix) The format of the records and data (*e.g.,* electronic or hard copy);

(x) A list of all sites that had early termination and the reason for early termination, if applicable;

(xi) A list of contractors who participated in the study, the role of each contractor, and the initiation and termination dates of the participation of each contractor;

(xii) A signed full report of all findings;

(xiii) For human subject studies:

(A) All versions of study materials (*e.g.,* consent forms, questionnaires, stimuli) used;

(B) All versions of case report forms used; and

(C) Individual case report forms related to participant deaths, other serious and unexpected adverse experiences, withdrawals, and participant discontinuation where the study participant was exposed to the tobacco product that is the subject of the PMTA or similar products; and

(xiv) For tobacco product perception and use intention studies that use advertising as stimuli, a statement describing whether the advertising used is representative of advertising that the applicant intends to use in marketing the product. If the advertising is not representative of the advertising an applicant intends to use in marketing the product, the applicant must describe whether the study results are still relevant to the likely impact of the advertising on tobacco product perceptions and use intentions.

(*l*) *The effect on the population as a whole.* The application must contain an analysis and discussion of how the data and information contained in the application establish that permitting the tobacco product to be marketed would be appropriate for the protection of public health determined with respect to the population as a whole, including users and nonusers of the tobacco product. The analysis and discussion must integrate all of the information in the application regarding the product and its likely effects on health, and tobacco use behavior, including tobacco use cessation and initiation, to provide an overall assessment of the likely effect that the marketing of the tobacco product may have on overall tobacco-related morbidity and mortality.

(m) *Certification statement.* The application must contain the following certification, with the appropriate information inserted (as indicated by parenthetical italicized text), signed by an authorized representative of the applicant:

''I (*name of responsible official*) on behalf of the applicant, (*applicant name*), hereby certify that the applicant will maintain all records to substantiate the accuracy of this application for the period of time required in 21 CFR 1114.45 and ensure that such records remain readily available to FDA upon request. I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.''

§ 1114.9 Amendments.

(a) *General.* FDA may request, or an applicant may submit on its own initiative, an amendment to a PMTA containing information that is necessary for FDA complete the review of a pending PMTA. An amendment must include the appropriate form and specify the STN assigned to the original submission and, if submitted other than at FDA's request, the reason for submitting the amendment. An amendment must also include the certification statement set forth in § 1114.7(m), with the appropriate information inserted, and signed by an authorized representative of the applicant.

(b) *Review of an amendment.* Submission of an amendment may affect the timing of review of an amended submission as follows:

(1) If the amendment is a major amendment (*e.g.,* an amendment that contains significant new data from a previously unreported study, detailed new analyses of previously submitted data, or substantial new manufacturing information), FDA will restart the 180-day review period after receipt of the amendment.

(2) If FDA requests a minor amendment (*i.e.,* an amendment that is not a major amendment) and receives a written response submitting the requested amendment, FDA may pause the review period for the number of days elapsed between the date of the request and the date that FDA receives the written response.

(c) *Failure to respond to amendment request.* If FDA requests an amendment and the applicant does not respond within the time period specified in FDA's request, FDA may consider the applicant to have submitted a request to voluntarily withdraw the pending PMTA under § 1114.11 and issue an acknowledgment letter notifying the applicant of the withdrawal.

(d) *No amendment to closed or withdrawn application.* An applicant may not amend an application after FDA has closed the application through an action under § 1114.29 or it has been withdrawn under § 1114.11.

§ 1114.11 Withdrawal by applicant.

(a) An applicant may at any time make a written request using the appropriate form to withdraw a PMTA that FDA has not acted on as described in § 1114.29. The withdrawal request must state:

(1) Whether the withdrawal is due to a health concern related to the tobacco product and, if so, a description of those concerns, including the extent, duration, and frequency of the health effects, and what gave rise to the concerns, such as reports of adverse experiences;

(2) The application STN; and

(3) The name(s) of the new tobacco product that is the subject of the application.

(b) An application will be considered withdrawn when FDA issues an acknowledgement letter stating that the application has been withdrawn.

(c) The application is an Agency record, even if withdrawn. FDA will retain the withdrawn application under Federal Agency records schedules. The availability of the withdrawn application will be subject to FDA's public information regulation in Part 20 of this chapter.

§ 1114.13 Change in ownership of an application.

An applicant may transfer ownership of a PMTA. At or before the time of transfer, the new owner and the former owner must submit information to FDA using the appropriate form as follows:

(a) The new and former owner must sign and submit a notice to FDA stating that all of the former applicant's rights and responsibilities relating to the PMTA have been transferred to the new owner. This notice must identify the name and address of the new owner and the PMTA transferred by tobacco product name(s) and STN.

(b) The new owner must sign and submit a notice to FDA containing the following:

(1) The new owner's commitment to agreements, promises, and conditions made by the former owner and contained in the application and marketing granted order, if applicable;

(2) The date that the change in ownership is effective;

(3) Either a statement that the new owner has a complete copy of the application, including all amendments, the marketing granted order (if applicable), and any records that are required to be kept under § 1114.45, or a request for a copy of the application, including all amendments, and the modified risk order (if applicable) from FDA's files in accordance with part 20 of this chapter. In accordance with the Freedom of Information Act, FDA will provide a copy of the application to the new owner under the fee schedule in FDA's public information regulations in § 20.45 of this chapter; and

(4) A certification that no modifications have been made to the tobacco product since the application, including amendments (if any), was submitted to FDA.

§ 1114.15 Supplemental applications.

(a) *Supplemental PMTA submission.* Applicants that have received a marketing granted order for a tobacco product may, as an alternative format of submitting an application that meets the content requirements of § 1114.7, submit a supplemental PMTA to seek marketing authorization for modifications to such product, which result in a new tobacco product under section 910(a)(1) of the Federal Food, Drug, and Cosmetic Act. Supplemental PMTAs must include new information concerning modifications that create the new tobacco product but allow the applicant to satisfy the remaining application requirements by cross-referencing applicable content from the previously submitted PMTA for the original tobacco product. Applicants may submit supplemental PMTAs only for modifications that require the submission of limited new information or where specified in a rule under section 907 of the FD&C Act. Except as permitted in a rule under section 907 of the Federal Food, Drug, and Cosmetic Act, an applicant may not submit a supplemental PMTA where:

(1) Modifications to the product that result in the new tobacco product require the submission of new information or revisions to the PMTA for the original product to the extent that reviewing a supplemental application for the new tobacco product would be confusing, cumbersome, or otherwise inefficient and submitting a standard PMTA under § 1114.7 would better facilitate review.

(2) The marketing granted order for the original tobacco product has been withdrawn; or

(3) The marketing granted order for the original tobacco product has been temporarily suspended or is subject to temporary suspension or withdrawal proceedings by FDA, except where authorized in writing by FDA.

(b) *Required format.* The supplemental PMTA must comply with format requirements of § 1114.7(b), except that an applicant must include certain content in a supplemental PMTA by cross-referencing a PMTA, or, where applicable, a supplemental PMTA, for an original tobacco product that is owned by that applicant, and may include other content by cross-referencing a tobacco product master file and postmarket reports for the original tobacco product. FDA will not consider content included by cross-reference to other sources of information outside of the submission.

(c) *Required content.* The supplemental PMTA must provide sufficient information for FDA to determine whether any of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply to the application.

(1) The application must contain the full text of all the information described in the following sections:

(i) General information that identifies the submission as a supplemental PMTA (as described in § 1114.7(c));

(ii) New product information (as described in paragraph (d) of this section);

(iii) Statement of compliance with 21 CFR part 25 (as described in § 1114.7(g));

(iv) Labeling (as described in § 1114.7(f)) if the labeling is not identical to the labeling submitted in the PMTA or postmarket reports for the original product;

(v) Postmarket information (as described in paragraph (e) of this section); and

(vi) Certification statement (as described in paragraph (f) of this section);

(2) The application must include the following sections by cross-reference to the PMTA for the original tobacco product and contain any additional information that is necessary to supplement or update the cross-referenced information:

(i) Descriptive information (as described in § 1114.7(d));

(ii) Product samples (as described in § 1114.7(e));

(iii) Labeling (as described in § 1114.7(f)) if the labeling is identical to the labeling that was submitted in the PMTA or postmarket reports for the original tobacco product;

(iv) Summary of all research findings (as described in § 1114.7(h));

(v) Product formulation (as described in § 1114.7(i));

(vi) Manufacturing (as described in § 1114.7(j)); and

(vii) Health risk investigations (as described in § 1114.7(k)).

(d) *New product information.* The application must contain a section that includes:

(1) Full descriptions of each modification to the product and comparisons to the original product version described in the previously authorized PMTA;

(2) A statement as to whether the new tobacco product, if it receives a marketing granted order, will replace the original tobacco product, will be a line extension of the original tobacco product, or will be introduced as an additional product by the same manufacturer;

(3) All data and information relating to each modification to the product that would be required in an application under § 1114.7; and

(4) A concluding summary of how the new tobacco product meets the requirements to receive a marketing granted order, including how the data and information contained in both the supplemental PMTA and cross-referenced from the previously authorized PMTA constitute valid scientific evidence and establishes that the PMTA meets the requirements of section 910(c) of the Federal Food, Drug, and Cosmetic Act to receive a marketing granted order, including that permitting the new tobacco product to be marketed would be appropriate for the protection of the public health determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product.

(e) *Postmarket reports.* (1) If an applicant has submitted postmarket reports for the original tobacco product, the applicant must include all such reports in the application by cross-reference.

(2) If an applicant is required to, but has not yet submitted a postmarket report, the applicant must submit a report as part of its application that contains all of the information for the original tobacco product that would otherwise be required in a report under § 1114.41 covering the period of time from when it received a marketing granted order for the original tobacco product to when it submits the supplemental PMTA.

