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

FEDERAL TRADE COMMISSION

16 CFR Part 305

[3084–AB15]

Energy Labeling Rule

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') issues amendments to update the comparability ranges and sample labels for central air conditioners in the Energy Labeling Rule (''Rule'').

DATES: The amendments are effective on January 1, 2023.

ADDRESSES: Copies of this document are available on the Commission's website, *www.ftc.gov*.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome (202–326–2889), Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Room CC–9528, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Energy Labeling Rule

The Commission issued the Energy Labeling Rule (''Rule'') in 1979,[1] pursuant to the Energy Policy and Conservation Act of 1975 (''EPCA'').[2] The Rule requires energy labeling for major home appliances and other consumer products to help consumers compare the energy usage and costs of competing models. It also contains labeling requirements for refrigerators, refrigerator-freezers, freezers, dishwashers, water heaters, clothes washers, room and portable air conditioners, furnaces, central air conditioners, heat pumps, plumbing products, lighting products, ceiling fans, and televisions.

The Rule requires manufacturers to attach yellow EnergyGuide labels to many of the covered products and prohibits retailers from removing these labels or rendering them illegible. In addition, it directs sellers, including retailers, to post label information on websites and in paper catalogs from which consumers can order products. EnergyGuide labels for most covered products contain three main disclosures: Estimated annual energy cost, a product's energy consumption or energy efficiency rating as determined by Department of Energy (''DOE'') test procedures, and a comparability range displaying the highest and lowest energy costs or efficiency ratings for all similar models. Under the Rule, the Commission periodically updates comparability range and annual energy cost information based on manufacturer data submitted pursuant to the Rule's reporting requirements.[3]

II. Updated Ranges for Central Air Conditioners

On February 12, 2021 (86 FR 9273), the Commission published conforming rule amendments reflecting new DOE efficiency descriptors on central air conditioner labels to ensure the Rule's consistency with DOE requirements, which become effective on January 1, 2023.[4] In the February document, the Commission stated it would update ranges in appendices H and I, and the sample labels in appendix L, once new efficiency numbers became available.

On June 2, 2021 (86 FR 29533), the Commission proposed to update the comparability ranges for central air conditioners to ensure manufacturers have information available for the upcoming transition to new efficiency descriptors required by DOE.[5] In the June 2021 document, the Commission proposed to update the range table data (appendices H and I) and sample labels in the Rule (appendix L) using new information from the Air-Conditioning, Heating, & Refrigeration Institute (''AHRI'') and DOE staff input.[6] In response to the June document, the Commission received 31 comments. Commenters were generally supportive of the proposed updates, and none opposed the proposed ranges.[7] Commenters also made various suggestions for EnergyGuide labeling improvements and Rule changes (*e.g.,* the use of QR codes) not directly relevant to the range updates set out in the June document.[8] The Commission may consider these suggestions, which would require further consideration and additional public comment, in connection with future regulatory reviews.

Based on this record, the Commission is finalizing the range amendments in this document.[9] Consistent with the February 2021 amendments to the new energy descriptors, the effective date for these ranges is January 1, 2023. As the Commission stated in the February 2021 document, manufacturers may begin using the new range information prior to that date, in a manner consistent with DOE guidance now that the FTC has issued the final updates to appendices H and I once the FTC issues the final updates to appendices H and I.

III. Paperwork Reduction Act

The current Rule contains recordkeeping, disclosure, testing, and reporting requirements that constitute information collection requirements as defined by 5 CFR 1320.3(c), the definitional provision within the Office of Management and Budget (''OMB'') regulations that implement the Paperwork Reduction Act (''PRA''). OMB has approved the Rule's existing

[1] 44 FR 66466 (Nov. 19, 1979).

[2] 42 U.S.C. 6294. EPCA also requires the Department of Energy (''DOE'') to develop test procedures that measure how much energy appliances use, and to determine the representative average cost a consumer pays for different types of energy.

[3] 16 CFR 305.10.

[4] In 2017, DOE announced changes to the rating methods and associated efficiency descriptors for central air conditioners (*e.g.,* from ''Seasonal Energy Efficiency Ratio (SEER)'' to ''Seasonal Energy Efficiency Ratio 2 (SEER2)''). 82 FR 1786 (Jan. 6, 2017); and 82 FR 24211 (May 26, 2017).

[5] Commissioner Christine S. Wilson issued a dissent stating that the Commission should also seek further comment on broader issues including the ''more prescriptive aspects of this Rule'' and other changes to ''maximize the positive impact of this Rule for consumers.''

[6] AHRI is a trade association representing central air conditioner manufacturers.

[7] The comments are posted at *regulations.gov*.

[8] Two industry commenters (AHRI (#0030–0031) and Goodman (#0030–0032)) urged the Commission to issue the range updates ''expeditiously'' so that manufacturers ''have certainty on the revised EnergyGuide labels and adequate time to implement the labels.'' These two commenters also urged the Commission to postpone considering other potential Rule changes discussed in Commissioner Wilson's dissenting statement.

[9] The final amendments contain a few minor corrections to the sample labels in the June document (the top range number on Prototype Label 3; inclusion of asterisks and updated geographic information on Sample Label 3, and the removal of optional capacity numbers on labels).

information collection requirements through December 31, 2022 (OMB Control No. 3084–0069). The amendments do not change the substance or frequency of the Rule's recordkeeping, disclosure, or reporting requirements and, therefore, do not require further OMB clearance.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–612, requires that the Commission conduct an analysis of the anticipated economic impact of the proposed amendment on small entities. The RFA requires that the Commission provide an Initial Regulatory Flexibility Analysis (''IRFA'') with a rule unless the Commission certifies that the rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605. The amendments merely update the Rule's appendices to include revised comparability ranges and sample labels for central air conditioners based on more recent data. The proposed amendments do not significantly change the substance or frequency of the recordkeeping, disclosure, or reporting requirements. Thus, the amendments will not have a ''significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605. The Commission has concluded, therefore, that a regulatory flexibility analysis is not necessary, and certifies, under Section 605 of the RFA (5 U.S.C. 605(b)), that the amendments will not have a significant economic impact on a substantial number of small entities.

V. Other Matters

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).

List of Subjects in 16 CFR Part 305

Advertising, Consumer protection, Energy conservation, Household appliances, Incorporation by reference, Labeling, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Commission amends part 305 of title 16 of the Code of Federal Regulations as follows:

PART 305—ENERGY AND WATER USE LABELING FOR CONSUMER PRODUCTS UNDER THE ENERGY POLICY AND CONSERVATION ACT (''ENERGY LABELING RULE'')

■ 1. The authority citation for part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

■ 2. Revise appendix H to part 305 to read as follows:

Appendix H to Part 305—Cooling Performance for Central Air Conditioners

Manufacturer's rated cooling capacity (btu's/hr)	Range of SEER2's	
	Low	High
Single Package Units		
Central Air Conditioners (Cooling Only): All capacities	13.4	19
Heat Pumps (Cooling Function): All capacities	13.4	19
Split System Units		
Central Air Conditioner models allowed only in northern states (listed in § 305.20(g)(13)) (Cooling Only): All capacities	13.4	27
Central Air Conditioner models allowed in all states (Cooling Only):		
All capacities	13.8	27
Heat Pumps (Cooling Function): All capacities	14.3	42
Small-duct, high-velocity Systems	12	15
Space-Constrained Products		
Central Air Conditioners (Cooling Only): All capacities	11.7	13.7
Heat Pumps (Cooling Function): All capacities	11.9	13.8

■ 3. Revise appendix I to part 305 to read as follows:

Appendix I to Part 305—Heating Performance and Cost for Central Air Conditioners

Manufacturer's rated heating capacity (btu's/hr)	Range of HSPF2's	
	Low	High
Single Package Units		
Heat Pumps (Heating Function): All capacities	6.7	8.4
Split System Units		
Heat Pumps (Heating Function): All capacities	7.5	14.6
Small-duct, high-velocity Systems	6.1	7.5
Space-Constrained Products		
Heat Pumps (Heating Function): All capacities	6.3	6.5

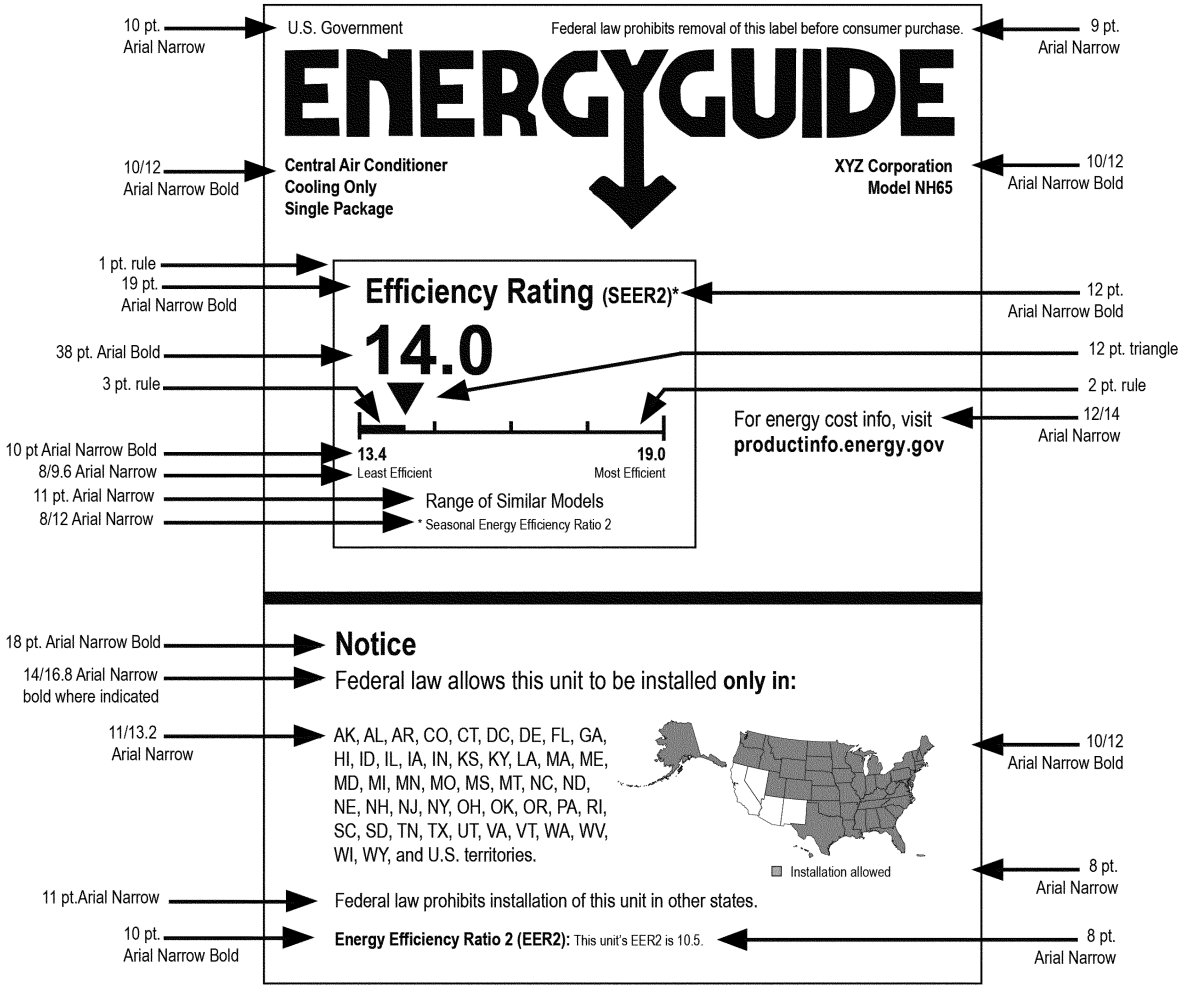
■ 4. Amend appendix L to part 305 by revising Prototype Label 3, Prototype Label 4, Sample Label 7, and Sample Label 8 to read as follows:

Appendix L to Part 305—Sample Labels

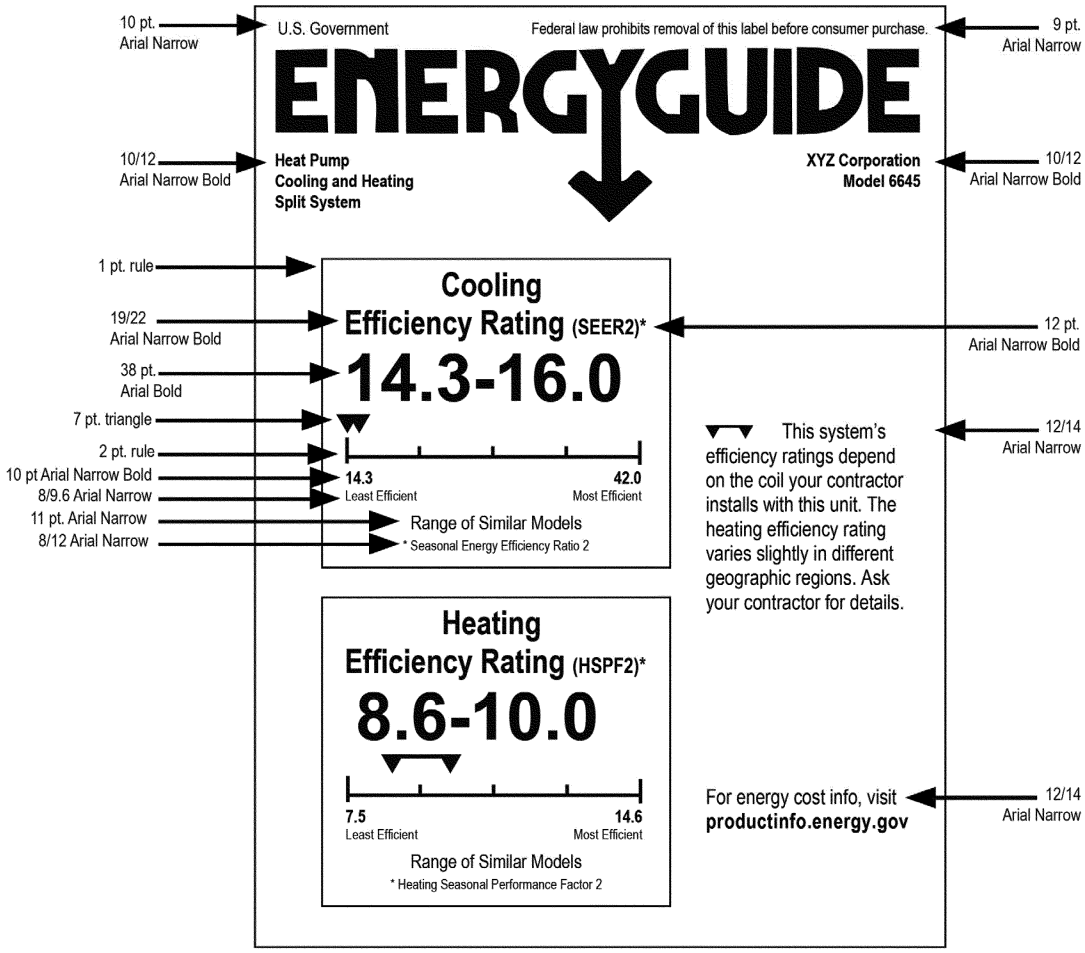
* * * * *

BILLING CODE 6750–01–P

Prototype Label 3 – Single-Package Central Air Conditioner



Prototype Label 4 – Split-system Heat Pump



* * * * *

Sample Label 7 – Split-system Central Air Conditioner

U.S. Government

Federal law prohibits removal of this label before consumer purchase.