(f) *Certification statement.* The application must contain the following certification, with the appropriate information inserted as indicated by parenthetical italicized text, signed by an authorized representative of the applicant:

''I, (*name of responsible official*), on behalf of (*name of applicant*), certify that (*new tobacco product name*) has a different (*describe each modification to the product*) than (*name of original tobacco product*) described in (*STN of the PMTA for the original product*) but is otherwise identical to (*name(s) of original tobacco product*). I certify that (*name of applicant*) understands this means there is no other modification to the materials, ingredients, design, composition, heating source, or any other feature of the original tobacco product. I also certify that (*name of applicant*) will maintain all records that substantiate the accuracy of this application and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.''

§ 1114.17 Resubmissions.

(a) *General.* An applicant may, as an alternative format of submitting an application that meets the content requirements of § 1114.7 or 1114.15 (if applicable), submit a resubmission to address deficiencies set forth in a marketing denial order. The resubmission must contain new information necessary to address application deficiencies and cross-reference applicable content from the PMTA that received the marketing denial order. An applicant may utilize the resubmission format for the same tobacco product for which FDA issued a marketing denial order or a new tobacco product that results from modifications to the product necessary to address the deficiencies described in a marketing denial order. An applicant may not submit a resubmission when:

(1) It incorporates new information or revisions to the PMTA for the original product to the extent that reviewing a resubmission for the new tobacco product would be confusing, cumbersome, or otherwise inefficient and submitting a standard PMTA under § 1114.7 would better facilitate review; or

(2) The marketing denial order states that the applicant may not submit a resubmission.

(b) *Required format.* The resubmission must comply with format requirements of § 1114.7(b), except that an applicant must include content in the resubmission by cross-referencing the PMTA, or, where applicable, supplemental PMTA, that received the marketing denial order. An applicant may also include content in a resubmission by cross-reference to a TPMF. FDA will not consider content included by cross-reference to other sources of information outside of the submission.

(c) *Required content.* The resubmission must provide sufficient information for FDA to determine whether any of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply to the application.

(1) The application must include the full text of the information described in the following paragraphs:

(i) General information that identifies the submission as a resubmission (as described in paragraph § 1114.7(c));

(ii) Response to deficiencies (as described in paragraph (d) of this section); and

(iii) Certification statement (as described in paragraph (e) of this section).

(2) The application must include the following sections from the PMTA that received a marketing denial order by cross-reference to the PMTA and contain all additional information, in full text or by reference to a tobacco product master file, that is necessary to supplement or update the cross-referenced information:

(i) Descriptive information (as described in § 1114.7(d));

(ii) Product samples (as described in § 1114.7(e));

(iii) Labeling (as described in § 1114.7(f));

(iv) Statement of compliance with 21 CFR part 25 (as described in § 1114.7(g));

(v) Summary of all research findings (as described in § 1114.7(h));

(vi) Product formulation (as described in § 1114.7(i));

(vii) Manufacturing (as described in § 1114.7(j)); and

(viii) Health risk investigations (as described in § 1114.7(k)).

(d) *Response to deficiencies.* (1) The application must include a section that lists and provides a separate response to each deficiency described by FDA in the original marketing denial order, including all data and information necessary to complete each response, and that also addresses any applicant-identified deficiencies.

(2) Where an applicant modifies the product in a way that would result in a new tobacco product under section 910(a)(1) of the Federal Food, Drug, and Cosmetic Act in order to address the deficiencies, the application must also include:

(i) A full description of each modification to the product and comparisons of that change to the original version of the product described in the previously submitted PMTA; and

(ii) All data and information relating to each modification to the product that would be required in an application under § 1114.7.

(e) *Certification statement.* The application must contain one of the two following certifications that corresponds to the application, with the appropriate information inserted as indicated by parenthetical italicized text, signed by an authorized representative of the applicant.

(1) *Same tobacco product certification.* An application for the same tobacco product must contain the following certification:

''I, (*name of responsible official),* on behalf of (*name of applicant*), certify that this submission for (*new tobacco product name(s)*) responds to all deficiencies outlined in the marketing denial order issued in response to (*STN of the previously submitted PMTA*) and the new tobacco product described herein is identical to the product described in the previously submitted PMTA. I certify that (*name of applicant*) understands this means there is no modification to the materials, ingredients, design, composition, heating source, or any other feature. I also certify that (*name of applicant*) will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.''

(2) *Different tobacco product certification.* An application for a different tobacco product than the original tobacco product that results from changes necessary to address the deficiencies must contain the following certification:

''I, (*name of responsible official*), on behalf of (*name of applicant*), certify that this submission for (*new tobacco product name(s)*) responds to all deficiencies outlined in the marketing denial order issued in response to (*STN of the previously submitted PMTA*) and the new tobacco product described herein has a different (*describe each modification to the product*) than (*name(s) of original tobacco product*) described in (*STN of the previously submitted PMTA*) but is otherwise identical to (*name(s) of original tobacco product*) described in (*STN of the previously submitted PMTA*). I certify that (*name of applicant*) understands this means there is no modification to the materials, ingredients, design features, heating source, or any other feature of the original tobacco product, except for the (*describe each modification to the tobacco product*). I also certify that (*name of applicant*) will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.''

Subpart C—FDA Review

§ 1114.25 Communication between FDA and applicants.

During the course of reviewing an application, FDA may communicate with an applicant about relevant matters, including scientific, medical, and procedural issues that arise during the review process and inspections. These communications may take the form of telephone conversations, letters, electronic communications, or meetings, and will be documented in the administrative file in accordance with § 10.65 of this chapter.

§ 1114.27 Review procedure.

(a) *Acceptance review.* (1) After an applicant submits a PMTA, FDA will perform an initial review of the PMTA to determine whether it may be accepted for further review. FDA may refuse to accept an application that:

(i) Does not comply with the applicable format requirements in § 1114.7(b), § 1114.15, or § 1114.17 (as applicable);

(ii) Is not administratively complete because it does not appear to contain the information required by § 1114.7 (excluding product samples), § 1114.15 or § 1114.17, as applicable;

(iii) Does not pertain to a tobacco product subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (as required by § 1105.10 of this chapter); or

(iv) FDA can otherwise refuse to accept under § 1105.10.

(2) If FDA accepts an application for further review, FDA will issue an acknowledgement letter to the applicant that specifies the PMTA STN. If FDA determines that it will require product samples as part of the PMTA, it will send instructions on how and where to submit product samples, as described in § 1114.7(e) of this chapter.

(3) If FDA refuses to accept an application, FDA will issue a letter to the applicant identifying the deficiencies, where practicable, that prevented FDA from accepting the application.

(b) *Filing review.* (1) After accepting a PMTA, FDA will make a threshold determination of whether the application contains sufficient information to permit a substantive review. FDA may refuse to file a PMTA if any of the following applies:

(i) The PMTA does not contain sufficient information required by section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act and by § 1114.7, § 1114.15, or § 1114.17, as applicable, to permit a substantive review of the application;

(ii) The application does not contain any substantive information, including information from published literature or bridged from an investigation of another tobacco product, regarding each of the following topics.

(A) The health risks of the new tobacco product as described in either § 1114.7(k)(1)(i)(A), (B), or (C));

(B) The health risks of the new tobacco product compared to the health risks generally presented by products in the same product category as well as products in at least one different category that are used by the consumers an applicant expects will use its new tobacco product (as described in a portion of § 1114.7(k)(1)(i)(D)).

(C) The abuse liability of the new tobacco product (as set forth in § 1114.7(k)(1)(ii)(A));

(D) How consumers would be expected to actually use the product, such as use frequency, use trends over time, and how such use affects the health risks of the product to individual users (as described in § 1114.7(k)(1)(ii)(B));

(E) The potential impact that the marketing of the new tobacco product would have on the likelihood that current tobacco product users would change their tobacco product use behavior, such as starting to using the new tobacco product, using the product in conjunction with other tobacco products, or, after using the product, switching to or switch back to other tobacco products that may present increased risks to individual health (*i.e.,* any of the information set forth in either § 1114.7(k)(1)(ii)(C), (D), (E), or (F));

(F) The impact of the tobacco product and its label, labeling, or advertising, to the extent that advertising has been studied, on tobacco product use behavior of current nonusers of tobacco products (*i.e.,* any of the information described in § 1114.7(k)(1)(iii));

(G) The impact of the product and its label, labeling, or advertising, to the extent that advertising has been studied, on individuals' perception of the product and their use intentions (*i.e.,* any of the information described in § 1114.7(k)(1)(iv)); and

(H) The ways in which human factors can affect the health risks of the new tobacco product (*i.e.,* any of the information described in § 1114.7(k)(1)(v));

(iii) The PMTA contains a false statement of material fact;

(iv) The PMTA is a supplemental PMTA that does not comply with § 1114.15; or

(v) The PMTA is a resubmission that does not comply with § 1114.17.

(2) If FDA refuses to file an application, FDA will issue a letter to the applicant identifying the deficiencies, where practicable, that prevented FDA from filing the application.

(3) If FDA files an application, FDA will issue a filing letter to the applicant.

(c) *Application review.* (1) Except as described in this paragraph and § 1114.9(b), within 180 days of receipt of an application described in section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act meeting the filing requirements set out in 1114.27(b), FDA will complete its review of the PMTA and act on the application.

(2) FDA will begin substantive review of the application after it is filed under paragraph (b) of this section. FDA may communicate with the applicant as set forth under § 1114.25 to seek additional or clarifying information.

(3) FDA may refer the PMTA or portions of the PMTA, upon its own initiative or applicant request, to TPSAC for reference and for the submission of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(4) FDA may conduct inspections of the applicant's manufacturing sites, and sites and entities involved with clinical and nonclinical research (including third parties and contract research organizations) to support FDA's review of the PMTA. Where an applicant prevents FDA from scheduling and conducting inspections that are necessary for FDA to complete its review of the PMTA in a timely manner, FDA may pause the 180-day review period for the number of days necessary to complete the inspection.

(5) FDA may defer review of a PMTA for a new product that, if introduced or delivered for introduction into interstate commerce, would be adulterated or misbranded due to the manufacturer or importer's failure to comply with user fee payment and reporting requirements under part 1150.

§ 1114.29 FDA action on an application.

After receipt of an application, FDA will:

(a) Refuse to accept the application as described in § 1114.27(a);

(b) Issue a letter administratively closing the application;

(c) Issue a letter canceling the application if FDA finds that it mistakenly accepted the application or that the application was submitted in error;

(d) Refuse to file the application as described in § 1114.27(b);

(e) Issue a marketing granted order as described in § 1114.31; or

(f) Issue a marketing denial order as described in § 1114.33.

§ 1114.31 Issuance of a marketing granted order.

(a) FDA will issue a marketing granted order if it finds that none of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply. A marketing granted order becomes effective on the date it is issued.

(b) FDA may include, as part of the marketing granted order:

(1) Restrictions on the sale and distribution of the product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, to the extent that it would be authorized to impose such restrictions under a regulation issued under section 906(d) of the Federal Food, Drug, and Cosmetic Act;

(2) Any restrictions on the sales, distribution, advertising, and promotion of the new tobacco product that the applicant proposed to be included as part of a marketing granted order under section 910(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act to support a finding by FDA that permitting the product to be marketed would be appropriate for the protection of the public health; and

(3) Requirements to establish and maintain records, and submit postmarket reports under section 910(f) of the Federal Food, Drug and Cosmetic Act in addition to those described in § 1114.41, including but not limited to

information such as labeling, advertising, marketing, promotional materials, or marketing plans not previously submitted to FDA.

§ 1114.33 Issuance of a marketing denial order.

(a) *Issuance.* FDA will issue a marketing denial order if:

(1) Upon the basis of the information submitted as part of the application and any other information before FDA with respect to the new tobacco product, FDA finds that any of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply;

(2) The applicant does not permit an authorized FDA employee, at a reasonable time and in a reasonable manner, an opportunity to:

(i) Inspect the facilities and controls described in the application; or

(ii) Have access to, copy, and verify all records pertinent to the application, which results in FDA finding that one or more of the grounds for denial specified in section 910(c)(2) of the Federal Food, Drug and Cosmetic Act apply.

(b) *Description of deficiencies.* The marketing denial order will, where practicable, identify measures to remove the application from deniable form.

§ 1114.35 Withdrawal of a marketing granted order.

(a) *Grounds for withdrawal.* FDA will withdraw a marketing granted order for a new tobacco product issued under this part if FDA determines that:

(1) Any of the grounds for withdrawal under section 910(d)(1) of the Federal Food, Drug, and Cosmetic Act apply; or

(2) Any postmarket requirement imposed by the marketing granted order or by this part has not been met, which results in FDA finding that one or more of the grounds for withdrawal specified in section 910(d)(1) of the Federal Food, Drug and Cosmetic Act apply.

(b) *Advice and other information.* (1) FDA may seek advice on scientific matters from any appropriate FDA advisory committee in deciding whether to withdraw a marketing granted order.

(2) FDA may use information other than that submitted by the applicant in deciding whether to withdraw a marketing granted order.

(c) *Informal hearing.* Prior to withdrawing a marketing granted order, FDA will offer the holder of the marketing granted order an opportunity for an informal hearing under part 16 of this chapter.

(d) *Order issuance.* If the applicant does not request a hearing or, if after the part 16 hearing is held, the Agency decides to proceed with the withdrawal, FDA will issue to the holder of the marketing granted order an order withdrawing the marketing granted order for the new tobacco product.

(e) *Public notice.* FDA will give the public notice of an order withdrawing a marketing granted order for a tobacco product and will announce the basis of the withdrawal.

§ 1114.37 Temporary suspension of a marketing granted order.

(a) FDA will temporarily suspend a marketing granted order if FDA determines that there is a reasonable probability that the continued distribution of such tobacco product would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market.

(b) Before temporarily suspending a marketing granted order of a tobacco product, FDA will offer the holder of the marketing granted order an opportunity for an informal hearing under part 16 of this chapter.

(c) If, after offering the holder of the marketing granted order an opportunity for a part 16 hearing, the Agency decides to proceed with the temporary suspension, FDA will issue an order temporarily suspending the marketing granted order for a tobacco product.

(d) After issuing an order temporarily suspending the marketing granted order, FDA will proceed expeditiously to withdraw the marketing granted order for the tobacco product.

Subpart D—Postmarket Requirements

§ 1114.39 Postmarket changes.

A marketing granted order authorizes the marketing of a new tobacco product in accordance with the terms of the order. Prior to the introduction or delivery for introduction into interstate commerce of a new tobacco product that results from modification(s) to the product, an applicant must submit a new PMTA under § 1114.7 or a supplemental PMTA under § 1114.15 and obtain a marketing granted order for the new tobacco product, unless the new tobacco product can be legally marketed through another premarket pathway.

§ 1114.41 Reporting requirements.

(a) *Required reports.* Each applicant that receives a marketing granted order must submit to FDA all information required by the terms of the marketing granted order and by this section as described below. Each postmarket report must be well-organized, legible, and written in English. Documents that have been translated from another language into English (*e.g.,* original study documents written in a language other than English) must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation.

(1) *Periodic reports.* Each applicant must submit a periodic report to the Center for Tobacco Products (CTP) within 60 calendar days of the reporting dates specified in the applicant's marketing granted order for the life of the order and as may be required for the submission of a supplemental PMTA under § 1114.15. The report must include the following:

(i) A cover letter that contains the PMTA STN, tobacco product name(s) (including the original name described in the PMTA if different), company name, date of report, and reporting period;

(ii) A description of all changes made to the manufacturing, facilities, or controls during the reporting period, including:

(A) A comparison of each change to what was described in the PMTA;

(B) The rationale for making each change and, if any, a listing of any associated changes; and

(C) The basis for concluding that each change does not result in a new tobacco product that is outside the scope of the marketing granted order and will not result in a finding that the marketing granted order must be withdrawn or temporarily suspended under section 910(d) of the Federal Food, Drug, and Cosmetic Act;

(iii) An inventory of ongoing and completed studies about the tobacco product conducted by, or on behalf of, the applicant that are within the scope of § 1114.7(k) and that have not been previously reported;

(iv) Full reports of information published or known to, or which should be reasonably known to, the applicant concerning scientific investigations and literature about the tobacco product that have not been previously reported, including significant findings from publications not previously reported;

(v) A summary and analysis of all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or that the applicant is aware of, accompanied by a statement of any changes to the overall risk associated with the tobacco product, and a summary of any changes in the health

risks, including the nature and frequency of the adverse experience, and potential risk factors;

(vi) A summary of sales and distribution of the tobacco product for the reporting period, to the extent that the applicant collects or receives such data, including:

(A) Total U.S. sales reported in dollars, units, and volume with breakdowns by U.S. census region, major retail markets, and channels in which the product is sold;

(B) The Universal Product Code that corresponds to the product(s) identified in the PMTA; and

(C) Demographic characteristics of product(s) purchasers, such as age, gender, race or ethnicity, geographic region, and tobacco use status;

(vii) A summary of the implementation and effectiveness of policies and procedures regarding verification of the age and identity of purchasers of the product; and

(viii) A summary of all formative consumer research studies conducted (if any), among any audiences, in the formation of new labeling, advertising, marketing, or promotional materials, not previously submitted, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions and behaviors toward using the products, and including the findings or these studies and copies of the stimuli used in testing;

(xi) A summary of all consumer evaluation research studies conducted (if any), among any audiences, not previously submitted, to determine the effectiveness of labeling, advertising, marketing, or promotional materials and shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including the findings of these studies and copies of the stimuli used in testing;

(xii) A summary of the creation and dissemination of the products' labeling, advertising, marketing, and promotional materials (if any), including a list of all entities involved and a description of their involvement, including a description of contractual agreements with such entities;

(xiii) Specimens of all labeling and descriptions of all labeling changes that have not been previously submitted under section 905(i) of the Federal Food, Drug, and Cosmetic Act, including the date the labeling was first disseminated and the date when dissemination was completely terminated;

(xiv) Full color copies of all advertising for the tobacco product that has not been previously submitted, and the original date the materials were first disseminated and the date when their dissemination was completely terminated;

(xv) A description of the implementation of all advertising and marketing plans, not previously submitted to FDA, by channel and by product, including strategic creative briefs and paid media plans, and the dollar amount(s) and flighting of such plans, by channel and by product, including a description of any of the following activities that an applicant may have engaged in:

(A) Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;

(B) Targeting of specific group(s) by age-range(s), including young adults, ages 21 to 24, and other demographic or psychographic characteristics that reflect the intended target audience, including the source of such data;

(C) With respect to individuals below the minimum age of sale, actions taken to restrict access to the products and exposure to the products' labeling, advertising, marketing, or promotion, or other consumer-directed activities;

(D) Use of owned, earned, shared, or paid media to create labeling for, advertise, market, or promote the product;

(E) Use of partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, or promote the product;

(F) Consumer engagements conducted by the applicant, on its behalf, or at its direction, including events at which the products were demonstrated and how access was restricted to individuals at or above the minimum age of sale;

(G) Use of public-relations or other communications outreach to create labeling for, advertise, market, or promote the products;

(xvi) A summary of media tracking and optimization, by channel, by product, and by audience demographics (*e.g.,* age, gender, race/ethnicity, geographic region), including a summary of any real-time digital media monitoring and including a summary of implementation of any corrective and preventive measures to identify, correct, and prevent delivery of advertising to individuals below the minimum age of sale, not previously submitted;

(xvii) An analysis of the actual delivery of advertising impressions, by channel, by product, and by audience demographics, that have not been previously submitted, and verified against post-launch delivery-verification reports submitted to the applicant from an accredited source, where applicable;

(xviii) Additional information required to be reported under the terms of a marketing granted order (if applicable); and

(xix) An overall assessment of how the tobacco product continues to be appropriate for the protection of the public health.