ENERGYGUIDE

Central Air Conditioner
Cooling Only
Split System

XYZ Corporation
Model NH65

Efficiency Rating (SEER2)**

14.1

13.4
Least Efficient

27.0
Most Efficient

Range of Similar Models

** Seasonal Energy Efficiency Ratio 2

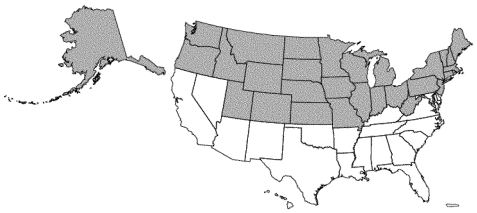
For energy cost info, visit
productinfo.energy.gov

* Your air conditioner's efficiency rating may be better depending on the coil your contractor installs.

Notice

Federal law allows this unit to be installed **only in:**

AK, CO, CT, ID, IL, IA, IN, KS, MA,
ME, MI, MN, MO, MT, ND, NE, NH
NJ, NY, OH, OR, PA, RI, SD, UT, VT
WA, WV, WI, and WY.

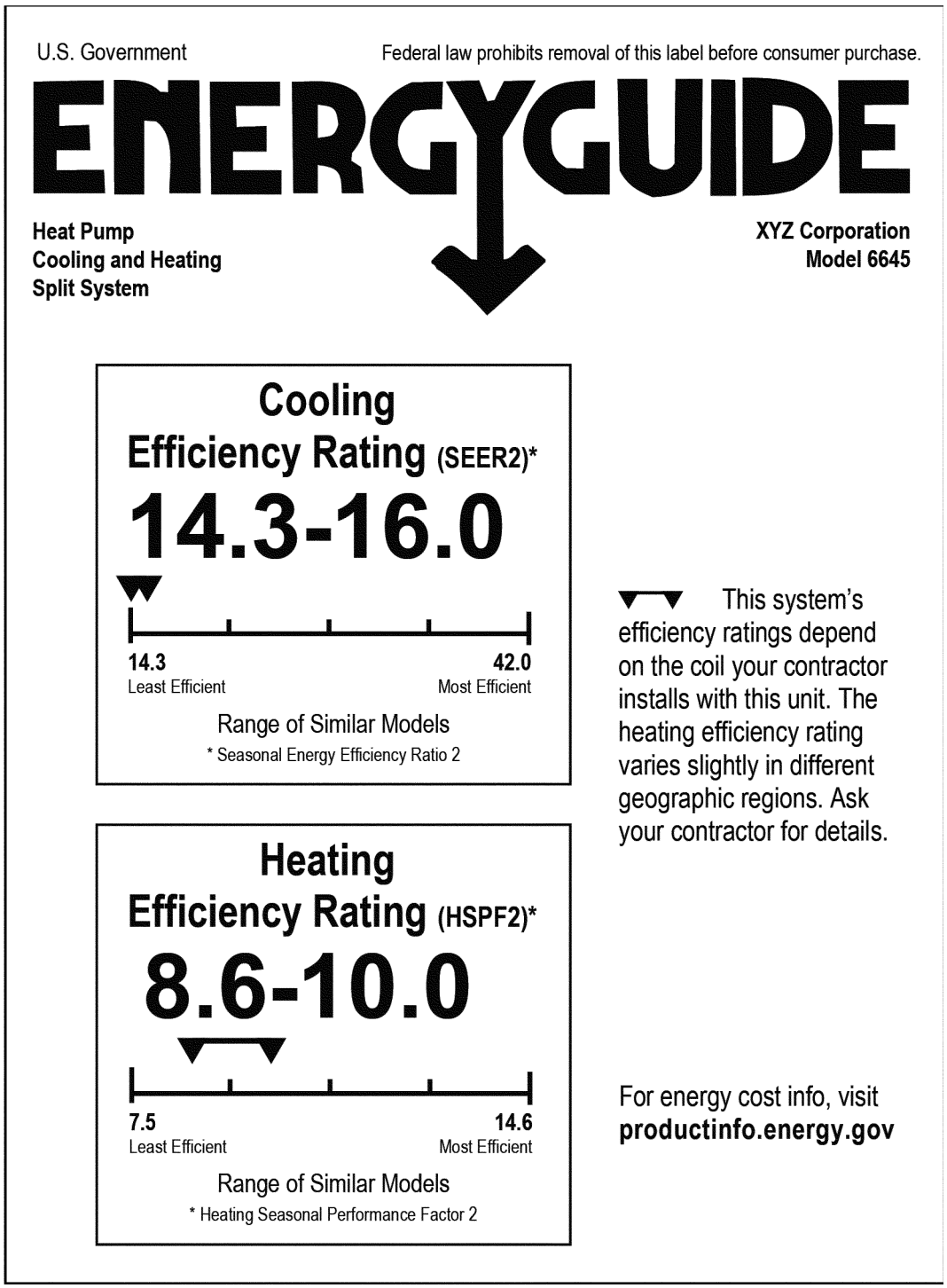


Installation allowed

Federal law prohibits installation of this unit in other states.

Energy Efficiency Ratio 2 (EER2): This unit's EER2 is 11.6.

Sample Label 8 – Split-system Heat Pump



* * * * *

By direction of the Commission, Commissioner Wilson dissenting.

April J. Tabor,

Secretary.

Note: The following will not appear in the Code of Federal Regulations.

Dissenting Statement of Commissioner Christine S. Wilson

Today the Commission announces required changes to the Energy Labeling Rule but makes no other changes to the Rule. Since 2015, the Commission has sought comment on provisions of this Rule multiple times and has made numerous amendments clarifying the Rule's requirements and making necessary changes. I have repeatedly urged the Commission to seek comment on the more prescriptive aspects of this Rule. I have explained my concerns about the highly prescriptive nature of this Rule in detail in my prior dissents. Regrettably, again today, the Commission chooses to make minor

changes to the Rule necessary for conformity but fails to conduct a full review of the Rule to consider removing all dated and prescriptive provisions. For these reasons, I dissent.

[FR Doc. 2021–22869 Filed 10–19–21; 8:45 am]

BILLING CODE 6750–01–C

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Part 122

[CBP Dec. 21–15]

Technical Amendment to List of User Fee Airports: Removal of One Airport

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security (DHS).

ACTION: Final rule; technical amendment.

SUMMARY: This document amends U.S. Customs and Border Protection (CBP) regulations by removing one airport from the list of user fee airports. User fee airports are airports that have been approved by the Commissioner of CBP to receive, for a fee, the customs services of CBP officers for processing aircraft, passengers, and cargo entering the United States, but do not qualify for designation as international or landing rights airports. Specifically, this technical amendment reflects the removal of the designation of user fee airport status for the Charlotte-Monroe Executive Airport in Monroe, North Carolina.

DATES: *Effective date:* October 20, 2021.

FOR FURTHER INFORMATION CONTACT: Ryan Flanagan, Director, Alternative Funding Program, Office of Field Operations, U.S. Customs and Border Protection at *Ryan.H.Flanagan@cbp.dhs.gov* or 202–550–9566.

SUPPLEMENTARY INFORMATION:

Background

Title 19, part 122 of the Code of Federal Regulations (19 CFR part 122) sets forth regulations relating to the entry and clearance of aircraft engaged in international commerce and the transportation of persons and cargo by aircraft in international commerce.[1] Generally, a civil aircraft arriving from outside the United States must land at an airport designated as an international airport. Alternatively, civil aircraft may request permission to land at a specific airport and, if landing rights are granted, the civil aircraft may land at that landing rights airport.[2]

Section 236 of the Trade and Tariff Act of 1984 (Pub. L. 98–573, 98 stat. 2948, 2994 (1984)), codified at 19 U.S.C. 58b, created an alternative option for civil aircraft seeking to land at an airport that is neither an international airport nor a landing rights airport. This alternative option allows the Commissioner of U.S. Customs and Border Protection (CBP) to designate an airport, upon request by the airport authority or other sponsoring entity, as a user fee airport.[3] Pursuant to 19 U.S.C. 58b, a requesting airport may be designated as a user fee airport only if CBP determines that the volume or value of business at the airport is insufficient to justify the unreimbursed availability of customs services at the airport and the governor of the state in which the airport is located approves the designation. As the volume or value of business cleared through this type of airport is insufficient to justify the availability of customs services at no cost, customs services provided by CBP at the airport are not funded by appropriations from the general treasury of the United States. Instead, the user fee airport pays for the customs services provided by CBP. The user fee airport must pay the fees charged, which must be in an amount equal to the expenses incurred by CBP in providing customs and related services at the user fee airport, including the salary and expenses of CBP employees to provide such services. *See* 19 U.S.C. 58b; *also* 19 CFR 24.17(a)–(b).

CBP designates airports as user fee airports in accordance with 19 U.S.C. 58b and 19 CFR 122.15 and on a case-by-case basis. If CBP decides that the conditions for designation as a user fee airport are satisfied, a Memorandum of Agreement (MOA) is executed between the Commissioner of CBP and the sponsor of the user fee airport. Pursuant to 19 CFR 122.15(c), the designation of an airport as a user fee airport must be withdrawn if either CBP or the airport authority gives 120 days written notice of termination to the other party, or if any amounts due to CBP are not paid on a timely basis.

The list of designated user fee airports is set forth in 19 CFR 122.15(b). Periodically, CBP updates the list to include newly designated airports that were not previously on the list, to reflect any changes in the names of the designated user fee airports, and to remove airports that are no longer designated as user fee airports.

Recent Change Requiring Update to the List of User Fee Airports

This document updates the list of user fee airports in 19 CFR 122.15(b) by removing the Charlotte-Monroe Executive Airport in Monroe, North Carolina. On February 3, 2021, the Monroe City Manager requested termination of the user fee status for the Charlotte-Monroe Executive Airport, and the Monroe City Manager and CBP mutually agreed to terminate the user fee status of Charlotte-Monroe Executive Airport effective on June 30, 2021.

Inapplicability of Public Notice and Delayed Effective Date Requirements

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency is exempted from the prior public notice and comment procedures if it finds, for good cause, that such procedures are impracticable, unnecessary, or contrary to the public interest. This final rule makes a conforming change by updating the list of user fee airports by removing one airport in light of the CBP Commissioner's withdrawal of its designation as a user fee airport, in accordance with 19 U.S.C. 58b. Because this conforming rule has no substantive impact, is technical in nature, and does not impose additional burdens on or take away any existing rights or privileges from the public, CBP finds for good cause that the prior public notice and comment procedures are impracticable, unnecessary, and contrary to the public interest. For the same reasons, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

Regulatory Flexibility Act and Executive Order 12866

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. This amendment does not meet the criteria

[1] For purposes of this technical rule, an ''aircraft'' is defined as any device used or designed for navigation or flight in air and does not include hovercraft. 19 CFR 122.1(a).

[2] A landing rights airport is ''any airport, other than an international airport or user fee airport, at which flights from a foreign area are given permission by Customs to land.'' 19 CFR 122.1(f).

[3] Sections 403(1) and 411 of the Homeland Security Act of 2002 (Pub. L. 107–296, 116 stat. 2135, 2178–79 (2002)), codified at 6 U.S.C. 203(1) and 211, transferred certain functions, including the authority to designate user fee facilities, from the U.S. Customs Service of the Department of the Treasury to the newly established U.S. Department of Homeland Security. The Secretary of Homeland Security delegated the authority to designate user fee facilities to the Commissioner of CBP through Department of Homeland Security Delegation, Sec. II.A., No. 7010.3 (May 11, 2006). The Commissioner subsequently delegated this authority to the Executive Assistant Commissioner of the Office of Field Operations on January 28, 2020.

for a ''significant regulatory action'' as specified in Executive Order 12866.

Paperwork Reduction Act

There is no new collection of information required in this document; therefore, the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) are inapplicable.

Signing Authority

This document is limited to a technical correction of CBP regulations. Accordingly, it is being signed under the authority of 19 CFR 0.1(b). Acting Commissioner Troy A. Miller, having reviewed and approved this document, is delegating the authority to electronically sign this document to Robert F. Altneu, who is the Director of the Regulations and Disclosure Law Division for CBP, for purposes of publication in the **Federal Register**.

List of Subjects in 19 CFR Part 122

Air carriers, Aircraft, Airports, Customs duties and inspection, Freight.

Amendments to Regulations

Part 122, of title 19 of the Code of Federal Regulations (19 CFR part 122) is amended as set forth below:

PART 122—AIR COMMERCE REGULATIONS

■ 1. The general authority citation for part 122 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1415, 1431, 1433, 1436, 1448, 1459, 1590, 1594, 1623, 1624, 1644, 1644a, 2071 note.

* * * * *

§ 122.15 [Amended]

■ 2. In § 122.15, amend the table in paragraph (b) by removing the entry for ''Monroe, North Carolina''.

Dated: October 15, 2021.

Robert F. Altneu,

Director, Regulations & Disclosure Law Division, Regulations & Rulings, Office of Trade, U.S. Customs and Border Protection.

[FR Doc. 2021–22880 Filed 10–19–21; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 526, 556 and 558

[Docket No. FDA–2021–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditional new animal drug applications (cNADAs) during January, February, and March 2021. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective October 20, 2021.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and conditional approval actions for cNADAs during January, February, and March 2021, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room*. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book*.