(2) *Serious and unexpected adverse experience reporting.* The applicant must report all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or of which the applicant is aware to CTP's Office of Science through the Health and Human Services' Safety Reporting Portal or in another manner designated by FDA (if applicable) within 15 calendar days after the report is received by the applicant.

(b) *FDA review of postmarket reports.* (1) As part of its review of a postmarket report, FDA may require the applicant to submit additional information to enable it to determine whether a change results in a new tobacco product, or to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing granted order.

(2) FDA may notify an applicant that FDA has determined that a change described in a periodic report made under this section results in a new tobacco product outside the scope of the marketing granted order, requiring the submission of a new PMTA under § 1114.7 or a supplemental PMTA under § 1114.15 and issuance of a marketing granted order if the applicant seeks to market the new tobacco product, unless the new tobacco product can be legally marketed through a different premarket pathway.

Subpart E—Miscellaneous

§ 1114.45 Record retention.

(a) *Record retention by the applicant.* (1) Each applicant that receives a marketing granted order must maintain all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing granted order, including records related to both the application and postmarket reports, and ensure that such records remain readily available to the Agency upon request (including where records are maintained by a third party on an applicant's behalf). These records include, but are not limited to:

(i) All documents submitted to FDA as part of an application, periodic postmarket reports, and adverse experience reports;

(ii) All documentation demonstrating whether each:

(A) Nonclinical laboratory study was conducted in accordance with good laboratory practices that support the reliability of the results, such as the records described in part 58 of this chapter; and

(B) Clinical investigator has any financial conflicts of interest that may be a source of bias, such as the documentation described in part 54 of this chapter;

(iii) All other documents generated during the course of a study necessary to substantiate the study results, including:

(A) Communications related to the investigation between the investigator and the sponsor, the monitor, or FDA; and

(B) All source data for human subject and nonclinical investigations included in the application and postmarket reports, including records of each study subject's case history and exposure to tobacco products used in the investigation, including case report forms, progress notes, hospital records, clinical charts, X-rays, lab reports, and subject diaries; and

(iv) A list of each complaint, and a summary and analysis of all complaints, associated with the tobacco product reported to the applicant;

(2) These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. Documents that have been translated from another language into English (*e.g.,* original study documents written in a language other than English) must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation.

(3) All records must be retained as follows:

(i) Records related to and including the PMTA must be retained for a period of at least 4 years from the date that the marketing granted order is issued.

(ii) Records related to postmarket reports, including both periodic and adverse experience reports, must be retained for a period of at least 4 years from the date the report was submitted to FDA or until FDA inspects the records, whichever occurs sooner.

(b) *Record retention by FDA.* FDA will retain information submitted to it in accordance with Federal Agency Records schedules and will provide a copy to persons to whom such information may legally be disclosed on request under the fee schedule in FDA's public information regulations in § 20.45 of this chapter.

§ 1114.47 Confidentiality.

(a) *General.* FDA will determine the public availability of any part of an application and other content related to such an application, including all data and information submitted with or incorporated by reference in the application, under this section and part 20 of this chapter.

(b) *Confidentiality of data and information prior to an order.* Prior to issuing an order under this part:

(1) FDA will not publicly disclose the existence of an application unless:

(i) The applicant has publicly disclosed or acknowledged (as such disclosure is defined in § 20.81 of this chapter), or has authorized FDA in writing to publicly disclose or acknowledge, that the applicant has submitted an application to FDA; or

(ii) FDA refers the application to TPSAC.

(2) Except as described in paragraph (b)(4) of this section, FDA will not disclose the existence or contents of an FDA communication with an applicant regarding its application except to the extent that the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence or contents of that particular FDA communication.

(3) Except as described in paragraph (b)(4) of this section, FDA will not disclose the existence or contents of information contained in an application unless the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence or contents of that particular information. If the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence or contents of that particular information contained in an application, FDA may disclose the existence or contents of that particular information.

(4) If FDA refers an application to TPSAC, the contents of the application will be available for public disclosure, except information that is exempt from disclosure under part 20 of this chapter.

(c) *Disclosure of data and information after issuance of a marketing granted order.* After FDA issues a marketing granted order, it may make the following information related to the application and order available for public disclosure upon request or at FDA's own initiative, including information from amendments to the application and FDA's reviews of the application:

(1) All data previously disclosed to the public, as such disclosure is defined in § 20.81 of this chapter;

(2) Any protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter;

(3) Information and data submitted to demonstrate that the new tobacco product is appropriate for the protection of public health, unless the information is shown to fall within the exemptions established in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy;

(4) Correspondence between FDA and the applicant, including any requests FDA made for additional information and responses to such requests, and all written summaries of oral discussions between FDA and the applicant, unless it is shown to fall within the exemptions in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy;

(5) In accordance with § 25.51(b) of this chapter, the environmental assessment or, if applicable, the claim for categorical exclusion from the requirement to submit an environmental assessment under part 25 of this chapter; and

(6) Information and data contained in postmarket reports submitted to FDA, unless the information is shown to fall within the exemptions established in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy

(d) *Disclosure of data and information after the issuance of a marketing denial order.* After FDA issues a marketing denial order, FDA may make certain information related to the application and the order available for public disclosure upon request or at FDA's own initiative unless the information is otherwise exempt from disclosure under part 20 of this chapter. Information FDA may disclose includes, but is not limited to the tobacco product category (*e.g.,* cigarette), tobacco product subcategory (*e.g.,* filtered, combusted cigarette), package size, product quantity, characterizing flavor, and the basis for the marketing denial order.

§ 1114.49 Electronic submission.

(a) *Electronic format requirement.* Applicants submitting any documents to the Agency under this part must provide all required information to FDA using the Agency's electronic system, except as provided in paragraph (b) of this section. The application and all supporting information must be submitted in an electronic format that FDA can process, review, and archive.

(b) *Waivers from electronic format requirement.* An applicant may submit a written request, that is legible and in English, to the Center for Tobacco Products asking that FDA waive the requirement for electronic format and content. Waivers will be granted if use of electronic means is not reasonable for the applicant. To request a waiver, applicants can send the written request to the address included on our website (*www.fda.gov/tobacco-products*). The request must include the following information:

(1) The name and address of the applicant, a list of individuals authorized by the applicant to serve as the contact person and contact information. If the applicant has submitted a PMTA previously, the regulatory correspondence should also include any identifying information about the previous submission.

(2) A statement that creation and/or submission of information in electronic format is not reasonable for the applicant, and an explanation of why creation and/or submission in electronic format is not reasonable. This statement must be signed by the applicant or by a representative who is authorized to make the declaration on behalf of the applicant.

(c) *Paper submission.* An applicant who has obtained a waiver from filing electronically must send a written application through the Document Control Center to the address provided in the FDA documentation granting the waiver.

Dated: September 21, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2021–21011 Filed 10–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0212]

Applications for Premarket Review of New Tobacco Products; Draft Guidance for Industry; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal of a draft guidance for industry entitled ''Applications for Premarket Review of New Tobacco Products.'' We are withdrawing this guidance because the topics discussed in the draft guidance are addressed in the final rule entitled ''Premarket Tobacco Product Applications and Recordkeeping Requirements.''

DATES: The draft guidance is withdrawn as of October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the withdrawal of a draft guidance for industry entitled ''Applications for Premarket Review of New Tobacco Products,'' the notice of availability for which appeared in the **Federal Register** of September 28, 2011 (76 FR 60055). The draft guidance was intended to assist persons submitting premarket tobacco product applications (PMTAs) for new tobacco products under section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387j(b)(1)). The draft guidance discussed, among other things, when and how to submit PMTAs, what information the FD&C Act requires a PMTA to contain, and what information FDA recommends that applicants submit to demonstrate its new tobacco product should receive a marketing granted order. We are withdrawing this draft guidance and not finalizing it because the final rule entitled ''Premarket Tobacco Product Applications and Recordkeeping Requirements'' covers the topics described in the draft guidance.

Dated: September 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21010 Filed 10–4–21; 8:45 am]

BILLING CODE 4164–01–P

FEDERAL REGISTER

Vol. 86 Tuesday,
No. 190 October 5, 2021

Part IV

The President

Federal Register
Vol. 86, No. 190
Tuesday, October 5, 2021

Presidential Documents

Title 3—

The President

Proclamation 10266 of September 30, 2021

Cybersecurity Awareness Month, 2021

By the President of the United States of America

A Proclamation

Our Nation is under a constant and ever-increasing threat from malicious cyber actors. Ransomware attacks have disrupted hospitals, schools, police departments, fuel pipelines, food suppliers, and small businesses—delaying essential services and putting the lives and livelihoods of Americans at risk. Any disruption, corruption, or dysfunction of our vital infrastructure can have a debilitating effect on national and economic security, public health, and our everyday safety.

Since its inception, Cybersecurity Awareness Month has elevated the central role that cybersecurity plays in our national security and economy. This Cybersecurity Awareness Month, we recommit to doing our part to secure and protect our internet-connected devices, technology, and networks from cyber threats at work, home, school, and anywhere else we connect online. I encourage all Americans to responsibly protect their sensitive data and improve their cybersecurity awareness by embracing this year's theme: ''Do Your Part. Be Cyber Smart.''

My Administration has worked to bolster the defense of our systems and protect the Federal Government's information and communications infrastructure. Earlier this year, I signed an Executive Order to modernize and improve the security of our technology, including areas like software security, information sharing, and Federal network modernization. The Executive Order also directs the Federal Government to only acquire products that meet strong cybersecurity standards—which, by spurring technology companies to raise the bar, will ultimately improve the security of those products for all Americans.

The reality is that most of our Nation's critical infrastructure—from transportation lines to energy suppliers to other vital fields—is owned and operated by the private sector. Therefore, the security of our critical infrastructure depends on Federal, State, local, Tribal, and territorial coordination with infrastructure owners and operators to achieve greater strength and security. My Administration is working in close coordination with the private sector. Earlier this year, we began to establish strong cybersecurity goals that outline our expectations for owners and operators of America's critical infrastructure. We also launched a 100-day initiative to improve cybersecurity across the electric sector. That initiative has already resulted in more than 150 utilities that serve 90 million Americans deploying or committing to deploy cybersecurity technology—and we are now in the process of extending that initiative to gas pipelines. My Administration is also working with the international community to elevate the profile of cybersecurity as a matter of global security interest.

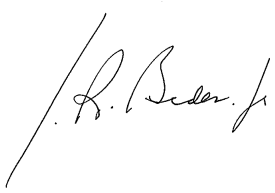
We recently convened a meeting with corporate, nonprofit, and educational leaders on how to protect their industries and our infrastructure. We are working closely with the private sector to share information, strengthen cybersecurity practices, and deploy technologies that increase resilience against cyberattacks. My Administration has also launched StopRansomware.gov to provide a one-stop resource for Americans to learn

how to avoid ransomware and the steps to take if their computer becomes compromised.

During Cybersecurity Awareness Month, I ask everyone to ''Do Your Part. Be Cyber Smart.'' All Americans can help increase awareness on cybersecurity best practices to reduce cyber risks. Whether you are at home, school, or the office—a few simple steps can help keep you and your online data safe and secure. By limiting the amount of personal information shared online, regularly updating devices and software, and using complex passwords and multifactor authentication methods, our entire Nation will be more resilient against the constant threat of malicious cyber actors.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2021 as Cybersecurity Awareness Month. Through events, training, and education, I call upon the people, businesses, and institutions of the United States to recognize the importance of cybersecurity, to take action to better protect yourselves against cyber threats, and to observe Cybersecurity Awareness Month in support of our national security and resilience.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2021–21881
Filed 10–4–21; 11:15 am]
Billing code 3395–F2–P

Presidential Documents

Proclamation 10267 of September 30, 2021

National Arts and Humanities Month, 2021

By the President of the United States of America

A Proclamation

As our Nation continues to grapple with consequential crises—from combating the ongoing global pandemic and addressing cries for racial justice to tackling the existential threat that climate change poses to our planet—the arts and humanities enable us to both understand our experiences and lift our sights. During this National Arts and Humanities Month, we celebrate the power of the arts and humanities to provide solace, understanding, and healing. We recognize the ability of the arts and humanities to amplify important and diverse voices and messages. We reflect on the fact that, as we have struggled with isolation, anxiety, and the loss of loved ones, we have turned to music and dance, literature and poetry, and philosophy and history to bring us together and help us persevere through, and grapple with, our current moment.

From our Nation's earliest days, we have recognized the arts as a foundation of our Republic. As George Washington wrote in 1781, ''The arts and sciences [are] essential to the prosperity of the State and to the ornament and happiness of human life.'' Today, any American—regardless of their background—can create art and turn to it for hope, acceptance, and inspiration. The arts and humanities have united us as a Nation—from the television programs we watch to the books and exhibits that inspire us—providing a sense of community when we need it most.

The COVID–19 pandemic has devastated our creative sectors. Before the pandemic, our Nation's arts and culture sectors were strong and vibrant—a nearly $1 trillion industry employing over 5 million Americans. But as the pandemic canceled events and closed theatres, concert halls, and performance venues, the unemployment rates for the cultural community spiked to among the highest in the Nation. Many museums, libraries, and arts venues closed their curtains and doors, some for a final time. For our Nation to fully recover and heal, we need the creative economy and our cultural sector to recover.

My Administration recognizes the essential role the arts and humanities play in our Nation's economy, democracy, health, and vitality and is committed to supporting the arts community. That is why my American Rescue Plan added another $1.25 billion in funding for the Shuttered Venues Operators Grant through the Small Business Administration, for a total of $16.25 billion. This critical program continues to provide much-needed relief to music and arts venues. My American Rescue Plan also provided an additional $135 million each for the National Endowment for the Arts (NEA) and the National Endowment for the Humanities (NEH) and $200 million for the Institute of Museum and Library Services (IMLS). My proposed budget for Fiscal Year 2022 also includes significant funding increases for the NEA, NEH, and IMLS. Collectively, these funds will help put people back to work and support our Nation's creators.

The arts can educate. To build vaccine confidence and communicate the benefits of vaccination in creative and culturally relevant ways, my Administration has partnered with artists and cultural icons to encourage Americans of all ages and from all corners of our Nation to get vaccinated. In this

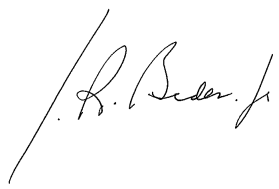
way, the arts can help us put an end to COVID–19. Thanks to the progress we are making with people getting vaccinated, tens of millions of Americans can go back to plays, concerts, and the movies. The arts can also heal Americans, from those who have suffered the traumas of loss or isolation during the pandemic to veterans and service members returning from war.

The pandemic has further revealed to us deep and unacceptable inequities in health care, education, and justice. The arts and humanities reveal the depths of these inequities and help us have the conversations and address the challenges that can be difficult to confront. The arts help us express and process our hurt and outrage as well as our joy and wonder—to better understand the experiences of our neighbors. By supporting and showcasing the creativity and experiences of those that have too often been discounted, we can advance our realization of a society that prioritizes equity and empathy.

This October, as we celebrate National Arts and Humanities Month, let us turn to the arts and humanities as a way to help America heal and grow. Let us build back better by ensuring that our cultural workers and creators are back at work and thriving. Let us ensure that everyone in America—regardless of race, geography, ability, and socioeconomic status—has equal and unrestricted access to the arts and humanities, and the opportunities they afford.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2021 as National Arts and Humanities Month. I call upon the people of the United States to observe this month with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2021–21884
Filed 10–4–21; 11:15 am]
Billing code 3395–F2–P

Presidential Documents

Proclamation 10268 of September 30, 2021

National Breast Cancer Awareness Month, 2021

By the President of the United States of America

A Proclamation

During National Breast Cancer Awareness Month, we stand with the courageous women and men who have been diagnosed with breast cancer and honor those who have lost their battle to this terrible disease. As the second most common cancer affecting women, an estimated 1 in 8 women will develop breast cancer over the course of their lifetime and 281,550 women will be diagnosed with breast cancer in the United States in 2021. Cancer touches so many families across the country—including ours. It is up to all of us to continue fighting for a cure and to ensure that every American has access to the quality care they need.

This year marks the 30th anniversary of the National Breast and Cervical Cancer Early Detection Program, which provides free breast and cervical cancer screenings to low-income, uninsured, and underinsured women in every State, as well as many Tribal organizations and Territories. To find information on how to get screened through this program, visit: cdc.gov/cancer/nbccedp/screenings.htm. Early detection is one of the most important strategies for treating breast cancer successfully, and regular screenings are the most reliable way to detect it early. The COVID–19 pandemic has disrupted many parts of our lives, and has produced new deficits in breast cancer early detection, so there is renewed urgency to getting these recommended screenings scheduled, before a cancer has spread and becomes less treatable. I encourage everyone to maintain their scheduled screenings, doctor appointments, and treatments without delay while observing coronavirus safety measures.

For decades, the medical community and advocates have helped our Nation make great progress in the fight against cancer. First Lady Jill Biden is proud to be a part of that movement, having founded the Biden Breast Health Initiative, which educated high school girls in Delaware about breast health and helped them spread the word to their own families. Still, our Nation has a long way to go before this disease no longer threatens American lives. I am committed to doing everything I can to bring together our cancer research community and give them the resources they need to make progress in the prevention, detection, and treatment of breast cancer. That is why I have called for the creation of an Advanced Research Projects Agency for Health at the National Institutes of Health (ARPA–H) which would invest $6.5 billion to develop breakthroughs that prevent, detect, and treat cancer and other deadly diseases. My American Rescue Plan also expands access to affordable health insurance coverage, ensuring that more women are able to receive these screenings and treatments without worrying about cost.

The Affordable Care Act (ACA) has expanded coverage to millions of women who were previously uninsured and has given millions of women access to preventive services, including screening tests such as mammograms with no out-of-pocket costs. Additionally, insurance companies can no longer discriminate against women with pre-existing conditions, such as breast cancer. My Administration is committed to protecting and building on the

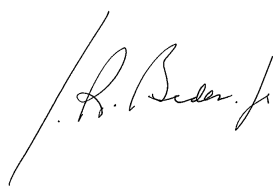
ACA to ensure that more people have access to quality, affordable health care and to lifting the inequitable health burden that falls on Black women.

As we observe National Breast Cancer Awareness Month, we are united in our commitment to ending breast cancer and improving the lives of all those affected by this illness. We applaud the advocates, medical professionals, researchers, and caregivers who dedicate their lives to making progress toward cures. This month, we stand in solidarity with breast cancer survivors across the country and reaffirm our commitment to advancing research efforts that deliver hope to patients everywhere.

More information on breast cancer is available at cancer.gov/breast. Information specialists at the National Cancer Institute are also available to help answer cancer-related questions in English and Spanish at 1–800–422–6237.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2021 as National Breast Cancer Awareness Month. I encourage citizens, government agencies, private businesses, nonprofit organizations, and other interested groups to join in activities that will increase awareness of what Americans can do to prevent and control breast cancer, and pay tribute to those who have lost their lives to this disease.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2021–21885
Filed 10–4–21; 11:15 am]
Billing code 3395–F2–P

Presidential Documents

Proclamation 10269 of September 30, 2021

National Clean Energy Action Month, 2021

By the President of the United States of America

A Proclamation

In the months leading up to this year's National Clean Energy Action Month, nearly 1 in 3 Americans has seen their community struck by weather disasters. The climate crisis is here and is threatening the safety and health of Americans across our Nation and people around the world. As the country continues to face droughts, heat waves, wildfires, floods, and hurricanes, we recognize that the window to avoid catastrophic outcomes is rapidly closing. The science is undeniable, and the cost of inaction is rising. At the same time, winter storms and hurricanes have tragically reminded us of the suffering and loss of life that can occur when access to energy is cut off or disrupted. During National Clean Energy Action Month, we recognize the importance of a clean energy future and the vital role we all have to play in working to avert the climate crisis.