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.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2021

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
January 8, 2021	141–336	ECO LLC, 344 Nassau St., Princeton, NJ 08540.	AIVLOSIN (62.5% w/w tylvalosin as tylvalosin tartrate) Water Soluble Granules.	Swine	Supplemental approval for the addition of *Mycoplasma hyopneumoniae* to the list of pathogens for the control of swine respiratory disease indication.	FOI Summary.
January 11, 2021	141–526	Anivive Lifesciences, Inc., 3250 Airflite Way, Suite 400, Long Beach, CA 90807.	LAVERDIA–CA1 (verdinexor tablets).	Dogs	Conditional approval for the treatment of lymphoma in dogs.	FOI Summary.
January 12, 2021	200–675	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Ractopamine hydrochloride and monensin Type B and Type C medicated feeds.	Cattle	Original approval as a generic copy of NADA 141–225.	FOI Summary.
January 12, 2021	200–676	Do	Ractopamine hydrochloride, monensin, and tylosin phosphate Type B and Type C medicated feeds.	Cattle	Original approval as a generic copy of NADA 141–224.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2021—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
January 12, 2021	200–677	Do	Ractopamine hydrochloride, monensin, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval as a generic copy of NADA 141–234.	FOI Summary.
January 12, 2021	200–678	Do	Ractopamine hydrochloride, monensin, tylosin phosphate, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval as a generic copy of NADA 141–233.	FOI Summary.
January 14, 2021	141–544	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	KBROVET–CA1 (potassium bromide chewable tablets) Chewable Tablet.	Dogs	Conditional approval for the control of seizures associated with idiopathic epilepsy in dogs.	FOI Summary.
January 15, 2021	141–539	Neogen Corp., 944 Nandino Blvd., Lexington, KY 40511.	THYROKARE (levothyroxine sodium tablets).	Dogs	Original approval for replacement therapy for diminished thyroid function in dogs.	FOI Summary.
February 1, 2021	200–683	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Melengestrol acetate and monensin Type C medicated feeds.	Cattle	Original approval as a generic copy of NADA 125–476.	FOI Summary.
February 1, 2021	200–684	Do	Ractopamine hydrochloride, monensin, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval as a generic copy of NADA 141–234.	FOI Summary.
February 1, 2021	200–685	Do	Melengestrol acetate, monensin, and tylosin phosphate Type C medicated feeds.	Cattle	Original approval as a generic copy of NADA 138–870.	FOI Summary.
February 1, 2021	200–686	Do	Monensin, ractopamine hydrochloride, tylosin phosphate, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval as a generic copy of NADA 141–233.	FOI Summary.
February 8, 2021	200–466	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215.	SPARMECTIN Plus Clorsulon (ivermectin and clorsulon) Injection.	Cattle	Supplemental approval reducing preslaughter withdrawal period to 21 days.	FOI Summary.
February 16, 2021	200–506	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.	ANIMEC PLUS (ivermectin and clorsulon) Injection.	Cattle	Original approval as a generic copy of NADA 140–833.	FOI Summary.
February 18, 2021	200–657	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	MACROSYN (tulathromycin injection) Injectable Solution.	Cattle	Original approval as a generic copy of NADA 141–244.	FOI Summary.
February 18, 2021	200–666	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	INCREXXA (tulathromycin injection) Injectable Solution.	Cattle	Original approval as a generic copy of NADA 141–244.	FOI Summary.
February 26, 2021	141–540	Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.	PENNITRACIN MD (bacitracin Type A medicated article) and COBAN (monensin Type A medicated article) to be used in the manufacture of Type C medicated feeds.	Turkeys	Original approval for the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis* and *E. gallopavonis,* and for increased rate of weight gain and improved feed efficiency in growing turkeys.	FOI Summary.
March 11, 2021	200–699	Akorn Animal Health, Inc., 1925 West Field Ct., Suite 300, Lake Forest, IL 60045.	Dexmedetomidine Hydrochloride Injection (dexmedetomidine hydrochloride).	Dogs and cats.	Original approval as a generic copy of NADA 141–267.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2021—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
March 15, 2021	141–530	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	MGA (melengestrol acetate Type A medicated article) and AUREOMYCIN (chlortetracycline Type A medicated article) to be used in the manufacture of Type C medicated feeds.	Cattle	Original approval for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat) in replacement dairy and beef heifers, or growing beef heifers fed in confinement for slaughter receiving medicated feed containing chlortetracycline for the treatment of bacterial enteritis or pneumonia, control of bacterial pneumonia associated with shipping fever complex, reduction of incidence of liver abscesses, and control of active infection of anaplasmosis.	FOI Summary.
March 19, 2021	141–531	Do	MGA (melengestrol acetate Type A medicated article), AUREOMYCIN (chlortetracycline Type A medicated article), and BOVATEC (lasalocid Type A medicated article) to be used in the manufacture of Type C medicated feeds.	Cattle	Original approval for suppression of estrus (heat) in replacement dairy and beef heifers, or growing beef heifers fed in confinement for slaughter receiving medicated feed containing chlortetracycline for the treatment of bacterial enteritis or pneumonia, control of bacterial pneumonia associated with shipping fever complex, or control of active infection of anaplasmosis; and lasalocid for control of coccidiosis, increased rate of weight gain, and improved feed efficiency.	FOI Summary.
March 22, 2021	200–625	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	KETOMED (ketoprofen) Sterile Solution.	Horses	Original approval as a generic copy of NADA 140–269.	FOI Summary.
March 24, 2021	132–872	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	SAFE–GUARD (fenbendazole) Paste 10%.	Cattle	Supplemental approval providing for tolerances, a tissue withdrawal period, and a milk discard time in accordance with a repartitioning of the acceptable daily intake; and the addition of indications for fourth-stage larvae of certain endoparasites.	FOI Summary.

II. Changes of Sponsor

The sponsors of the following approved applications have informed FDA that they have transferred ownership of, and all rights and interest in, these applications to another sponsor:

File No.	Product name	Transferring sponsor	New sponsor	21 CFR section
141–175	CAPSTAR (nitenpyram) Tablets	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	Sergeant's Pet Care Products, Inc., 10077 S 134th St., Omaha, NE 68138.	520.1510.
141–120	CLOMICALM (clomipramine hydrochloride) Tablets.	Do	Virbac AH, Inc., P.O. Box 162059, Fort Worth, TX 76161.	520.455.
141–474	ITRAFUNGOL (itraconazole oral solution).	Do	Do	520.1189.
065–081	GO–DRY (penicillin G procaine) Intramammary Infusion.	G. C. Hanford Mfg. Co., P.O. Box 1017, Syracuse, NY 13201.	HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652.	526.1696.
200–335	Ampicillin Sodium Powder for Injection.	Do	Do	522.90c.
200–372	HAN–PEN (penicillin G potassium) Soluble Powder.	Do	Do	520.1696a.
065–071	Chlortetracycline (chlortetracycline hydrochloride) Soluble Powder.	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.	520.441.
065–440	CHLORONEX (chlortetracycline hydrochloride) Soluble Powder.	Do	Do	Do.
200–441	A-MYCIN (chlortetracycline hydrochloride) Soluble Powder.	Do	Do	Do.
200–528	SAVALAN 60 (salinomycin sodium) Type A medicated article.	Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	558.550.

File No.	Product name	Transferring sponsor	New sponsor	21 CFR section
200–237	Isoflurane, U.S.P	Piramal Enterprises Ltd., Ananta, Agastya Corporate Park, Opp Fire Brigade, Kamani Junction, LBS Mag Kurla (West), Mumbai, 400070, India.	Piramal Pharma Ltd., Ground Floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra, 400070, India.	N/A.

Following these changes of sponsorship, G. C. Hanford Manufacturing Co. and Piramal Enterprises Ltd. are no longer the sponsor of an approved application. Accordingly, the regulations in 21 CFR 510.600(c) are being amended to reflect these changes.

III. Technical Amendments

FDA is making the following amendments to improve the accuracy, consistency, and readability of the animal drug regulations:

- 21 CFR 510.600 is amended by revising the entries for Cronus Pharma Specialities India Private Ltd. to reflect the correct address for the firm.
- 21 CFR 520.2090 is amended to reflect the current approved indications for use for sarolaner, moxidectin, and pyrantel tablets.
- 21 CFR 522.970 is amended to reflect the approved species for a flunixin injectable solution.
- 21 CFR 558.76 for use of bacitracin methylenedisalicylate in medicated feed is amended to reflect a current tabular format organized by species.
- 21 CFR 558.128 is amended to reflect sponsors of combination medicated feeds containing chlortetracycline for which there is no preslaughter withdrawal period.
- 21 CFR 558.355 for use of monensin in medicated feeds is amended to reflect the sponsor of an approved generic product and to remove a redundant condition of use.

IV. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires **Federal Register** publication of ''notice[s] . . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a ''rule of particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 526

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR parts 510, 516, 520, 522, 526, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600:

■ a. In the table in paragraph (c)(1):

■ i. Add in alphabetical order an entry for ''Anivive Lifesciences, Inc.'';

■ ii. Revise the entry for ''Cronus Pharma Specialities India Private Ltd.'';

■ iii. Remove the entries for ''G. C. Hanford Manufacturing Co.'' and ''Piramal Enterprises Ltd.''; and

■ iv. Add in alphabetical order an entry for ''Piramal Pharma Ltd.''; and

■ b. In the table in paragraph (c)(2):

■ i. Remove the entry for ''010515'';

■ ii. Revise the entries for ''065085'' and ''069043''; and

■ iii. Add in numerical order an entry for ''086121''.

The revisions and additions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Anivive Lifesciences, Inc., 3250 Airflite Way, Suite 400, Long Beach, CA 90807	086121
* * * * * * *	
Cronus Pharma Specialities India Private Ltd., Sy No–99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India	069043
* * * * * * *	
Piramal Pharma Ltd., Ground Floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra, 400070, India	065085

.

Firm name and address	Drug labeler code
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
065085	Piramal Pharma Ltd., Ground Floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra, 400070, India
* * * * * * *	
069043	Cronus Pharma Specialities India Private Ltd., Sy No–99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India
* * * * * * *	
086121	Anivive Lifesciences, Inc., 3250 Airflite Way, Suite 400, Long Beach, CA 90807
* * * * * * *	

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc, 360ccc–2, 371.

■ 4. Add § 516.1858 to subpart E to read as follows:

§ 516.1858 Potassium bromide.

(a) *Specifications.* Each chewable tablet contains 250 or 500 milligrams (mg) potassium bromide.

(b) *Sponsor.* See No. 055246 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 25 to 68 mg per kilogram (11 to 31 mg per pound) of body weight once daily. The dosage can be divided and should be adjusted to clinical response.

(2) *Indications for use.* For the control of seizures associated with idiopathic epilepsy in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

■ 5. Add § 516.2980 to subpart E to read as follows:

§ 516.2980 Verdinexor.

(a) *Specifications.* Each tablet contains 2.5, 10, or 50 milligrams (mg) verdinexor.

(b) *Sponsor.* See No. 086121 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer verdinexor tablets orally at an initial dose of 1.25 mg per kilogram (mg/kg) of body weight twice per week with at least 72 hours between doses. If tolerated after 2 weeks, increase the dose to 1.5 mg/kg twice per week with at least 72 hours between doses.

(2) *Indications for use.* For the treatment of lymphoma in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 6. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 7. In § 520.441, revise paragraph (b)(1) to read as follows:

§ 520.441 Chlortetracycline powder.

* * * * *

(b) * * *

(1) Nos. 000010, 054771, and 069254 for use as in paragraph (d) of this section.

* * * * *

■ 8. In § 520.455, revise the section heading and paragraph (b) to read as follows:

§ 520. 455 Clomipramine.

* * * * *

(b) *Sponsors.* See Nos. 051311 and 086039 in § 510.600(c) of this chapter.

* * * * *

■ 9. In § 520.905c, revise paragraph (e)(2) to read as follows:

§ 520.905c Fenbendazole paste.

* * * * *

(e) * * *

(2) *Beef and dairy cattle*—(i) *Amount.* Administer orally 2.3 mg/lb (5 mg/kg) body weight.

(ii) *Indications for use.* For the treatment and control of: Lungworms: Adult (*Dictyocaulus viviparus*); Stomach worms: Adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): Hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).

(iii) *Limitations.* Milk taken during treatment and for 96 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves.

■ 10. In § 520.1189, revise paragraph (b) to read as follows:

§ 520.1189 Itraconazole.

* * * * *

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

* * * * *

■ 11. In § 520.1248, revise paragraphs (b) and (c)(1) to read as follows:

§ 520.1248 Levothyroxine.

* * * * *

(b) *Sponsors.* See Nos. 059051 and 061690 in § 510.600(c) of this chapter.

(c) * * *

(1) *Amount.* Administer by mouth as follows:

(i) No. 061690: 0.1 mg/10 pounds (lb) body weight (0.022 mg/kilogram (kg)) as a single dose every 24 hours or as a divided dose every 12 hours.

(ii) No. 059051: 0.1 mg/10 lb (0.01 mg/lb, 0.022 mg/kg) body weight twice daily.

* * * * *

■ 12. In § 520.1510, revise paragraph (b)(1) to read as follows:

§ 520. 1510 Nitenpyram.

* * * * *

(b) * * *

(1) No. 021091 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii)(A), and (d)(2) of this section.

* * * * *

■ 13. In § 520.1696a, revise paragraph (b) to read as follows:

§ 520.1696a Penicillin G powder.

* * * * *

(b) *Sponsors.* See Nos. 016592, 042791, 054771, 061133, and 076475 in § 510.600(c) of this chapter.

* * * * *

■ 14. In § 520.2090, revise paragraph (c)(2) to read as follows:

§ 520.2090 Sarolaner, moxidectin, and pyrantel.

* * * * *

(c) * * *

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*) and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections. Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, and the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick) for 1 month in dogs and puppies 8 weeks of age and older, and weighing 2.8 pounds or greater.

* * * * *

■ 15. In § 520.2645, revise paragraph (d)(2) to read as follows:

§ 520.2645 Tylvalosin.

* * * * *

(d) * * *

(2) *Indications for use.* For control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine intended for slaughter in buildings experiencing an outbreak of PPE; and for control of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica, Haemophilus parasuis, Pasteurella multocida, Streptococcus suis,* and *Mycoplasma hyopneumoniae* in groups of swine intended for slaughter in buildings experiencing an outbreak of SRD.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 16. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 17. In § 522.90c, revise paragraph (b) to read as follows:

§ 522.90c Ampicillin sodium.

* * * * *

(b) See Nos. 042791 and 054771 in § 510.600(c) of this chapter.

* * * * *

■ 18. In § 522.558, revise paragraphs (b)(1) and to read as follows:

§ 522.558 Dexmedetomidine.

* * * * *

(b) * * *

(1) Nos. 026637 and 059399 for use of product described in paragraph (a)(2) of this section.

* * * * *

■ 19. In § 522.970, revise paragraph (b)(1) and add paragraph (b)(3) to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(1) See Nos. 000061, 055529, 058198, and 061133 for use as in paragraph (e) of this section.

* * * * *

(3) See No. 016592 for use as in paragraphs (e)(1) and (e)(2) of this section.

* * * * *

■ 20. In § 522.1193, revise paragraphs (b) and (e)(2) and (3) to read as follows:

§ 522.1193 Ivermectin and clorsulon.

* * * * *

(b) *Sponsors.* See Nos. 000010, 055529, 058005, 061133, and 061651 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(2) *Indications for use.* For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei, Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum;* lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); liver flukes (adults only) (*Fasciola hepatica*); cattle grubs (parasitic stages) (*Hypoderma bovis, H. lineatum*); sucking lice (*Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus*); mange mites (cattle scab) (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*); and for control of infections of *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi, T. axei,* and *C. punctata* for 21 days after treatment; and *H. placei* and *C. oncophora* for 14 days after treatment.

(3) *Limitations.* Do not treat cattle within 21 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

■ 21. In § 522.1225, revise paragraph (b) to read as follows:

§ 522.1225 Ketoprofen.

* * * * *

(b) *Sponsors.* See Nos. 054771 and 061133 in § 510.600(c) of this chapter.

* * * * *

■ 22. In § 522.1696a, revise paragraph (d)(2)(iii) to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations.* Not for use within 30 days of slaughter. For No. 016592: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

■ 23. In § 522.2630, revise paragraphs (b) and (d)(1)(iii)(A) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 054771, 058198, and 061133 for use of product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii)(A), and (d)(2) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) as in

paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(A) Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 24. The authority citation for part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 25. In § 526.1696, revise paragraph (b) to read as follows:

§ 526.1696 Penicillin G procaine.

* * * * *

(b) See Nos. 042791 and 061133 in § 510.600(c) of this chapter.

* * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 26. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 27. In § 556.275:

■ a. Revise paragraph (b)(1)(ii);

■ b. Remove paragraph (b)(1)(iii); and

■ c. Remove and reserve paragraphs (b)(3)(ii), (b)(4)(ii), and (b)(5)(ii).

The revision reads as follows:

§ 556.275 Fenbendazole.

* * * * *

(b) * * *

(1) * * *

(ii) Milk: 0.22 ppm fenbendazole sulfoxide (marker residue).

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 28. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 29. In § 558.76:

■ a. Revise paragraphs (a)(1) and (2) and (d)(1);

■ b. Redesignate paragraph (d)(2) as paragraph (d)(6); and

■ c. Add new paragraph (d)(2) and paragraphs (d)(3) through (5).

The revisions and additions read as follows:

§ 558.76 Bacitracin methylenedisalicylate.

(a) * * *

(1) Type A medicated articles containing feed grade bacitracin methylenedisalicylate equivalent to 10, 25, 30, 40, 50, 60, or 75 grams bacitracin per pound.

(2) Type A medicated article containing feed grade bacitracin methylenedisalicylate equivalent to 50 grams bacitracin per pound.

* * * * *

(d) * * *

(1) *Chickens*—

Bacitracin in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50	Broiler and replacement chickens: For increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration	054771 069254
(ii) 10 to 25	Laying hens: For increased egg production and improved feed efficiency.	Feed continuously as sole ration for the first 7 months of egg production.	054771
(iii) 50	Broiler and replacement chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration	054771
(iv) 100 to 200	Broiler and replacement chickens: As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Start at first clinical signs of disease. Vary dosage based on severity of infection. Administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 grams/ton).	054771

(2) *Turkeys*—

Bacitracin in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50	Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration	054771 069254
(ii) 200	Growing turkeys: As an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylenedisalicylate.	Feed continuously as the sole ration	054771

(3) *Swine*—

Bacitracin in grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 30	Growing and finishing swine: For increased rate of weight gain and improved feed efficiency.		054771

Bacitracin in grams per ton	Indications for use	Limitations	Sponsor
(ii) 250	Growing and finishing swine: For control of swine dysentery (bloody scours) associated with *Brachyspira hyodysenteriae* in pigs up to 250 lbs body weight.	Feed as the sole ration. Feed 250 grams per ton of complete feed on premises with a history of swine dysentery, but where signs of the disease have not yet occurred or following an approved treatment of the disease condition. Diagnosis should be confirmed by a veterinarian a when results are not satisfactory.	054771
(iii) 250	Pregnant sows: For control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets.	As the sole ration. Feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.	054771

(4) *Cattle*—

Bacitracin amount	Indications for use	Limitations	Sponsor
(i) 70 mg per head per day.	Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses.	Administer continuously throughout the feeding period.	054771 069254
(ii) 250 mg per head per day.	Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses.	Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.	054771 069254

(5) *Game birds*—

Bacitracin in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50	Growing pheasants: For increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration	054771 069254
(ii) 5 to 20	Growing quail: For increased rate of weight gain and improved feed efficiency in quail not over 5 weeks of age.	Feed continuously as sole ration to quail not over 5 weeks of age.	054771 069254
(iii) 200	Growing quail: For the prevention of ulcerative enteritis in growing quail due to *Clostridium colinum* susceptible to bacitracin methylenedisalicylate.	Feed continuously as the sole ration	054771

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■ 30. In § 558.128, revise paragraphs (d)(4) and (e)(4) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(d) * * *

(4) Manufacture for use in free-choice feeds as in paragraph (e)(4)(vi) of this section must conform to § 510.455 of this chapter.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) to provide 70 mg/head/day.	.....	Growing cattle (over 400 lb): For reduction of liver condemnation due to liver abscesses.	Feed to provide chlortetracycline at the rate of 70 mg per animal daily. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal.	054771 066104 069254
(ii) 5.83 to 14 g/ton to provide 70 mg/head/day.	Melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg melengestrol acetate per head per day.	Growing beef heifers fed in confinement for slaughter (over 400 lb): For reduction of the incidence of liver abscesses, increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing 5.83 to 14 g/ton chlortetracycline. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iii) to provide 0.5 mg/lb of body weight daily.	.....	Beef cattle (over 700 lb): For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Feed to provide chlortetracycline at the rate of 0.5 mg per pound of body weight daily in beef cattle under 700 pounds. Withdraw 48 hours prior to slaughter. To sponsor Nos. 054771 and 069254: Zero withdrawal time.	054771 066104 069254
(iv) 33.33 to 50 g/ton to provide 0.5 mg/lb of body weight per day.	Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg melengestrol acetate per head per day.	Replacement beef heifers over 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for suppression of estrus (heat).	Melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 33.33 to 50 g/ton chlortetracycline. Feeding a Type C top-dress medicated feed containing melengestrol acetate shall not exceed 24 days. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 25 to 1,100 g/ton to provide 0.5 mg/lb of body weight daily.	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, beef replacement heifers) over 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis 0.5 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(vi) 25 to 1,100 g/ton to provide 0.5 mg/lb of body weight daily.	Lasalocid, 30 to 600; melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate.	Replacement beef heifers on pasture over 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline, increased rate of weight gain, and suppression of estrus (heat).	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 1,100 g/ton of chlortetracycline and 30 to 600 g/ton lasalocid to provide 0.5 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day in at least 1 pound of feed. Do not exceed 24 days of feeding. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(vii) to provide 0.5 to 2.0 mg/lb of body weight daily.	.....	Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	In free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(4) of this section.	054771 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(viii) to provide 10 mg/lb of body weight daily.	.....	Calves, beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 days. To sponsor No. 054771 (NADAs 048–761 and 046–699) and to sponsor No. 069254 (ANADA 200–510): May be mixed in the cattle's daily ration or administered as a top-dress. In feed including milk replacers withdraw 10 days prior to slaughter. To sponsor Nos. 054771 and 069254: Zero withdrawal time. See paragraph (d)(3) of this section.	054771 066104 069254
(ix) to provide 10 mg/lb of body weight daily.	.....	Calves (up to 250 lb): For the treatment of bacterial enteritis caused by *Escherichia coli* susceptible to chlortetracycline.	A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	054771 066104 069254
(x) to provide 10 mg/lb of body weight daily.	Laidlomycin, 5	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight and improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xi) to provide 10 mg/lb of body weight daily.	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xii) 500 to 2,000 to provide 10 mg/lb of body weight daily.	Lasalocid, 10 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 100 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xiii) to provide 10 mg/lb of body weight daily.	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 250 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xiv) 500 to 4,000 to provide 10 mg/lb of body weight daily.	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xv) 500 to 4,000 g/ton to provide 10 mg/lb of body weight daily.	Lasalocid, 30 to 600: Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate.	Replacement dairy heifers on pasture less than 20 months of age and replacement beef heifers on pasture: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, increased rate of weight gain, and suppression of estrus (heat).	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 500 to 4,000 g/ton of chlortetracycline and 30 to 600 g/ton lasalocid to provide 10 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day in at least 1 pound of feed for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone for a total time not exceeding 24 days of feeding. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xvi) 500 to 4,000 g/ton ..	.....	Calves, beef and nonlactating dairy cattle: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.	Hand feed continuously for not more than 5 days to provide 10 mg/lb body weight per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To sponsor No. 054771 under NADA 046–699: 24-hour withdrawal period. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: Zero withdrawal period.	054771 069254
(xvii) 500 to 4,000 g/ton	Decoquinate, 12.9 to 90.8.	Calves, beef and non-lactating dairy cattle: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Feed at a rate of 1g chlortetracycline per 100 lb body weight/day and 22.7 mg decoquinate per 100 lb of body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xviii) 500 to 4,000 to provide 10 mg per pound of body weight.	Melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg melengestrol acetate per head per day.	Growing beef heifers fed in confinement for slaughter: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 500 to 4,000 g/ton chlortetracycline for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xix) 500 to 4,000 to provide 10 mg per pound of body weight.	Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg melengestrol acetate per head per day.	Replacement dairy heifers less than 20 months of age and replacement beef heifers: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, and for suppression of estrus (heat).	Melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 500 to 4,000 g/ton chlortetracycline for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone for a total time not exceeding 24 days. Use in dairy heifers less than 20 months of age may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xx) 4,000 to 20,000 g/ton.	.....	Calves, beef and nonlactating dairy cattle: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.	Administer as a top dress, varying with body weight and feed consumption, to provide 10 mg/lb per day. Treat for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	054771 069254
(xxi) 4,000 to 20,000 g/ton.	Decoquinate, 90.8 to 535.7.	Calves, beef and non-lactating dairy cattle: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Feed at a rate of 1g chlortetracycline per 100 lb body weight/day and 22.7 mg decoquinate per 100 lb of body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xxii) 4,000 to 20,000 g/ton to provide 10 mg/lb of body weight per day.	Melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg melengestrol acetate per head per day.	Growing beef heifers fed in confinement for slaughter: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Top dress 0.5 to 2 pounds of this medicated feed containing both drugs onto or mix at feeding with a non-medicated feed for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxiii) 4,000 to 20,000 g/ton to provide 10 mg/lb of body weight per day.	Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg melengestrol acetate per head per day.	Replacement dairy heifers less than 20 months of age and replacement beef heifers: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, and for suppression of estrus (heat).	Top dress 0.5 to 2 pounds of this medicated feed containing both drugs onto or mix at feeding with a non-medicated feed for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone for a total time not exceeding 24 days. Use in dairy heifers less than 20 months of age may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xxiv) to provide 350 mg/head/day.	.....	Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Feed to provide chlortetracycline at the rate of 350 mg per animal daily. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Withdrawal periods: To sponsor No. 054771 under NADAs 046–699 and 049–287, No. 066104 under NADA 092–286, and No. 069254 under NADA 048–480: Withdraw 48 hours prior to slaughter. To sponsor No. 054771 under NADA 048–761 and No. 069254 under NADA 138–935 and ANADA 200–510: Zero withdrawal period.	054771 066104 069254
(xxv) to provide 350 mg/head/day.	.....	Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Feed to provide chlortetracycline at the rate of 350 mg per animal daily. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Withdrawal periods: To sponsor No. 054771 under NADAs 046–699 and 049–287, No. 066104 under NADA 092–286, and No. 069254 under NADA 048–480: Withdraw 48 hours prior to slaughter. To sponsor No. 054771 under NADA 048–761 and No. 069254 under NADA 138–935 and ANADA 200–510: Zero withdrawal period.	054771 066104 069254
(xxvi) 50 to 350 g/ton to provide 350 mg/head/day.	Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg melengestrol acetate per head per day.	Replacement beef heifers under 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for suppression of estrus (heat).	Melengestrol acetate Type C top-dress medicated feed must be top dressed or mixed at feeding with the Type C medicated feed containing 50 to 350 g/ton chlortetracycline for up to 24 days of feeding. Do not exceed 24 days of feeding. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxvii) 20 to 350 g/ton	.....	Beef cattle and replacement dairy heifers: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Feed to provide chlortetracycline at the rate of 350 mg per head per day. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: Zero withdrawal period.	054771 069254
(xxviii) 20 to 350 g/ton to provide 350 mg/head/day.	Melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg melengestrol acetate per head per day.	Growing beef heifers fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing 20 to 350 g/ton chlortetracycline. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xxix) 20 to 350 g/ton to provide 350 mg/head/day.	Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg melengestrol acetate per head per day.	Replacement dairy heifers less than 20 months of age and replacement beef heifers: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and suppression of estrus (heat).	Melengestrol acetate Type C top-dress medicated feed must be top dressed or mixed at feeding with the Type C medicated feed containing 20 to 350 g/ton chlortetracycline. Use in dairy heifers less than 20 months of age may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxx) to provide 350 mg/head/day.	Laidlomycin, 5	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for increased rate of weight and improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxxi) to provide 350 mg/head/day.	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxxii) 25 to 42.2 g/ton to provide 350 mg/head/day.	Lasalocid, 25 to 30	Cattle under 700 pounds fed in confinement for slaughter: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xxxiii) 25 to 42.2 g/ton to provide 350 mg/head/day.	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xxxiv) 25 to 100 g/ton to provide 350 mg/head/day.	Lasalocid, 10 to 30	Cattle under 700 pounds fed in confinement for slaughter: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xxxv) 25 to 100 g/ton to provide 350 mg/head/day.	Lasalocid, 10 to 30	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xxxvi) 25 to 700 to provide 350 g/head/day.	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg nor more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xxxvii) 25 to 700 g/ton to provide 350 mg/head/day.	Lasalocid, 30 to 600; melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate.	Replacement beef heifers on pasture: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, increased rate of weight gain, and suppression of estrus (heat).	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 700 g/ton of chlortetracycline and 30 to 600 g/ton lasalocid to provide 350 mg chlortetracycline per head daily and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed. Do not exceed 24 days of feeding. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xxxviii) 25 to 700 to provide 350 mg/head/day.	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, beef replacement heifers) under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg nor more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xxxix) 25 to 700 g/ton to provide 350 mg/head/day.	Lasalocid, 30 to 600; melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate.	Replacement beef heifers on pasture under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline, increased rate of weight gain, and suppression of estrus (heat).	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 700 g/ton of chlortetracycline and 30 to 600 g/ton lasalocid to provide 350 mg chlortetracycline per head daily and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed. Do not exceed 24 days of feeding. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xl) 25 to 2,800 to provide 350 mg/head/day.	Lasalocid, 30 to 181.8 ...	Beef cattle weighing under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Chlortetracycline and lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xli) 25 to 2,80 g/ton to provide 350 mg/head/day.	Lasalocid, 30 to 181.8; melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg/head/day melengestrol acetate.	Growing beef heifers fed in confinement for slaughter under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 2,800 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb. of body weight daily with a maximum of 360 mg lasalocid per head per day. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xlii) 25 to 2,800 to provide 350 mg/head/day.	Lasalocid, 30 to 181.8 ...	Beef cattle weighing up to 800 pounds: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xliii) 25 to 2,800 g/ton to provide 350 mg/head/day.	Lasalocid, 30 to 181.8; melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg/head/day melengestrol acetate.	Growing beef heifers fed in confinement for slaughter up to 800 pounds: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 2,800 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 350 mg chlortetracycline per head daily and 1 mg lasalocid per 2.2 lb. of body weight daily with a maximum of 360 mg lasalocid per head per day. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xliv) 25 to 2,800 g/ton to provide 350 mg/head/day.	Lasalocid, 30 to 181.8; melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate.	Replacement beef heifers up to 800 pounds: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* and suppression of estrus (heat).	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 2,800 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 350 mg chlortetracycline per head daily and 1 mg lasalocid per 2.2 lb. of body weight daily with a maximum of 360 mg lasalocid per head per day. Do not exceed 24 days of feeding. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xlv) 500 to 4,000 to provide 10 mg/head/day.	Lasalocid, 30 to 181.8 ...	Cattle weighing up to 800 pounds: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Hand feed continuously for not more than 5 days at a rate of 10 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xlvi) 500 to 4,000 g/ton to provide 10 mg/lb of body weight daily.	Lasalocid, 30 to 181.8; melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg/head/day melengestrol acetate.	Growing beef heifers fed in confinement for slaughter up to 800 pounds: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 500 to 4,000 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 10 mg chlortetracycline per lb of body weight per day and 1 mg lasalocid per 2.2 lb of body weight per day with a maximum of 360 mg lasalocid per head per day for not more than 5 days of feeding. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xlvii) 500 to 4,000 g/ton to provide 10 mg/lb of body weight daily.	Lasalocid, 30 to 181.8; melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate.	Replacement dairy heifers up to 800 pounds and less than 20 months of age and replacement beef heifers up to 800 pounds: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* and suppression of estrus (heat).	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 500 to 4,000 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 10 mg chlortetracycline per lb of body weight per day and 1 mg lasalocid per 2.2 lb of body weight per day with a maximum of 360 mg lasalocid per head per day for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

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■ 31. In § 558.342, revise paragraph (e)(1)(iv) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(1) * * *

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
*	*	*	*	*
(iv) 0.25 to 0.5	Monensin, 10 to 40	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat); and for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 40 g of monensin per ton to provide 0.25 to 0.5 mg melengestrol acetate/head/day and 0.14 to 0.42 mg monensin/lb body weight, depending on severity of coccidiosis challenge, up to 480 mg monensin/head/day. See § 558.355(d) of this chapter. Monensin as provided by No. 016592 or 058198; melengestrol acetate as provided by No. 016952, 054771, or 058198 in § 510.600(c) of this chapter.	016592 045771 058198

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
*	*	*	*	*

* * * * *

■ 32. In § 558.355, revise paragraphs (b)(2), (f)(2)(ii), (f)(3), and (f)(4)(i) and (ii), remove paragraph (f)(4)(v), redesignate paragraph (f)(4)(vi) as paragraph (f)(4)(v) and revise it, and revise paragraphs (f)(6)(i) and (f)(7)(viii)

The revisions read as follows:

§ 558.355 Monensin.