Today, the energy sector accounts for more than 80 percent of United States emissions. My Administration has set ambitious and attainable goals of reducing United States greenhouse gas emissions by achieving a 100 percent clean electricity sector by 2035 and reaching net zero emissions economy-wide by no later than 2050. The path forward is clear: we must move quickly and decisively to power America with clean energy. This will require investment and innovation and will result not only in cleaner energy but also new jobs and lower bills.

That is why my Administration has been working aggressively to scale the deployment of large-scale and rooftop solar, offshore and onshore wind, and other clean energy technologies. We are committed to investing in American innovation to drive down costs and reduce our overall demand for energy. We are committed to upgrading, modernizing, and expanding our power grid to include clean power and to ensuring our grid is more resilient in the face of everything from extreme weather to cyber attacks. We are also investing in emerging technologies and bolstering our domestic supply chain for batteries and other clean technologies so that our clean energy future is made in America. At the same time, we are investing in the communities that are home to coal and fossil-fuel power plants to create new good-paying job opportunities for the workers who have powered our country and economy for over a century.

While the Federal Government can leverage powerful tools to help our Nation reach our climate goals, we cannot do it alone. Every American has a role to play in making smarter, more conscientious choices about how we use power within our homes, offices, schools, and places of worship. Simple actions like turning off the lights when we leave a room or upgrading our energy monitoring systems using tools like smart thermostats can help conserve energy and save money on energy bills. These small, intentional acts can add up to significant savings.

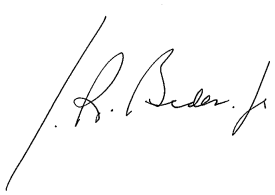
During National Clean Energy Action Month, we also recognize that for too long, low-income communities and communities of color have borne a disproportionate burden of pollution from fossil fuels and other industries.

That is why I signed an Executive Order establishing a White House Environmental Justice Advisory Council to prioritize environmental justice and ensure a whole-of-government approach to addressing current and historical environmental injustices. Our goal is to ensure that historically underserved communities also benefit from clean energy.

Throughout National Clean Energy Action Month, we recommit to acting on the climate crisis with urgency and moving quickly toward 100 percent clean energy, so we can create a safer, healthier, more prosperous future for all Americans.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2021 as National Clean Energy Action Month. I call upon the citizens of the United States to recognize this month by working together to mitigate climate change and achieve a healthier environment for all.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2021–21886
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Billing code 3395–F2–P

Presidential Documents

Proclamation 10270 of September 30, 2021

National Disability Employment Awareness Month, 2021

By the President of the United States of America

A Proclamation

When we passed the Americans with Disabilities Act (ADA) 31 years ago, our Nation moved closer to fulfilling its foundational promise of liberty, justice, dignity, and equality for all. I was enormously proud to co-sponsor the ADA as a member of the United States Senate—a truly bipartisan effort that was personal to millions of families. For more than 60 million disabled Americans, the ADA is much more than just a law. It provides a vital source of opportunity and self-sufficiency, allows for increased economic participation, and serves as a powerful shield against discrimination in the workplace. National Disability Employment Awareness Month is a chance for us to celebrate workers with disabilities and recommit ourselves to dismantling barriers to access and inclusion in the workplace.

This year, the Office of Disability Employment Policy in the Department of Labor celebrates 20 years of helping advance opportunity for workers with disabilities across the Nation. As part of its mission, the agency remains at the forefront of emerging challenges in the workplace, such as developing comprehensive resources to ensure that workers grappling with the long-term effects of COVID–19 have access to the rights and resources they are due under disability law—including flexibilities, tools, and accommodations in the workplace.

Despite the progress our Nation has made in recent decades, people with disabilities are still too often marginalized and denied access to the American dream. Americans with disabilities—particularly women and people of color—have faced long-standing gaps in employment, advancement, and income. The COVID–19 pandemic has compounded these inequities, as people with disabilities have faced heightened risks—particularly the disproportionate share of people with disabilities employed in the hardest-hit industries. Our Nation will never fully recover and rebuild unless every single community—including disabled Americans—is fully included.

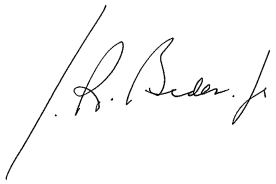
My Administration remains focused on ensuring that every single American has the chance to thrive, succeed, and contribute their talents. That is why I have issued Executive Orders to advance diversity, equity, inclusion, and accessibility to bolster career paths and promote economic stability for Americans with disabilities. I have proposed eliminating outdated, discriminatory provisions in the Fair Labor Standards Act that allow employers to pay disabled workers less than the minimum wage. Young people with disabilities in particular must be part of an inclusive economic recovery so that they can find the fulfilling careers, apprenticeships, and futures they deserve in every industry; to that end, we must promote the technologies and tools, as well as the attitudes, that foster welcoming work environments for young Americans. Our Nation's future will be brighter and more secure when everyone is dealt into the economy we build together.

All Americans should be proud that we have made substantial progress since the days before the ADA—when an employer could refuse to hire you because of a disability, when a person using a wheelchair could not take a bus or a train to work, and when a person with a disability could be denied service in a restaurant or grocery store. Now, 31 years later,

it is the shared responsibility of all of us to tear down the barriers that remain for people with disabilities and to ensure that all Americans have the chance to find good jobs and build good lives—for themselves and for the good of our entire Nation.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2021 as National Disability Employment Awareness Month. I urge all Americans to embrace the talents and skills that workers with disabilities bring to the national recovery and to promote the right to equal employment opportunity for all people.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2021–21887
Filed 10–4–21; 11:15 am]
Billing code 3395–F2–P

FEDERAL REGISTER

Vol. 86 Tuesday,
No. 190 October 5, 2021

Part V

The President

Federal Register
Vol. 86, No. 190
Tuesday, October 5, 2021

Presidential Documents

Title 3—

The President

Proclamation 10271 of September 30, 2021

National Domestic Violence Awareness and Prevention Month, 2021

By the President of the United States of America

A Proclamation

For too long, domestic violence was considered a ''family issue'' and was left for families to address in private. That is why, decades ago, I created and pushed for the Violence Against Women Act (VAWA) to be passed. Today, we recognize the important roles of the public and private sectors, non-profit organizations, communities, and individuals in helping to prevent and address domestic violence and create a culture that refuses to tolerate abuse. Domestic violence affects millions of people in the United States, causes significant harm to the physical and mental health of survivors and their families, undermines their economic stability and overall well-being, and is a stain on the conscience of our country. While significant progress has been made in reducing domestic violence and improving services and support for survivors, much work remains to be done to expand prevention efforts and provide greater access to safety and healing. During National Domestic Violence Awareness and Prevention Month, we come together to reaffirm our commitment to ending domestic violence and supporting survivors.

Domestic violence is an abuse of power that tears apart the fabric of relationships and families and undermines the well-being of communities. One in 4 women and 1 in 10 men have experienced sexual violence, physical violence, or stalking by an intimate partner during their lifetime. Homicide is one of the leading causes of death in the United States for women under the age of 44, and nearly half are killed by a current or former male intimate partner. During the COVID–19 pandemic, domestic violence has become a pandemic within a pandemic, with many victims facing the added pressures of increased economic insecurity, increased time in isolation with their abusers, and limited contact with their support networks. This has made it even more difficult for victims to access the lifesaving services and support they need.

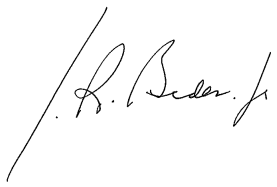
To strengthen our response to domestic violence and all forms of gender-based violence, my American Rescue Plan allocated an additional $450 million to increase support for domestic violence and sexual assault service providers and to further assist survivors in their short- and long-term transition away from their abusers. It also includes a historic commitment to funding culturally-specific community-based organizations to address the needs of survivors in historically marginalized communities. My Administration also allocated an additional $550 million for domestic violence shelters and supportive service providers to develop and employ COVID–19 detection and mitigation strategies and help survivors access health care during the pandemic. In the Fiscal Year 2022 budget, I proposed an historic $1 billion for grant programs administered by the Department of Justice's Office on Violence Against Women, and more than doubled investments through the Family Violence Prevention and Services Act. I was also proud to sign into law the Victims of Crime Act Fix to Sustain the Crime Victims Fund Act, which increases resources available to help thousands of survivors of domestic violence.

To accelerate this progress, the White House Gender Policy Council is working to develop our Nation's first ever National Action Plan to End Gender-Based Violence and the Council is collaborating with the Department of State and other Federal agencies to update and strengthen our Strategy to Prevent and Respond to Gender-Based Violence Globally. My Administration is also working to prevent and improve the response to intimate partner violence in our military and pushing to strengthen VAWA. Authoring and championing VAWA remains one of my proudest legislative achievements as a Senator, and its reauthorization is long overdue. Legislation to reauthorize and strengthen VAWA, which already passed the House of Representatives with bipartisan support, would reduce intimate partner homicides by strengthening common sense gun laws, expand protections for Native American survivors, increase access to safe housing, expand training for trauma-informed policing, and support programs centered on restorative practices. We are also committed to reauthorizing the Family Violence Prevention and Services Act to strengthen efforts to address domestic violence as a public health issue and to increase support for life-saving services and prevention programs across the Nation.

During National Domestic Violence Awareness and Prevention Month, we honor the tremendous dedication of advocates and service providers, honor the courage and resilience of survivors, and recommit ourselves to standing with them for safety, dignity, and justice. There is still much work to do, and it will take all of us to do it. We must rededicate ourselves to creating a society where domestic violence is not tolerated, where survivors are supported, and where all people have an opportunity to thrive without fear of violence or abuse.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2021 as National Domestic Violence Awareness and Prevention Month. I call on all Americans to speak out against domestic violence and support efforts to educate young people about healthy relationships centered on respect; support victims and survivors in your own families and networks; and to support the efforts of victim advocates, service providers, health care providers, and the legal system, as well as the leadership of survivors, in working to end domestic violence.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2021–21895
Filed 10–4–21; 11:15 am]
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Presidential Documents

Proclamation 10272 of September 30, 2021

National Youth Justice Action Month, 2021

By the President of the United States of America

A Proclamation

I have often said that America's young people are the kite strings that hold our national ambitions aloft—they carry the possibilities of our country and the sacred promise of a democracy where every one of us is treated equally and entitled to equal justice under the law. However, far too many of our young people are effectively excluded from participating in our democracy, having been sidelined by unnecessary encounters with the justice system. They deserve a second chance.