* * * * *

(b) * * *

(2) No. 016592 for use of a Type A medicated article containing 90.7 grams monensin, USP, per pound as in paragraphs (f)(3), (f)(4)(v), and (f)(6) of this section.

* * * * *

(f) * * *

(2) * * *

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(ii) 54 to 90	Bacitracin methylenedisalicylate, 4 to 50.	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. The optimum level depends upon the severity of coccidiosis exposure. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 054771 or 069254 in § 510.600(c) of this chapter.	058198 069254
*	*	*	*	*

(3) * * *

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 5 to 40	Growing beef steers and heifers fed in confinement for slaughter: For improved feed efficiency.	Feed continuously in complete feed at a rate of 50 to 480 milligrams of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 milligrams per head per day). See special labeling considerations in paragraph (d) of this section.	016592 058198
(ii) 10 to 40	Growing beef steers and heifers fed in confinement for slaughter: For prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day. See special labeling considerations in paragraph (d) of this section.	016592 058198
(iii) 10 to 200	Calves excluding veal calves: For prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Feed at a rate of 0.14 to 1.0 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 200 milligrams per head per day. See special labeling considerations in paragraph (d) of this section.	016592 058198
(iv) 11 to 22	Dairy cows: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).	Feed continuously to dry and lactating dairy cows in a total mixed ration (“complete feed”). See special labeling considerations in paragraph (d) of this section.	016592 058198
(v) 11 to 400	Dairy cows: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).	Feed continuously to dry and lactating dairy cows in a component feeding system (including top dress). The Type C medicated feed must be fed in a minimum of 1 lb of feed to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. See special labeling considerations in paragraph (d) of this section.	016592 058198

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(vi) 15 to 400	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) or in a dry lot and replacement beef and dairy heifers: For increased rate of weight gain, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	For increased rate of weight gain, feed at a rate of 50 to 200 milligrams monensin per head per day in not less than 1 pound of feed or, after the 5th day, feed at a rate of 400 milligrams per head per day every other day in not less than 2 pounds of feed. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending on severity of challenge, up to 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per day in not less than 1 pound of feed. See special labeling considerations in paragraph (d) of this section.	016592 058198
(vii) 25 to 400	Beef cows: For improved feed efficiency when receiving supplemental feed, and for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Feed as supplemental feed, either hand-fed in a minimum of 1 pound of feed or mixed in a total ration. For improved feed efficiency, feed continuously at a rate of 50 to 200 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon severity of challenge, up to a maximum of 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per head per day in not less than 1 pound of feed. See special labeling considerations in paragraph (d) of this section.	016592 058198

(4) * * *

Monensin amount	Indications for use	Limitations	Sponsor
(i) 150 milligrams per pound of protein-mineral block (0.033%).	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) and replacement beef heifers on pasture: For increased rate of weight gain, and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle which may require supplemental feed.	Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds of block) per head per day, at least 1 block per 10 to 12 head of cattle. Roughage must be available at all times. Do not allow animals access to other protein blocks, salt or mineral, while being fed this product. See paragraph (d)(10)(i) of this section.	012286
(ii) 175 milligrams per pound of protein-mineral block (0.038%).	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter): For increased rate of weight gain.	Provide 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day, at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. See paragraph (d)(10)(i) of this section.	017800
*	* * *	* *	*
(v) 1,620 grams per ton of mineral granules as specified in paragraph (f)(4)(v)(A) of this section.	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) or in a dry lot and replacement beef and dairy heifers: For increased rate of weight gain, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Feed at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement.	016592 058198

(A) *Specifications.* Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6–01–082
Sodium chloride (salt)	24.37	6–04–152
Dried cane molasses	20.0	4–04–695
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6–02–632

Ingredient	Percent	International feed No.
Cane molasses	3.0	4–04–696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix [1]	2.5	
Monensin Type A article, 90.7 grams per pound	0.89	
Antidusting oil	1.0	

[1] Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide should comply with FDA Compliance Policy Guide Sec. 651.100 (CPG 7125.18).

(B) [Reserved]

(6) * * *

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Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 20	Goats maintained in confinement: For the prevention of coccidiosis caused by *Eimeria crandallis, E. christenseni,* and *E. ninakohlyakimovae*.	Feed continuously. Do not feed to lactating goats. See paragraph (d)(11) of this section for provisions for monensin liquid Type C goat feeds.	016592 058198
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(7) * * *

(viii) Ractopamine as in § 558.500.

* * * * *

■ 33. In § 558.500, revise paragraphs (e)(2)(ii), (iv), (v), and (vii) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(2) * * *

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	* * *	* *	* *	*
(ii) 8.2 to 24.6 to provide 70 to 430 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in § 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
*	* * *	* *	* *	*
(iv) 9.8 to 24.6 to provide 90 to 430 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in § 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(v) 9.8 to 24.6 to provide 90 to 430 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii,* and suppression of estrus (heat) during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in §§ 558.342(d) and 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198; melengestrol acetate as provided by No. 016592, 054771 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	* *	*	* *	*
(vii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 28 to 42 days on feed.	Top dress ractopamine at a minimum of 1.0 lb/head/day of medicated feed continuously during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in § 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
*	* *	*	* *	*

* * * * *

■ 34. In § 558. 550, revise paragraphs (a), (b), (e)(1)(i), and (e)(2)(i) to read as follows:

§ 558. 550 Salinomycin.

(a) *Specifications.* Type A medicated articles containing 30 or 60 grams of salinomycin sodium activity per pound.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

* * * * *

(e) * * *

(1) * * *

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 40 to 60	.....	Broiler, roaster, and replacement (breeder and layer) chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*.	Feed continuously as sole ration. Do not feed to birds producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses.	016592
*	* *	*	* *	*

(2) * * *

Salinomycin in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 50	.....	Quail: For the prevention of coccidiosis caused by *Eimeria dispersa* and *E. lettyae*.	Feed continuously as sole ration. Do not feed to birds producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses.	016592
*	* *	*	* *	*

* * * * *

■ 35. In § 558.625, revise paragraphs (e)(2)(i) and (e)(2)(ix) through (xiii) to read as follows:

§ 558.625 Tylosin.

* * * * *

(e) * * *

(2) * * *

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8 to 10	.....	Beef cattle: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*.	Feed continuously as the sole ration to provide 60 to 90 mg/head/day tylosin.	016592 054771 058198 066104

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
(ix) 8 to 10	Monensin 10 to 40 plus melengestrol 0.25 to 2.0.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes;* for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously as sole ration to heifers at a rate of 0.5 to 2 pounds per head per day to provide 0.25 to 0.5 mg/head/day melengestrol acetate and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. The melengestrol acetate portion of this Type C medicated feed must be mixed into the complete feed containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin at feeding into the amount of complete feed consumed by an animal per day. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. See §§ 558.342(d) and 558.355(d) of this chapter. Tylosin provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; melengestrol provided by No. 016592, 054771, or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(x) 8 to 10	Monensin 10 to 40 plus ractopamine 8.2 to 24.6.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes;* for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* and for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.	Feed continuously as sole ration to provide 70 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. See special labeling considerations in §§ 558.355(d) and 558.500(d) of this chapter. Tylosin provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; ractopamine provided by No. 016592, 054771, or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(xi) 8 to 10	Monensin 10 to 40 plus ractopamine, not to exceed 800.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes;* for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* and for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.	Feed a minimum of 1.0 lb/head/day ractopamine Type C top dress feed continuously to cattle fed in confinement for slaughter, to provide 70 to 400 mg/head/day ractopamine for the last 28 to 42 days on feed. Feed on top of a ration containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin phosphate, to provide 0.14 to 0.42 mg monensin/lb body weight/day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. See special labeling considerations in §§ 558.355(d) and 558.500(d) of this chapter. Tylosin provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; ractopamine provided by No. 016592, 054771, or 058198 in § 510.600(c) of this chapter.	016592 054771 058198

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xii) 8 to 10	Monensin 10 to 40 plus ractopamine 9.8 to 24.6.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes;* for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.	Feed continuously as sole ration to provide 90 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. See special labeling considerations in §§ 558.355(d) and 558.500(d) of this chapter. Tylosin as provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; ractopamine as provided by No. 016592, 054771, or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(xiii) 8 to 10	Monensin, 10 to 40 plus ractopamine, 9.8 to 24.6, plus melengestrol, 0.125 to 1 mg/lb.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes;* for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed.	Feed continuously as sole ration to provide 90 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. Feed melengestrol as a top dress or mixed with a complete ration at the rate of 0.5 to 2.0 pound/head/day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate/head/day (specify one level). A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. See special labeling considerations in §§ 558.342(d), 558.355(d), and 558.500(d) of this chapter. Tylosin provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; ractopamine as provided by No. 016592, 054771, or 058198; melengestrol acetate as provided by No. 016592 or 054771 in § 510.600(c) of this chapter.	016592 054771 058198
*	*	*	*	*	*	*

* * * * *

Dated: October 12, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–22604 Filed 10–19–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Web General License 7 and Subsequent Iterations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing four Venezuela-related web general licenses (GLs) in the **Federal Register***:* GL 7, GL 7A, and GL 7B, each of which is now expired and was previously issued on OFAC's website, as well as GL 7C, which was also previously issued on OFAC's website.

DATES: GL 7C was issued on August 5, 2019. See **SUPPLEMENTARY INFORMATION** of this document for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treasury.gov/ofac.*

Background

On March 8, 2015, the President, invoking the authority of, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), issued Executive Order (E.O.) 13692, ''Blocking Property and Suspending Entry of Persons Contributing to the

Situation in Venezuela'' (80 FR 12747, March 11, 2015). In E.O. 13692, the President found that the situation in Venezuela, including the Government of Venezuela's erosion of human rights guarantees, persecution of political opponents, curtailment of press freedoms, use of violence and human rights violations and abuses in response to antigovernment protests, and arbitrary arrest and detention of antigovernment protestors, as well as the exacerbating presence of significant public corruption, constitutes an unusual and extraordinary threat to the national security and foreign policy of the United States, and declared a national emergency to deal with that threat.

The President issued six additional E.O.s pursuant to the national emergency declared in E.O. 13692: E.O. 13808 of August 24, 2017, ''Imposing Additional Sanctions With Respect to the Situation in Venezuela'' (82 FR 41155, August 29, 2017); E.O. 13827 of March 19, 2018, ''Taking Additional Steps to Address the Situation in Venezuela'' (83 FR 12469, March 21, 2018); E.O. 13835 of May 21, 2018, ''Prohibiting Certain Additional Transactions With Respect to Venezuela'' (83 FR 24001, May 24, 2018); E.O. 13850 of November 1, 2018, ''Blocking Property of Additional Persons Contributing to the Situation in Venezuela'' (83 FR 55243, November 2, 2018); E.O. 13857 of January 25, 2019, ''Taking Additional Steps To Address the National Emergency With Respect to Venezuela'' (84 FR 509, January 30, 2019); and E.O. 13884 of August 5, 2019, ''Blocking Property of the Government of Venezuela'' (84 FR 38843, August 7, 2019).

OFAC, in consultation with the Department of State, issued GL 7 on January 28, 2019, pursuant to E.O. 13850, as amended. Paragraph (a) of GL 7 authorized certain transactions and activities with respect to PDV Holding, Inc. (PDVH), CITGO Holding, Inc., and any of their subsidiaries. Paragraph (b) of GL 7 authorized PDVH, CITGO Holding, Inc., and any of their subsidiaries to engage in certain transactions and activities ordinarily incident and necessary to the purchase and importation of petroleum and petroleum products from PdVSA and any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest. Subsequently, OFAC issued three further iterations of GL 7, which extended the authorization, and in later iterations, modified the scope of the authorization, and incorporated additional Executive orders.

The authorization found in paragraph (a) of GL 7 was valid through 12:01 a.m. eastern daylight time, July 27, 2019. The authorization found in paragraph (a) in each of GLs 7A, 7B, and 7C automatically renews on the first day of each month and is valid for a period of 18 months from the effective date of the respective GL or the date of any subsequent renewal of the respective GL, whichever is later. As such, the authorization found in paragraph (a) of GL 7C remains effective until it is revoked by OFAC or until GL 7C is superseded by a subsequent renewal. The authorization found in paragraph (b) in each of GLs 7, 7A, 7B, and 7C expired on April 28, 2019.

On March 14, 2019, OFAC issued GL 7A, which replaced and superseded GL 7; on June 6, 2019, OFAC issued GL 7B, which replaced and superseded GL 7A; and on August 5, 2019, OFAC issued GL 7C, which replaced and superseded GL 7B. The texts of the following four Venezuela GLs are provided below: GLs 7, 7A, 7B, and 7C.

OFFICE OF FOREIGN ASSETS CONTROL

Executive Order 13850 of November 1, 2018—Blocking Property of Additional Persons Contributing to the Situation in Venezuela

GENERAL LICENSE NO. 7

Authorizing Certain Activities Involving PDV Holding, Inc. and CITGO Holding, Inc.

(a) Except as provided in paragraphs (c) and (d) of this general license, all transactions and activities prohibited by Executive Order 13850 with respect to PDV Holding, Inc. (PDVH), CITGO Holding, Inc., and any of their subsidiaries are authorized, where the only Petróleos de Venezuela, S.A. (PdVSA) entities involved are PDVH, CITGO Holding, Inc., or any of their subsidiaries. This authorization is valid through 12:01 a.m. eastern daylight time, July 27, 2019.

(b) Except as provided in paragraphs (c) and (d) of this general license, PDVH, CITGO Holding, Inc., and any of their subsidiaries are authorized to engage in all transactions and activities prohibited by Executive Order 13850 that are ordinarily incident and necessary to the purchase and importation of petroleum and petroleum products from PdVSA and any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest. This authorization is valid through 12:01 a.m. eastern daylight time, April 28, 2019.

(c) Any payment to or for the direct or indirect benefit of a blocked person other than PDVH, CITGO Holding, Inc., and any of their subsidiaries that is ordinarily incident and necessary to give effect to transactions authorized in paragraphs (a) or (b) of this general license must be made into a blocked, interest-bearing account located in the United States in accordance with 31 CFR 591.203.

(d) This general license does not authorize:

(1) Any exportation or reexportation of any goods, services, or technology, directly or indirectly, by U.S. persons, wherever located, or from the United States, to PdVSA or any entity owned 50 percent or more, directly or indirectly, by PdVSA, other than PDVH, CITGO Holding, Inc., or any of their subsidiaries, or to any other blocked persons;

(2) Any transaction that is otherwise prohibited under Executive Order 13850 of November 1, 2018, Executive Order 13835 of May 21, 2018, Executive Order 13827 of March 19, 2018, Executive Order 13808 of August 24, 2017, Executive Order 13692 of March 8, 2015, or any part of 31 CFR chapter V, or any transactions or dealings with any blocked person other than the transactions described in paragraphs (a) and (b) of this general license; or

(3) The unblocking of any property blocked pursuant to any part of 31 CFR chapter V, except as authorized by paragraphs (a) or (b).

Dated: January 28, 2019.

Andrea Gacki,

Director, Office of Foreign Assets Control.

OFFICE OF FOREIGN ASSETS CONTROL

Executive Order 13850 of November 1, 2018—Blocking Property of Additional Persons Contributing to the Situation in Venezuela

GENERAL LICENSE NO. 7A

Authorizing Certain Activities Involving PDV Holding, Inc. and CITGO Holding, Inc.

(a) Except as provided in paragraphs (c) and (d) of this general license, all transactions and activities prohibited by Executive Order 13850 with respect to PDV Holding, Inc. (PDVH), CITGO Holding, Inc., and any of their subsidiaries are authorized, where the only Petróleos de Venezuela, S.A. (PdVSA) entities involved are PDVH, CITGO Holding, Inc., or any of their subsidiaries. This authorization automatically renews on the first day of each month, and is valid for a period of 18 months from the effective date of General License No. 7A or the date of any subsequent renewal of General License No. 7A, whichever is later.

(b) Except as provided in paragraphs (c) and (d) of this general license, PDVH, CITGO Holding, Inc., and any of their subsidiaries are authorized to engage in all transactions and activities prohibited by Executive Order 13850 that are ordinarily incident and necessary to the purchase and importation of petroleum and petroleum products from PdVSA and any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest. This authorization is valid through 12:01 a.m. eastern daylight time, April 28, 2019.

(c) Any payment to or for the direct or indirect benefit of a blocked person other than PDVH, CITGO Holding, Inc., and any of their subsidiaries that is ordinarily incident and necessary to give effect to transactions authorized in paragraphs (a) or (b) of this general license must be made into a blocked, interest-bearing account located in the United States in accordance with 31 CFR 591.203.

(d) This general license does not authorize:

(1) Any exportation or reexportation of any goods, services, or technology, directly or

indirectly, by U.S. persons, wherever located, or from the United States, to PdVSA or any entity owned 50 percent or more, directly or indirectly, by PdVSA, other than PDVH, CITGO Holding, Inc., or any of their subsidiaries, or to any other blocked persons;

(2) Any transaction that is otherwise prohibited under Executive Order 13850 of November 1, 2018, Executive Order 13835 of May 21, 2018, Executive Order 13827 of March 19, 2018, Executive Order 13808 of August 24, 2017, Executive Order 13692 of March 8, 2015, or any part of 31 CFR chapter V, or any transactions or dealings with any blocked person other than the transactions described in paragraphs (a) and (b) of this general license; or

(3) The unblocking of any property blocked pursuant to any part of 31 CFR chapter V, except as authorized by paragraphs (a) or (b).

(e) Effective March 14, 2019, General License No. 7, dated January 28, 2019, is replaced and superseded in its entirety by this General License No. 7A.

Andrea Gacki,

Director, Office of Foreign Assets Control.

Dated: March 14, 2019.

OFFICE OF FOREIGN ASSETS CONTROL

Executive Order 13850 of November 1, 2018—Blocking Property of Additional Persons Contributing to the Situation in Venezuela

GENERAL LICENSE NO. 7B

Authorizing Certain Activities Involving PDV Holding, Inc. and CITGO Holding, Inc.

(a) Except as provided in paragraphs (c) and (d) of this general license, all transactions and activities prohibited by Executive Order (E.O.) 13850, as amended by E.O. 13857 of January 25, 2019, with respect to PDV Holding, Inc. (PDVH), CITGO Holding, Inc., and any of their subsidiaries are authorized, where the only Petróleos de Venezuela, S.A. (PdVSA) entities involved are PDVH, CITGO Holding, Inc., or any of their subsidiaries. This authorization automatically renews on the first day of each month, and is valid for a period of 18 months from the effective date of General License No. 7B or the date of any subsequent renewal of General License No. 7B, whichever is later.

(b) Except as provided in paragraphs (c) and (d) of this general license, PDVH, CITGO Holding, Inc., and any of their subsidiaries are authorized to engage in all transactions and activities prohibited by E.O. 13850 that are ordinarily incident and necessary to the purchase and importation of petroleum and petroleum products from PdVSA and any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest. This authorization is valid through 12:01 a.m. eastern daylight time, April 28, 2019.

(c) Any payment to or for the direct or indirect benefit of a blocked person other than PDVH, CITGO Holding, Inc., and any of their subsidiaries that is ordinarily incident and necessary to give effect to transactions authorized in paragraphs (a) or (b) of this general license must be made into a blocked, interest-bearing account located in the United States in accordance with 31 CFR 591.203.

(d) This general license does not authorize:

(1) Any exportation or reexportation of any goods, services, or technology, directly or indirectly, by U.S. persons, wherever located, or from the United States, to PdVSA or any entity owned 50 percent or more, directly or indirectly, by PdVSA, other than PDVH, CITGO Holding, Inc., or any of their subsidiaries, or to any other blocked persons;

(2) Any transactions or dealings related to the exportation or reexportation of diluents, directly or indirectly, to Venezuela;

(3) Any transaction that is otherwise prohibited by E.O. 13850, E.O. 13835 of May 21, 2018, E.O. 13827 of March 19, 2018, E.O. 13808 of August 24, 2017, E.O. 13692 of March 8, 2015, each as amended by E.O. 13857, or any part of 31 CFR chapter V, or any transactions or dealings with any blocked person other than the transactions described in paragraphs (a) and (b) of this general license; or

(4) The unblocking of any property blocked pursuant to any part of 31 CFR chapter V, except as authorized by paragraphs (a) or (b).

(e) Effective June 6, 2019, General License No. 7A, dated March 14, 2019, is replaced and superseded in its entirety by this General License No. 7B.

Andrea Gacki,

Director, Office of Foreign Assets Control.

Dated: June 6, 2019

OFFICE OF FOREIGN ASSETS CONTROL

Executive Order 13850 of November 1, 2018—Blocking Property of Additional Persons Contributing to the Situation in Venezuela

Executive Order of August 5, 2019—Blocking Property of the Government of Venezuela

GENERAL LICENSE NO. 7C

Authorizing Certain Activities Involving PDV Holding, Inc. and CITGO Holding, Inc.

(a) Except as provided in paragraphs (c) and (d) of this general license, all transactions and activities prohibited by Executive Order (E.O.) 13850, as amended by E.O. 13857 of January 25, 2019, or E.O. of August 5, 2019, with respect to PDV Holding, Inc. (PDVH), CITGO Holding, Inc., and any of their subsidiaries are authorized, where the only Government of Venezuela entities involved are PDVH, CITGO Holding, Inc., or any of their subsidiaries. This authorization automatically renews on the first day of each month, and is valid for a period of 18 months from the effective date of General License No. 7C or the date of any subsequent renewal of General License No. 7C, whichever is later.

(b) Except as provided in paragraphs (c) and (d) of this general license, PDVH, CITGO Holding, Inc., and any of their subsidiaries are authorized to engage in all transactions and activities prohibited by E.O. 13850, as amended, that are ordinarily incident and necessary to the purchase and importation of petroleum and petroleum products from Petróleos de Venezuela, S.A. (PdVSA) and any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest. This authorization is valid through 12:01 a.m. eastern daylight time, April 28, 2019.

(c) Any payment to or for the direct or indirect benefit of a blocked person other than PDVH, CITGO Holding, Inc., and any of their subsidiaries that is ordinarily incident and necessary to give effect to transactions authorized in paragraphs (a) or (b) of this general license must be made into a blocked, interest-bearing account located in the United States in accordance with 31 CFR 591.203.

(d) This general license does not authorize:

(1) Any exportation or reexportation of any goods, services, or technology, directly or indirectly, by U.S. persons, wherever located, from the United States to the Government of Venezuela, other than to PDVH, CITGO Holding, Inc., or any of their subsidiaries, or to any other blocked persons;

(2) Any transactions or dealings related to the exportation or reexportation of diluents, directly or indirectly, to Venezuela;

(3) Any transaction that is otherwise prohibited by E.O. of August 5, 2019, or E.O. 13850, E.O. 13835 of May 21, 2018, E.O. 13827 of March 19, 2018, E.O. 13808 of August 24, 2017, or E.O. 13692 of March 8, 2015, each as amended by E.O. 13857, or any part of 31 CFR chapter V, or any transactions or dealings with any blocked person other than the transactions described in paragraphs (a) and (b) of this general license; or

(4) The unblocking of any property blocked pursuant to any part of 31 CFR chapter V, except as authorized by paragraphs (a) or (b).

(e) Effective August 5, 2019, General License No. 7B, dated June 6, 2019, is replaced and superseded in its entirety by this General License No. 7C.

Andrea Gacki,

Director, Office of Foreign Assets Control.

Dated: August 5, 2019.

Dated: October 15, 2021.

Bradley T. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2021–22834 Filed 10–19–21; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 425, 455, and 495

[CMS–1752–F2 and CMS–1762–F2]

RIN 0938–AU44 and 0938–AU56

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program; Corrections

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule; correction and correcting amendment.

SUMMARY: This document corrects technical and typographical errors in the final rule that appeared in the August 13, 2021, issue of the **Federal Register** titled ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program.''

DATES:

Effective date: The final rule corrections and correcting amendment are effective on October 19, 2021.

Applicability date: The final rule corrections and correcting amendment are applicable to discharges occurring on or after October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Donald Thompson, (410) 786–4487, and Michele Hudson, (410) 786–4487, Operating Prospective Payment, Wage Index, Hospital Geographic Reclassifications, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Graduate Medical Education, and Critical Access Hospital (CAH) Issues. Mady Hue, (410) 786–4510, and Andrea Hazeley, (410) 786–3543, MS–DRG Classification Issues.

Allison Pompey, (410) 786–2348, New Technology Add-On Payments Issues. Julia Venanzi, *julia.venanzi@cms.hhs.gov,* Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2021–16519 of August 13, 2021 (86 FR 44774), there were a number of technical and typographical errors that are identified and corrected in this final rule correction and correcting amendment. The final rule corrections and correcting amendment are applicable to discharges occurring on or after October 1, 2021, as if they had been included in the document that appeared in the August 13, 2021, **Federal Register**.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 44878, we are correcting an inadvertent error in the reference to the number of technologies for which we proposed to allow a one-time extension of new technology add-on payments for fiscal year (FY) 2022.

On page 44889, we are correcting an inadvertent typographical error in the International Classification of Disease, 10th Revision, Procedure Coding System (ICD–10–PCS) procedure code describing the percutaneous endoscopic repair of the esophagus.

On page 44960, in the table displaying the Medicare-Severity Diagnosis Related Groups (MS–DRGs) subject to the policy for replaced devices offered without cost or with a credit for FY 2022, we are correcting inadvertent typographical errors in the MS–DRGs describing Hip Replacement with Principal Diagnosis of Hip Fracture with and without MCC, respectively.

On pages 45047, 45048, and 45049, in our discussion of the new technology add-on payments for FY 2022, we are correcting typographical and technical errors in referencing sections of the final rule.

On page 45133, we are correcting an error in the maximum new technology add-on payment for a case involving the use of Aprevo™ Intervertebral Body Fusion Device.

On page 45150, we inadvertently omitted ICD–10–CM codes from the list of diagnosis codes used to identify cases involving the use of the INTERCEPT Fibrinogen Complex that would be eligible for new technology add-on payments.

On page 45157, we inadvertently omitted the ICD–10–CM diagnosis codes used to identify cases involving the use of FETROJA® for HABP/VABP.

On page 45158, we inadvertently omitted the ICD–10–CM diagnosis codes used to identify cases involving the use of RECARBRIO™ for HABP/VABP.

On pages 45291, 45293, and 45294, in three tables that display previously established, newly updated, and estimated performance standards for measures included in the Hospital Value-Based Purchasing Program, we are correcting errors in the numerical values for all measures in the Clinical Outcomes Domain that appear in the three tables.

On page 45312, in our discussion of payments for indirect and direct graduate medical education costs and Intern and Resident Information System (IRIS) data, we made a typographical error in our response to a comment.

On page 45386, we made an inadvertent typographical error in our discussion of the Hospital Inpatient Quality Reporting (IQR) Program Severe Hyperglycemia electronic clinical quality measure (eCQM).

On page 45400, in our discussion of the Hospital Inpatient Quality Reporting (IQR) Program measures for fiscal year (FY) 2024, we mislabeled the table title and inadvertently included a measure not pertaining to the FY 2024 payment determination along with its corresponding footnote.

On page 45404, in our discussion the Hospital Inpatient Quality Reporting (IQR) Program, we included a table with the measures for the FY 2025 payment determination. In the notes that immediately followed the table, we made a typographical error in the date associated with the voluntary reporting period for the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure.

B. Summary of Errors in the Regulations Text

On page 45521, in the regulations text for § 413.24(f)(5)(i) introductory text and (f)(5)(i)(A) regarding cost reporting forms and teaching hospitals, we inadvertently omitted revisions that were discussed in the preamble.

C. Summary of Errors in the Addendum

In the FY 2022 Hospital Inpatient Prospective Payment Systems and Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) final rule (85 FR 45166), we stated that we excluded the wage data for critical access hospitals (CAHs) as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation

of the wage index. We inadvertently excluded a hospital that converted to CAH status after January 24, 2021, the cut-off date for CAH exclusion from the FY 2022 wage index. (CMS Certification Number (CCN) 230118) Therefore, we restored the wage data for this hospital and included it in our calculation of the wage index. This correction necessitated the recalculation of the FY 2022 wage index for rural Michigan (rural state code 23), as reflected in Table 3, and affected the final FY 2022 wage index for rural Michigan 23 as well as the rural floor for the State of Michigan. As discussed in this section, the final FY 2022 IPPS wage index is used when determining total payments for purposes of all budget neutrality factors (except for the MS–DRG reclassification and recalibration budget neutrality factor) and the final outlier threshold.

We note, in the final rule, we correctly listed the number of hospitals with CAH status removed from the FY 2022 wage index (86 FR 45166), the number of hospitals used for the FY 2022 wage index (86 FR 45166) and the number of hospital occupational mix surveys used for the FY 2022 wage index (86 FR 45173). Additionally, the FY 2022 national average hourly wage (unadjusted for occupational mix) (86 FR 45172), the FY 2022 occupational mix adjusted national average hourly wage (86 FR 45173), and the FY 2022 national average hourly wages for the occupational mix nursing subcategories (86 FR 45174) listed in the final rule remain unchanged. Because the numbers and values noted previously are correctly stated in the preamble of the final rule and remain unchanged, we do not include any corrections in section IV.A. of this final rule correction and correcting amendment.