During National Youth Justice Action Month, I call upon States and communities to join me in seeking justice for our youth and modernizing our juvenile justice system, a system that should allow young people to build their lives and grow with freedom and dignity.

Long-standing inequities in our society—including in our juvenile and criminal justice systems—continue to disproportionately burden people of color and people with disabilities. Nationwide, Black youth are more than four times as likely as their white peers to be held in juvenile facilities, and they come into contact with both the juvenile justice and the child welfare systems at far higher rates. Additionally, one-third of young people in juvenile justice facilities have a disability, including many with emotional distress and learning disabilities. To deliver equal justice and equal dignity to all people, it is imperative that we root out racial inequities and other forms of discrimination from these systems.

Although youth arrests are at their lowest levels in decades, each arrest can create a ripple effect of heightened risks and negative consequences for young people. Once in the system, young people may face abusive treatment and dangerous conditions, including excessive use of restraint, guard-instigated fights, and sexual assault. Adverse environments and lack of support make it difficult for young people who enter the carceral system to lead healthy, productive lives upon exiting.

To give all of our young people a chance to live up to their full potential, we need to shift our approach from a default stance of incarceration to one of prevention—a strategy that recognizes that children's developmental stages and needs are starkly different from those of adults. Addressing racial disparities in school discipline and supporting proven early intervention efforts like afterschool and mentoring programs are simple steps we can take to help all young people find a sense of purpose and contribute to their communities. Many States are making a greater effort to keep teenagers under the jurisdiction of juvenile courts, which take their developmental needs into account and are better equipped to support their rehabilitation than systems built for adults.

In my Fiscal Year 2022 budget, I proposed an $800 million investment to more than double our current funding for juvenile justice and youth reentry programs that protect children and help young people get the services they need to get back on their feet. This includes incentives for States and communities that introduce reforms to reduce youth incarceration—including repurposing juvenile detention facilities to focus more on youth development. It also includes resources to develop research-based solutions

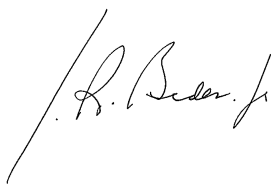
to steer kids away from detention and toward more positive alternatives. Through grants provided by the Office of Juvenile Justice and Delinquency Prevention at the Department of Justice, we are giving young people access to high-quality legal representation and resources to help them better manage the consequences of their contact with the system. We will ensure that young people in the juvenile justice system receive the counsel they are entitled to and will work to address the disproportionately high enforcement directed against young people of color.

Moreover, my Administration is working to ensure that all young people have the support they need to avoid entering the justice system in the first place. I have proposed $1 billion for a new School-Based Health Professionals grant program to help double the number of counselors, nurses, social workers, and other health professionals in our schools. In addition, I have proposed $443 million for Full-Service Community Schools, which would provide comprehensive wrap-around services to students and their families. Programs like these help ensure that more young people grow up in supportive environments and have what they need to reach their full potential.

It is the responsibility of all of us to support America's youth and ensure that they are in a position to thrive in every community. By shifting our focus from incarceration to prevention, we can bring about a brighter future for our young people and our country as a whole. Together, we can fulfill the promise of an America that is just and equitable for all.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2021 as National Youth Justice Action Month. I call upon all Americans to observe this month by taking action to support our youth and by participating in appropriate ceremonies, activities, and programs in their communities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2021–21896
Filed 10–4–21; 11:15 am]
Billing code 3395–F2–P

Presidential Documents

Proclamation 10273 of September 30, 2021

National Youth Substance Use Prevention Month, 2021

By the President of the United States of America

A Proclamation

Far too many families across our Nation have been impacted by addiction and the overdose epidemic. In 2020, more than 93,000 people died from an overdose—93,000 families forced to bury a piece of their souls. The impact of this crisis echoes in communities across the Nation, in the empty chairs in classrooms and around kitchen tables. During National Youth Substance Use Prevention Month, we reaffirm our commitment to helping America's youth overcome this epidemic and lead healthy, fulfilling lives.

The COVID–19 pandemic has only exacerbated the need to provide more resources to address substance use disorder. Substance use disorder touches families in every community, and it is essential that we invest in a broad range of services, including prevention, harm reduction, treatment, and recovery support services for mental health and substance use.

My Administration has been working to expand evidence-based prevention programs along with access to care and recovery support services. We are committed to preventing substance use among our Nation's youth—including alcohol, tobacco products, illicit drugs, and misused prescription medications—by bringing communities together to find local solutions. Through the White House's Office of National Drug Control Policy, the Drug-Free Communities Support Program helps equip community coalitions to reduce youth substance use at the local level. We must continue to encourage parents, caregivers, educators, and other members of the community to play an active role in promoting evidence-based prevention efforts that encourage healthy lifestyles, promote alternatives to substance use, and educate young people about the harms associated with substance use. We know that delaying substance use until after adolescence, when the brain has fully developed, decreases the likelihood of an individual developing a substance use disorder. We also know that smart investments in effective school-based prevention programs save lives and save our economy money in the form of averted medical costs and improved productivity.

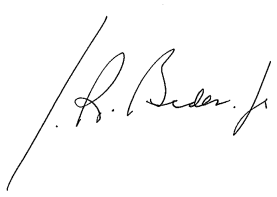
My Administration is also committed to advancing racial equity in our approach to drug policy—implementing fairer, more effective, and more culturally resonant policies to prevent, address, and treat substance use disorder. That is why we are supporting the development of tailored tools that strengthen prevention efforts in diverse communities. These include racial equity trainings, resources on inclusion and diversity, and racial equity decision-making frameworks. Our youth-focused efforts must also account for the fact that poverty, homelessness, trauma, and other adverse childhood experiences affect drug use and the overall health of our Nation's youth—especially with respect to people of color, who are disproportionately impacted by these factors. By advancing equity in every part of our society—including our education, health care, criminal justice, and housing systems—we can build a future where all Americans can lead healthy and fulfilling lives.

This October, we honor all those who champion evidence-based youth substance use prevention and recommit ourselves to ensuring that all Americans have the skills, knowledge, and resources to live full and healthy lives.

Substance use disorder is a disease, and I will do everything within my power to expand access to evidence-based prevention, treatment, harm reduction, and recovery support services as well as reduce the supply of illicit drugs to keep more Americans safe.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2021 as National Youth Substance Use Prevention Month. I call on communities, parents, caregivers, educators, employers, healthcare professionals, law enforcement officials, faith and community leaders, and all Americans to take action to promote evidence-based prevention and improve the health of our Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2021–21906
Filed 10–4–21; 11:15 am]
Billing code 3395–F2–P

Presidential Documents

Proclamation 10274 of September 30, 2021

National Manufacturing Day, 2021

By the President of the United States of America

A Proclamation

On National Manufacturing Day, we celebrate all that is made in America and recognize the importance of our Nation's manufacturers to every aspect of our lives. From the electronics we rely on, to the safely packaged foods we eat, to the clothing we wear, to the appliances and furniture in our homes, to the cars we drive—American manufacturing is essential to our economy. It employs over 12 million Americans directly and many more indirectly—providing high quality jobs to communities across the country and producing the highest quality goods in the world.

In the early days of the COVID–19 pandemic, our manufacturing sector was upended—578,000 manufacturing jobs were lost in 2020. Supply chain disruptions left our Nation short of lifesaving protective equipment, ventilators, and other essential health equipment at a time when we needed it most. However, our Nation's manufacturers and manufacturing workers stepped up—refitting their operations to produce needed materials and working long hours to make sure our Nation had what we needed.

The pandemic brought into even sharper focus the fragility of many of our global supply chains, which were already subject to everything from accidents and extreme weather to other countries engaging in unfair trade practices. In the name of our national and economic security and in support of American-based companies, American manufacturing, and American jobs—especially union jobs—I have committed our Nation to building our own resilient supply chains. That is why, during my first days in office, I signed an Executive Order to support manufacturing, rebuild our industrial base, and strengthen our supply chains—all while creating good-paying, union jobs. My order, ensuring that our future is made in all of America by American workers, also strengthens domestic manufacturing by directing Federal agencies to buy more American-made products.

My Administration has also called for historic investments in making our supply chains more resilient as well as investments in new and cleaner manufacturing technologies that will help us innovate and lead in manufacturing in the 21st century. The clean energy economy presents an enormous opportunity to revitalize American manufacturing, maintaining and creating good-paying, union jobs, while cleaning up the air and water in communities across the country. That's why my Administration is calling for investments to ensure that as we build everything from wind turbines to electric vehicles and that they are made in the United States with clean, American-made materials. The Federal Government is a major buyer in markets for goods and services. One of the most effective ways to support and grow American companies, put more Americans to work, and to strengthen American manufacturing is to buy American. My Administration is making the biggest enforcement change to the Buy American Act in 70 years, raising the amount of domestic content required to be considered ''Made in America'' from 55 percent to 75 percent.

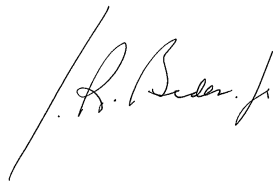
My Administration has also invested in our Nation's communities and the manufacturing base that builds them. Through programs like the Manufacturing Extension Partnership, Manufacturing USA, and opportunities sponsored by the Economic Development Administration of the Department of Commerce, we are providing resources to support and strengthen STEM education, infrastructure, technology hubs, and economic opportunities for all people in every region of our country.