We made an inadvertent error in the Medicare Geographic Classification Review Board (MGCRB) reclassification status of one hospital in the FY 2022 IPPS/LTCH PPS final rule. Specifically, CCN 360259 is incorrectly listed in Table 2 as reclassified to CBSA 19124. The correct reclassification area is to its geographic ''home'' of CBSA 45780. This correction necessitated the recalculation of the FY 2022 wage index for CBSA 19124 and affected the final FY 2022 wage index with reclassification. The final FY 2022 IPPS wage index with reclassification is used when determining total payments for purposes of all budget neutrality factors (except for the MS–DRG reclassification and recalibration budget neutrality factor and the wage index budget neutrality adjustment factor) and the final outlier threshold.

As discussed further in section II.E. of this final rule correction and correcting amendment, we made updates to the calculation of Factor 3 of the uncompensated care payment methodology to reflect updated information on hospital mergers received in response to the final rule and made corrections for report upload errors. Factor 3 determines the total amount of the uncompensated care payment a hospital is eligible to receive for a fiscal year. This hospital-specific payment amount is then used to calculate the amount of the interim uncompensated care payments a hospital receives per discharge. Per discharge uncompensated care payments are included when determining total payments for purposes of all of the budget neutrality factors and the final outlier threshold. As a result, the revisions made to the calculation of Factor 3 to address additional merger information and report upload errors directly affected the calculation of total payments and required the recalculation of all the budget neutrality factors and the final outlier threshold.

Due to the correction of the combination of errors that are discussed previously (correcting the number of hospitals with CAH status, the correction to the MGCRB reclassification status of one hospital, and the revisions to Factor 3 of the uncompensated care payment methodology), we recalculated all IPPS budget neutrality adjustment factors, the fixed-loss cost threshold, the final wage indexes (and geographic adjustment factors (GAFs)), the national operating standardized amounts and capital Federal rate. We note that the fixed-loss cost threshold was unchanged after these recalculations. Therefore, we made conforming changes to the following:

- On page 45532, the table titled ''Summary of FY 2022 Budget Neutrality Factors''.
- On page 45537, the estimated total Federal capital payments and the estimated capital outlier payments.
- On pages 45542 and 45543, the calculation of the outlier fixed-loss cost threshold, total operating Federal payments, total operating outlier payments, the outlier adjustment to the capital Federal rate and the related discussion of the percentage estimates of operating and capital outlier payments.
- On page 45545, the table titled ''Changes from FY 2021 Standardized Amounts to the FY 2022 Standardized Amounts''.

On pages 45553 through 45554, in our discussion of the determination of the Federal hospital inpatient capital related prospective payment rate update, due to the recalculation of the GAFs, we have made conforming corrections to the capital Federal rate. As a result of these changes, we also made conforming corrections in the table showing the comparison of factors and adjustments for the FY 2021 capital Federal rate and FY 2022 capital Federal rate. As we noted in the final rule, the capital Federal rate is calculated using unrounded budget neutrality and outlier adjustment factors. The unrounded GAF/DRG budget neutrality factor, the unrounded Quartile/Cap budget neutrality factor, and the unrounded outlier adjustment to the capital Federal rate were revised because of these errors. However, after rounding these factors to 4 decimal places as displayed in the final rule, the rounded factors were unchanged from the final rule.

On pages 45570 and 45571, we are making conforming corrections to the national adjusted operating standardized amounts and capital standard Federal payment rate (which also include the rates payable to hospitals located in Puerto Rico) in Tables 1A, 1B, 1C, and 1D as a result of the conforming corrections to certain budget neutrality factors, as previously described.

D. Summary of Errors in the Appendices

On pages 45576 through 45580, 45582 through 45583, and 45598 through 45600, in our regulatory impact analyses, we have made conforming corrections to the factors, values, and tables and accompanying discussion of the changes in operating and capital IPPS payments for FY 2022 and the effects of certain IPPS budget neutrality factors as a result of the technical errors that lead to changes in our calculation of the operating and capital IPPS budget neutrality factors, outlier threshold, final wage indexes, operating standardized amounts, and capital Federal rate (as described in section II.C. of this final rule correction and correcting amendment). These conforming corrections include changes to the following:

- On pages 45576 through 45578, the table titled ''Table I—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2022''.
- On pages 45582 and 45583, the table titled ''Table II—Impact Analysis of Changes for FY 2022 Acute Care Hospital Operating Prospective Payment System (Payments per discharge)''.
- On pages 45599 and 45600, the table titled ''Table III—Comparison of

Total Payments per Case [FY 2021 Payments Compared to FY 2022 Payments]''.

On pages 45584 and 45585 we are correcting the maximum new-technology add-on payment for a case involving the use of Fetroja, Recarbrio, Tecartus, and Abecma and related information in the untitled tables as well as making conforming corrections to the total estimated FY 2022 payments in the accompanying discussion of applications approved or conditionally approved for new technology add-on payments.

On pages 45587 through 45589, we are correcting the discussion of the ''Effects of the Changes to Medicare DSH and Uncompensated Care Payments for FY 2022'' for purposes of the Regulatory Impact Analysis in Appendix A of the FY 2022 IPPS/LTCH PPS final rule, including the table titled ''Modeled Uncompensated Care Payments for Estimated FY 2022 DSHs by Hospital Type: Uncompensated Care Payments ($ in Millions)*—from FY 2021 to FY 2022'', in light of the corrections discussed in section II.E. of this final rule correction and correcting amendment.

On pages 45610 and 45611, we are making conforming corrections to the estimated expenditures under the IPPS as a result of the corrections to the maximum new technology add-on payment for a case involving the use of Aprevo™ Intervertebral Body Fusion Device, Fetroja, Recarbrio, Abecma, and Tecartus as described in this section and in section II.A. of this final rule correction and correcting amendment.

E. Summary of Errors in and Corrections to Files and Tables Posted on the CMS Website

We are correcting the errors in the following IPPS tables that are listed on pages 45569 and 45570 of the FY 2022 IPPS/LTCH PPS final rule and are available on the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* The tables that are available on the internet have been updated to reflect the revisions discussed in this final rule correction and correcting amendment.

Table 2—Case-Mix Index and Wage Index Table by CCN–FY 2022 Final Rule. As discussed in section II.C. of this final rule correction and correcting amendment, we inadvertently excluded a hospital that converted to CAH status after January 24, 2021, the cut-off date for CAH exclusion from the FY 2022 wage index. (CMS Certification Number (CCN) 230118). Therefore, we restored provider 230118 to the table. Also, as discussed in section II.C. of this final rule correction and correcting amendment, CCN 360259 is incorrectly listed as reclassified to CBSA 19124. The correct reclassification area is to its geographic ''home'' of CBSA 45780. In this table, we are correcting the columns titled ''Wage Index Payment CBSA'' and ''MGCRB Reclass'' to accurately reflect its reclassification to CBSA 45780. This correction necessitated the recalculation of the FY 2022 wage index for CBSA 19124. As also discussed later in this section, because the wage indexes are one of the inputs used to determine the out-migration adjustment, some of the out-migration adjustments changed. Therefore, we are making corresponding changes to the affected values.

Table 3.—Wage Index Table by CBSA—FY 2022 Final Rule. As discussed in section II.C. of this final rule correction and correcting amendment, we inadvertently excluded a hospital that converted to CAH status after January 24, 2021, the cut-off date for CAH exclusion from the FY 2022 wage index. (CMS Certification Number (CCN) 230118). Therefore, we recalculated the wage index for rural Michigan (rural state code 23), as reflected in Table 3, as well as the rural floor for the State of Michigan. Also, as discussed in section II.C. of this final rule correction and correcting amendment, CCN 360259 is incorrectly listed as reclassified to CBSA 19124. The correct reclassification area is to its geographic ''home'' of CBSA 45780. In this table, we are correcting the values that changed as a result of these corrections as well as any corresponding changes.

Table 4A.—List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2022 Final Rule. As discussed in section II.C. of this final rule correction and correcting amendment, we inadvertently excluded a hospital that converted to CAH status after January 24, 2021, the cut-off date for CAH exclusion from the FY 2022 wage index. (CMS Certification Number (CCN) 230118). Also, as discussed in section II.C. of this final rule correction and correcting amendment, CCN 360259 is incorrectly listed as reclassified to CBSA 19124. The correct reclassification area is to its geographic ''home'' of CBSA 45780. As a result, as discussed previously, we are making changes to the FY 2022 wage indexes. Because the wage indexes are one of the inputs used to determine the out-migration adjustment, some of the out-migration adjustments changed. Therefore, we are making corresponding changes to some of the out-migration adjustments listed in Table 4A.

Table 6B.—New Procedure Codes—FY 2022. We are correcting this table to reflect the assignment of procedure codes XW033A7 (Introduction of ciltacabtagene autoleucel into peripheral vein, percutaneous approach, new technology group 7) and XW043A7 (Introduction of ciltacabtagene autoleucel into central vein, percutaneous approach, new technology group 7) to Pre-MDC MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies). Table 6B inadvertently omitted Pre-MDC MS–DRG 018 in Column E (MS–DRG) for assignment of these codes. Effective with discharges on and after April 1, 2022, conforming changes will be reflected in the Version 39.1 ICD–10 MS–DRG Definitions Manual and ICD–10 MS–DRG Grouper and Medicare Code Editor software.

Table 6P.—ICD–10–CM and ICD–10–PCS Codes for MS–DRG Changes—FY 2022. We are correcting Table 6P.1d associated with the final rule to reflect three procedure codes submitted by the requestor that were inadvertently omitted, resulting in 79 procedure codes listed instead of 82 procedure codes as indicated in the final rule (see pages 44808 and 44809).

Table 18.—Final FY 2022 Medicare DSH Uncompensated Care Payment Factor 3. For the FY 2022 IPPS/LTCH PPS final rule, we published a list of hospitals that we identified to be subsection (d) hospitals and subsection (d) Puerto Rico hospitals projected to be eligible to receive interim uncompensated care payments for FY 2022. As stated in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45249), we allowed the public an additional period after the issuance of the final rule to review and submit comments on the accuracy of the list of mergers that we identified in the final rule. Based on the comments received during this additional period, we are updating this table to reflect the merger information received in response to the final rule and to revise the Factor 3 calculations for purposes of determining uncompensated care payments for the FY 2022 IPPS/LTCH PPS final rule. We are revising Factor 3 for all hospitals to reflect the updated merger information received in response to the final rule. We are also revising the amount of the total uncompensated care payment calculated for each DSH eligible hospital. The total uncompensated care payment that a hospital receives is used to calculate the amount of the interim uncompensated care payments the hospital receives per discharge;

accordingly, we have also revised these amounts for all DSH eligible hospitals. These corrections will be reflected in Table 18 and the Medicare DSH Supplemental Data File. Per discharge uncompensated care payments are included when determining total payments for purposes of all of the budget neutrality factors and the final outlier threshold. As a result, these corrections to uncompensated care payments required the recalculation of all the budget neutrality factors as well as the outlier fixed-loss cost threshold. We note that the fixed-loss cost threshold was unchanged after these recalculations. In section IV.C. of this final rule correction and correcting amendment, we have made corresponding revisions to the discussion of the ''Effects of the Changes to Medicare DSH and Uncompensated Care Payments for FY 2022'' for purposes of the Regulatory Impact Analysis in Appendix A of the FY 2022 IPPS/LTCH PPS final rule to reflect the corrections discussed previously and to correct minor typographical errors. The files that are available on the internet have been updated to reflect the corrections discussed in this final rule correction and correcting amendment.

In addition, we are correcting the inadvertent omission of the following 32 ICD–10–PCS codes describing percutaneous cardiovascular procedures involving one, two, three or four arteries from the GROUPER logic for MS–DRG 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents) and MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents).

ICD-10-PCS code	Description
02703Z6	Dilation of coronary artery, one artery, bifurcation, percutaneous approach.
02703ZZ	Dilation of coronary artery, one artery, percutaneous approach.
02704Z6	Dilation of coronary artery, one artery, bifurcation, percutaneous endoscopic approach.
02704ZZ	Dilation of coronary artery, one artery, percutaneous endoscopic approach.
02C03Z6	Extirpation of matter from coronary artery, one artery, bifurcation, percutaneous approach.
02C03ZZ	Extirpation of matter from coronary artery, one artery, percutaneous approach.
02C04Z6	Extirpation of matter from coronary artery, one artery, bifurcation, percutaneous endoscopic approach.
02C04ZZ	Extirpation of matter from coronary artery, one artery, percutaneous endoscopic approach.
02713Z6	Dilation of coronary artery, two arteries, bifurcation, percutaneous approach.
02713ZZ	Dilation of coronary artery, two arteries, percutaneous approach.
02714Z6	Dilation of coronary artery, two arteries, bifurcation, percutaneous endoscopic approach.
02714ZZ	Dilation of coronary artery, two arteries, percutaneous endoscopic approach.
02C13Z6	Extirpation of matter from coronary artery, two arteries, bifurcation, percutaneous approach.
02C13ZZ	Extirpation of matter from coronary artery, two arteries, percutaneous approach.
02C14Z6	Extirpation of matter from coronary artery, two arteries, bifurcation, percutaneous endoscopic approach.
02C14ZZ	Extirpation of matter from coronary artery, two arteries, percutaneous endoscopic approach.
02723Z6	Dilation of coronary artery, three arteries, bifurcation, percutaneous approach.
02723ZZ	Dilation of coronary artery, three arteries, percutaneous approach.
02724Z6	Dilation of coronary artery, three arteries, bifurcation, percutaneous endoscopic approach.
02724ZZ	Dilation of coronary artery, three arteries, percutaneous endoscopic approach.
02C23Z6	Extirpation of matter from coronary artery, three arteries, bifurcation, percutaneous approach.
02C23ZZ	Extirpation of matter from coronary artery, three arteries, percutaneous approach.
02C24Z6	Extirpation of matter from coronary artery, three arteries, bifurcation, percutaneous endoscopic approach.
02C24ZZ	Extirpation of matter from coronary artery, three arteries, percutaneous endoscopic approach.
02733Z6	Dilation of coronary artery, four or more arteries, bifurcation, percutaneous approach.
02733ZZ	Dilation of coronary artery, four or more arteries, percutaneous approach.
02734Z6	Dilation of coronary artery, four or more arteries, bifurcation, percutaneous endoscopic approach.
02734ZZ	Dilation of coronary artery, four or more arteries, percutaneous endoscopic approach.
02C33Z6	Extirpation of matter from coronary artery, four or more arteries, bifurcation, percutaneous approach.
02C33ZZ	Extirpation of matter from coronary artery, four or more arteries, percutaneous approach.
02C34Z6	Extirpation of matter from coronary artery, four or more arteries, bifurcation, percutaneous endoscopic approach.
02C34ZZ	Extirpation of matter from coronary artery, four or more arteries, percutaneous endoscopic approach.