As we continue to recover from the pandemic and millions of Americans return to work, there will be good opportunities available at all levels of the manufacturing industry that will need to be filled over the next decade.

On National Manufacturing Day, we commit to strengthening and supporting the American manufacturers and hardworking manufacturing employees of today as well as the manufacturers and workers of the future. We commit to building a future that is made in America.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 1, 2021, as National Manufacturing Day. I encourage all Americans to look for ways to get involved in your community and join me in participating in National Manufacturing Day, and, most importantly, buy American.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2021–21907
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Presidential Documents

Executive Order 14048 of September 30, 2021

Continuance or Reestablishment of Certain Federal Advisory Committees and Amendments to Other Executive Orders

By the authority vested in me as President, by the Constitution and the laws of the United States of America, and consistent with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), it is hereby ordered as follows:

Section 1. Each advisory committee listed below is continued or, to the extent necessary, reestablished until September 30, 2023.

(a) Committee for the Preservation of the White House; Executive Order 11145, as amended (Department of the Interior).

(b) President's Commission on White House Fellowships; Executive Order 11183, as amended (Office of Personnel Management).

(c) President's Committee on the National Medal of Science; Executive Order 11287, as amended (National Science Foundation).

(d) Federal Advisory Council on Occupational Safety and Health; Executive Order 11612, as amended (Department of Labor).

(e) President's Export Council; Executive Order 12131, as amended (Department of Commerce).

(f) President's Committee on the International Labor Organization; Executive Order 12216, as amended (Department of Labor).

(g) President's National Security Telecommunications Advisory Committee; Executive Order 12382, as amended (Department of Homeland Security).

(h) National Industrial Security Program Policy Advisory Committee; Executive Order 12829, as amended (National Archives and Records Administration).

(i) Trade and Environment Policy Advisory Committee; Executive Order 12905 (Office of the United States Trade Representative).

(j) Governmental Advisory Committee to the United States Representative to the North American Commission for Environmental Cooperation; Executive Order 12915 (Environmental Protection Agency).

(k) National Advisory Committee to the United States Representative to the North American Commission for Environmental Cooperation; Executive Order 12915 (Environmental Protection Agency).

(l) Good Neighbor Environmental Board; Executive Order 12916, as amended (Environmental Protection Agency).

(m) Presidential Advisory Council on HIV/AIDS; Executive Order 12963, as amended (Department of Health and Human Services).

(n) President's Committee for People with Intellectual Disabilities; Executive Order 12994, as amended (Department of Health and Human Services).

(o) Invasive Species Advisory Committee; Executive Order 13112, as amended (Department of the Interior).

(p) Advisory Board on Radiation and Worker Health; Executive Order 13179 (Department of Health and Human Services).

(q) National Infrastructure Advisory Council; Executive Order 13231, as amended (Department of Homeland Security).

(r) President's Council on Sports, Fitness, and Nutrition; Executive Order 13265, as amended (Department of Health and Human Services).

(s) Interagency Task Force on Veterans Small Business Development; Executive Order 13540 (Small Business Administration).

(t) State, Local, Tribal, and Private Sector (SLTPS) Policy Advisory Committee; Executive Order 13549 (National Archives and Records Administration).

(u) President's Advisory Commission on Educational Excellence for African Americans; Executive Order 13621 (Department of Education).

(v) President's Advisory Council on Doing Business in Africa; Executive Order 13675, as amended (Department of Commerce).

(w) Commerce Spectrum Management Advisory Committee; initially established pursuant to Presidential Memorandum on Improving Spectrum Management for the 21st Century (November 29, 2004) (Department of Commerce).

(x) National Space-Based Positioning, Navigation, and Timing Advisory Board; National Security Presidential Directive–39, ''U.S. National Space-Based Position, Navigation, and Timing Policy'' (December 8, 2004) (National Aeronautics and Space Administration).

(y) Grand Staircase-Escalante National Monument Advisory Committee; Proclamation 6920 of September 18, 1996, as amended (Department of the Interior).

(z) San Juan Islands National Monument Advisory Committee; Proclamation 8947 of March 25, 2013 (Department of the Interior).

(aa) Bears Ears National Monument Advisory Committee; Proclamation 9558 of December 28, 2016, as amended (Department of the Interior).

(bb) Gold Butte National Monument Advisory Committee; Proclamation 9559 of December 28, 2016 (Department of the Interior).

(cc) President's Council of Advisors on Science and Technology; Executive Order 14007, as amended (Department of Energy).

(dd) White House Environmental Justice Advisory Council; Executive Order 14008 (Environmental Protection Agency).

(ee) President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders; Executive Order 14031 (Department of Health and Human Services).

(ff) President's Board of Advisors on Historically Black Colleges and Universities; Executive Order 14041 (Department of Education).

(gg) Presidential Advisory Commission on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics; Executive Order 14045 (Department of Education).

Sec. 2. Notwithstanding the provisions of any other Executive Order, the functions of the President under the Federal Advisory Committee Act that are applicable to the committees listed in section 1 of this order shall be performed by the head of the department or agency designated after each committee, in accordance with the regulations, guidelines, and procedures established by the Administrator of General Services.

Sec. 3. Sections 1 and 2 of Executive Order 13889 of September 27, 2019, are hereby superseded by sections 1 and 2 of this order.

Sec. 4. Executive Order 11287 of June 28, 1966, as amended, is further amended in section 2(a) by striking ''twelve'' and inserting in lieu thereof ''fourteen.''

Sec. 5. Executive Order 12382 of September 13, 1982, as amended, is further amended as follows:

(a) by striking section 1, except subsection (c), and inserting before subsection (c) the following:

''**Section 1**. *Establishment.* (a) There is established the President's National Security Telecommunications Advisory Committee, which shall be composed of no more than 30 members. These members shall have particular knowledge and expertise in the fields of cybersecurity and of information and communications technology (ICT) and shall represent various elements of the Nation's telecommunications industry. Members of the Committee shall be appointed by the President.

(b) The President shall designate a Chair and Vice Chair from among the members of the Committee, each for a term of up to 2 years.''

(b) by striking sections 2 and 3, and inserting in lieu thereof the following new sections 2 and 3:

''**Sec. 2**. *Functions.* (a) The Committee shall provide to the President, through the Secretary of Homeland Security, information and advice from the perspective of relevant cybersecurity, ICT, and telecommunications industries on information assurance, cybersecurity, and the ICT ecosystem with respect to national security and emergency preparedness (NS/EP) concerns.

(b) The Committee shall provide information and advice to the President, through the Secretary of Homeland Security, regarding the feasibility of implementing specific measures to improve the resiliency and security of the digital and communications infrastructure of the United States.

(c) The Committee shall provide technical information, advice, and recommendations as it relates to NS/EP policy issues concerning cybersecurity, ICT, and telecommunications matters.

(d) The Committee shall periodically report on matters in this section to the President, through the Secretary of Homeland Security.

Sec. 3. *Administration.* (a) The heads of Executive agencies shall, to the extent permitted by law, provide the Committee with information concerning NS/EP policy issues specific to cybersecurity, ICT, and telecommunications matters in order for it to carry out its functions and mission. Information supplied to the Committee shall not, to the extent permitted by law, be available for public inspection.

(b) Members of the Committee shall serve without any compensation for their work on the Committee. However, to the extent permitted by law, they shall be entitled to travel expenses, including per diem in lieu of subsistence.

(c) Any expenses of the Committee shall, to the extent permitted by law, be paid from funds available to the Secretary of Homeland Security.''

(c) by striking section 4, except subsection (b) thereof, and inserting immediately preceding subsection (b) the following:

''**Sec. 4**. *General.* (a) Notwithstanding any other Executive Order, the functions of the President under the Federal Advisory Committee Act, as amended (5 U.S.C. App.), which are applicable to the Committee, except that of reporting annually to the Congress, shall be performed by the Secretary of Homeland Security, in accord with guidelines and procedures established by the Administrator of General Services.''

Sec. 6. Executive Order 13231 of October 16, 2001, as amended, is further amended in section 3(a) by striking ''The President shall designate from among the members of the NIAC a Chair and a Vice Chair, who shall perform the functions of the Chair if the Chair is absent or disabled, or in the instance of a vacancy in the Chair'' and inserting in lieu thereof ''The President shall designate from among the members of the NIAC a Chair and a Vice Chair, who shall perform the functions of the Chair if the Chair is absent or disabled, or in the instance of a vacancy in the Chair, each for a term of up to two years.''

Sec. 7. Executive Order 13265 of June 6, 2002, as amended, is further amended as follows:

(a) in section 2(a), by striking ''develop a national strategy'' and inserting in lieu thereof ''continue to promulgate a national strategy (the National Youth Sports Strategy).''

(b) in section 2, by striking the ''and'' at the end of subsection (a)(iii); striking the period at the end of subsection (a)(iv) and inserting in lieu thereof a semicolon; and inserting the following new subsections:

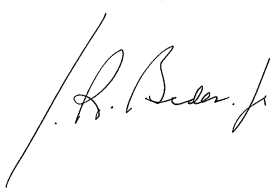
''(v) expand national awareness of the importance of mental health as it pertains to physical fitness and nutrition; and

(vi) share information about the positive effects of physical activity on mental health, particularly as it relates to children and adolescents, to combat the negative mental health impacts of the coronavirus disease 2019 (COVID–19) pandemic.''

(c) in section 4, by inserting after subsection (c) the following new subsection:

''(d) The Council members shall function as liaisons and spokespersons on behalf of the Council to relevant State, local, and private entities, and share information about the work of the Council in order to advise the Secretary regarding opportunities to extend and improve physical activity, fitness, sports, and nutrition programs and services at the State, local, and national levels.''

Sec. 8. This order shall be effective September 30, 2021.



THE WHITE HOUSE,
September 30, 2021.

[FR Doc. 2021–21908
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Federal Register

Vol. 86, No. 190

Tuesday, October 5, 2021

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The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available at *https://www.govinfo.gov*. Some laws may not yet be available.

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