We have corrected the ICD–10 MS–DRG Definitions Manual Version 39 and the ICD–10 MS–DRG GROUPER and MCE Version 39 Software to correctly reflect the inclusion of these codes in the arterial logic lists for MS–DRGs 246 and 248 for FY 2022.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rulemaking in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rulemaking in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date APA requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe that this final rule correction and correcting amendment does not constitute a rule that would be subject to the notice and comment or

delayed effective date requirements. This document corrects technical and typographical errors in the preamble, regulations text, addendum, payment rates, tables, and appendices included or referenced in the FY 2022 IPPS/LTCH PPS final rule, but does not make substantive changes to the policies or payment methodologies that were adopted in the final rule. As a result, this final rule correction and correcting amendment is intended to ensure that the information in the FY 2022 IPPS/LTCH PPS final rule accurately reflects the policies adopted in that document.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the final rule or delaying the effective date would be contrary to the public interest because it is in the public's interest for providers to receive appropriate payments in as timely a manner as possible, and to ensure that the FY 2022 IPPS/LTCH PPS final rule accurately reflects our policies. Furthermore, such procedures would be unnecessary, as we are not altering our payment methodologies or policies, but rather, we are simply implementing correctly the methodologies and policies that we previously proposed, requested comment on, and subsequently finalized. This final rule correction and correcting amendment is intended solely to ensure that the FY 2022 IPPS/LTCH PPS final rule accurately reflects these payment methodologies and policies. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements. Moreover, even if these corrections were considered to be retroactive rulemaking, they would be authorized under section 1871(e)(1)(A)(ii) of the Act, which permits the Secretary to issue a rule for the Medicare program with retroactive effect if the failure to do so would be contrary to the public interest. As we have explained previously, we believe it would be contrary to the public interest not to implement the corrections in this final rule correction and correcting amendment because it is in the public's interest for providers to receive appropriate payments in as timely a manner as possible, and to ensure that the FY 2022 IPPS/LTCH PPS final rule accurately reflects our policies.

IV. Correction of Errors

In FR Doc. 2021–16519 of August 13, 2021 (86 FR 44774), we are making the following corrections:

A. Correction of Errors in the Preamble

1. On page 44878, second column, last paragraph, line 10, ''15 technologies'' is corrected to read ''technologies.''

2. On page 44889, lower two-thirds of the page, third column, partial paragraph, line 10, the procedure code ''0DQ540ZZ'' is corrected to read ''0DQ54ZZ.''

3. On page 44960, in the untitled table, last 2 lines are corrected to read as follows:

MDC	MS–DRG	MS–DRG title
*	*	* * * * * * *
08	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC.
08	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC.

4. On page 45047:

a. Second column, first full paragraph, lines 21 through 24, the sentence ''We summarize comments related to this comment solicitation and provide our responses as well as our finalized policy in section XXX of this final rule.'' is corrected to read ''We summarize comments related to this comment solicitation and provide our responses in section II.F.7. of the preamble of this final rule.''.

b. Third column, first full paragraph, line 28, the reference ''section XXX'' is corrected to read ''section II.F.8.''.

5. On page 45048, second column, second full paragraph, lines 20 through 24, the sentence ''We summarize comments related to this comment solicitation and provide our responses as well as our finalized policy in section XXX of this final rule.'' is corrected to read ''We summarize comments related to this comment solicitation and provide our responses in section II.F.7. of the preamble of this final rule.''.

6. On page 45049:

a. Second column:

(1) First full paragraph, line 12, the reference, ''section XXX of this final rule'' is corrected to read ''section II.F.8. of the preamble of this final rule''.

(2) Second full paragraph, lines 1 and 2, the reference, ''section XXX of this final rule'' is corrected to read ''section II.F.7. J95.851 (Ventilator associated pneumonia) and one of the following: B96.1 (Klebsiella pneumoniae [K. pneumoniae] as the cause of diseases classified elsewhere), B96.20 (Unspecified Escherichia coli [E. coli] as the cause of diseases classified elsewhere), B96.21 (Shiga toxin-producing Escherichia coli [E. coli] [STEC] O157 as the cause of diseases classified elsewhere), B96.22 (Other specified Shiga toxin-producing Escherichia coli [E. coli] [STEC] as the cause of diseases classified elsewhere), B96.23 (Unspecified Shiga toxin-producing Escherichia coli [E. coli] [STEC] as the cause of diseases classified elsewhere, B96.29 (Other Escherichia coli [E. coli] as the cause of diseases classified elsewhere), B96.3 (Hemophilus influenzae [H. influenzae] as the cause of diseases classified elsewhere, B96.5 (Pseudomonas (aeruginosa) (mallei) (pseudomallei) as the cause of diseases classified elsewhere), or B96.89 (Other specified bacterial agents as the cause of diseases classified elsewhere) for VABP.''

10. On page 45158, third column, first partial paragraph, last line the phrase, ''technology group 5).'' is corrected to read ''technology group 5) in combination with the following ICD–10–CM codes: Y95 (Nosocomial condition) and one of the following: J14.0 (Pneumonia due to Hemophilus influenzae) J15.0 (Pneumonia due to Klebsiella pneumoniae), J15.1 (Pneumonia due to Pseudomonas), J15.5 (Pneumonia due to Escherichia coli), J15.6 (Pneumonia due to other Gram-negative bacteria), or J15.8 (Pneumonia due to other specified bacteria) for HABP and ICD10–PCS codes: XW033A6 (Introduction of cefiderocol antinfective into peripheral vein, percutaneous approach, new technology group 6) or XW043A6 (Introduction of cefiderocol anti-infective into central vein, percutaneous approach, new technology group 6) in combination with the following ICD–10–CM codes: J95.851 (Ventilator associated pneumonia) and one of the following: B96.1 (Klebsiella pneumoniae [K. pneumoniae] as the cause of diseases classified elsewhere), B96.20 (Unspecified Escherichia coli [E. coli] as the cause of diseases classified elsewhere), B96.21 (Shiga toxin-producing Escherichia coli [E. coli]

[STEC] O157 as the cause of diseases classified elsewhere), B96.22 (Other specified Shiga toxin-producing Escherichia coli [E. coli] [STEC] as the cause of diseases classified elsewhere), B96.23 (Unspecified Shiga toxin-producing Escherichia coli [E. coli] [STEC] as the cause of diseases classified elsewhere, B96.29 (Other Escherichia coli [E. coli] as the cause of diseases classified elsewhere), B96.3 (Hemophilus influenzae [H. influenzae] as the cause of diseases classified elsewhere, B96.5 (Pseudomonas (aeruginosa) (mallei)(pseudomallei) as the cause of diseases classified elsewhere), or B96.89 (Other specified bacterial agents as the cause of diseases classified elsewhere) for VABP.''

11. On page 45291, middle of the page, the table titled ''Table V.H–11: Previously Established and Newly Updated Performance Standards for the FY 2024 Program Year'' is corrected to read as follows:

TABLE V.H–11—PREVIOUSLY ESTABLISHED AND ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2024 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain		
MORT–30–AMI #	0.869247	0.887868
MORT–30–HF #	0.882308	0.907773
MORT–30–PN (updated cohort) #	0.840281	0.872976
MORT–30–COPD #	0.916491	0.934002
MORT–30–CABG #	0.969499	0.980319
COMP–HIP–KNEE * #	0.025396	0.018159

♦ As discussed in section V.H.4.b. of this final rule, we are finalizing the updates to the FY 2024 baseline periods for measures included in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction domains to use CY 2019. Therefore, the performance standards displayed in this table for the Safety domain measures were calculated using CY 2019 data.

* Lower values represent better performance.

Previously established performance standards.

12. On page 45293, top of the page, the table titled ''V.H–13 Previously Established and Estimated Performance Standards for the FY 2025 Program Year'' is corrected to read as follows:

TABLE V.H–13—PREVIOUSLY ESTABLISHED AND ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2025 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain		
MORT–30–AMI #	0.872624	0.889994
MORT–30–HF #	0.883990	0.910344
MORT–30–PN (updated cohort) #	0.841475	0.874425
MORT–30–COPD #	0.915127	0.932236
MORT–30–CABG #	0.970100	0.979775
COMP–HIP–KNEE * #	0.025332	0.017946

* Lower values represent better performance.

Previously established performance standards.

13. On page 45294, top of page, the table titled ''V.H–14 Previously Established and Estimated Performance Standards for the FY 2026 Program Year'' is corrected to read as follows:

TABLE V.H–14—PREVIOUSLY ESTABLISHED AND ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2026 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain		
MORT–30–AMI #	0.874426	0.890687
MORT–30–HF #	0.885949	0.912874
MORT–30–PN (updated cohort) #	0.843369	0.877097
MORT–30–COPD #	0.914691	0.932157
MORT–30–CABG #	0.970568	0.980473
COMP–HIP–KNEE * #	0.024019	0.016873

* Lower values represent better performance.

Previously established performance standards.

14. On page 45312, second column, first full paragraph, lines 7 through 9, the phrase ''rejection of the cost report if the submitted IRIS GME and IME FTEs do match'' is corrected to read ''rejection of the cost report if the submitted IRIS GME and IME FTEs do not match''.

15. On page 45386, third column, first full paragraph, line 12, the phrase ''mellitus and who either'' is corrected to read ''mellitus, who''.

16. On page 45400, top of the page, the table titled ''Measures for the FY 2024 Payment Determination and Subsequent Years'', is corrected by—

a. Correcting the title to read ''Measures for the FY 2023 Payment Determination and Subsequent Years''.

b. Removing the heading ''Claims and Electronic Data Measures'' and the entry ''Hybrid HWR**'' (rows 20 and 21).

c. Following the table, lines 3 through 8, removing the second table note.

17. On page 45404, bottom of the page, after the table titled ''Measures for the FY 2025 Payment Determination and Subsequent Years'', in the third note to the table, line 10, the parenthetical phrase ''(July 1, 2023–June 30, 2023)'' is corrected to read ''(July 1, 2022–June 30, 2023)''.

B. Correction of Errors in the Addendum

1. On page 45532, bottom of the page, the table titled ''Summary of FY 2022 Budget Neutrality Factors'' is corrected to read as follows:

SUMMARY OF FY 2022 BUDGET NEUTRALITY FACTORS

MS-DRG Reclassification and Recalibration Budget Neutrality Factor	1.000107
Wage Index Budget Neutrality Factor	1.000715
Reclassification Budget Neutrality Factor	0.986741
*Rural Floor Budget Neutrality Factor	0.992868
Rural Demonstration Budget Neutrality Factor	0.999361
Low Wage Index Hospital Policy Budget Neutrality Factor	0.998029
Transition Budget Neutrality Factor	0.999859

* The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

2. On page 45537, first column, first full paragraph, lines 4 through 10, the parenthetical phrase ''(estimated capital outlier payments of $ 430,689,396 divided by (estimated capital outlier payments of $430,689,396 plus the estimated total capital Federal payment of $7,676,990,253)).'' is corrected to read ''(estimated capital outlier payments of $430,698,533 divided by (estimated capital outlier payments of $430,698,533 plus the estimated total capital Federal payment of $7,676,964,386)).''.

3. On page 45542, third column, last paragraph, lines 23 and 24, the figure ''$5,326,356,951'' is corrected to read ''$5,326,379,560''.

4. On page 45543:

a. Top of the page, first column, first partial paragraph:

(1) Line 1, the figure ''$100,164,666,975'' is corrected to read ''$100,165,281,272''.

(2) Line 17, the figure ''$31,108'' is corrected to read ''$31,109''.

b. Middle of the page, the untitled table is corrected to read as follows:

	Operating standardized amounts	Capital Federal rate *
National	0.949	0.947078

* The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2022 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III. A. 2 in the Addendum of this final rule.

5. On page 45545, the table titled ''CHANGES FROM FY 2021 STANDARDIZED AMOUNTS TO THE FY 2022 STANDARDIZED AMOUNTS'' is corrected to read as follows:

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CHANGES FROM FY 2021 STANDARDIZED AMOUNTS TO THE FY 2022 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2022 Base Rate after removing: 1. FY 2021 Geographic Reclassification Budget Neutrality (0.986616) 2. FY 2021 Operating Outlier Offset (0.949)	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22
3. FY 2021 Rural Demonstration Budget Neutrality Factor (0.999626) 4. FY 2021 Lowest Quartile Budget Neutrality Factor (0.99797) 5. FY 2021 Transition Budget Neutrality Factor (0.998851)	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04
FY 2022 Update Factor	1.02	0.99975	1.01325	0.993
FY 2022 MS-DRG Reclassification and Recalibration Budget Neutrality Factor	1.000107	1.000107	1.000107	1.000107
FY 2022 Wage Index Budget Neutrality Factor	1.000715	1.000715	1.000715	1.000715
FY 2022 Reclassification Budget Neutrality Factor	0.986741	0.986741	0.986741	0.986741
FY 2022 Rural Demonstration Budget Neutrality Factor	0.999361	0.999361	0.999361	0.999361
FY 2022 Lowest Quartile Budget Neutrality Factor	0.998029	0.998029	0.998029	0.998029
FY 2022 Transition Budget Neutrality Factor	0.999859	0.999859	0.999859	0.999859
FY 2022 Operating Outlier Factor	0.949	0.949	0.949	0.949
Adjustment for FY 2022 Required under Section 414 of Pub. L. 114-10 (MACRA)	1.005	1.005	1.005	1.005
National Standardized Amount for FY 2022 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (67.6/32.4)	**Labor: $4,138.24 Nonlabor $1,983.41**	**Labor: $4,056.08 Nonlabor: $1,944.03**	**Labor: $4,110.85 Nonlabor: $1,970.28**	**Labor: $4,028.70 Nonlabor: $1,930.91**
National Standardized Amount for FY 2022 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $3,795.42 Nonlabor: $2,326.23**	**Labor: $3,720.07 Nonlabor: $2,280.04**	**Labor: $3,770.30 Nonlabor: $2,310.83**	**Labor: $3,694.96 Nonlabor: $2,264.65**

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6. On page 45553, second column, last paragraph, line 9, the figure ''$472.60'' is corrected to read ''$472.59''.

7. On page 45554, top of the page, in the table titled ''COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2021 CAPITAL FEDERAL RATE AND THE FY 2022 CAPITAL FEDERAL RATE'', the list entry (row 5) is corrected to read as follows:

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2021 CAPITAL FEDERAL RATE AND THE FY 2022 CAPITAL FEDERAL RATE

	FY 2021	FY 2022	Change	Percent change
* * * * * * * *				
Capital Federal Rate	$466.21	$472.59	1.0137	[4] 1.37

8. On page 45570:

a. The table titled ''TABLE 1A.—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (67.6 PERCENT LABOR SHARE/32.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2022'' is corrected to read as follows:

TABLE 1A—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (67.6 PERCENT LABOR SHARE/32.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2022

Hospital submitted quality data and is a meaningful EHR user (update = 2.0 percent)		Hospital submitted quality data and is not a meaningful EHR user (update = −0.025 percent)		Hospital did not submit quality data and is a meaningful EHR user (update = 1.325 percent)		Hospital did not submit quality data and is not a meaningful EHR user (update = −0.7 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,138.24	$1,983.41	$4,056.08	$1,944.03	$4,110.85	$1,970.28	$4,028.70	$1,930.91

b. The table titled ''TABLE 1B.—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2022'' is corrected to read as follows:

TABLE 1B—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2022

Hospital submitted quality data and is a meaningful EHR user (update = 2.0 percent)		Hospital submitted quality data and is not a meaningful EHR user (update = −0.025 percent)		Hospital did not submit quality data and is a meaningful EHR user (update = 1.325 percent)		Hospital did not submit quality data and is not a meaningful EHR user (update = −0.7 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,795.42	$2,326.23	$3,720.07	$2,280.04	$3,770.30	$2,310.83	$3,694.96	$2,264.65

9. On page 45571, the top of page:

a. The table titled ''Table 1C.—ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2022'' is corrected to read as follows:

TABLE 1C—ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2022

	Rates if wage index greater than 1		Hospital is a meaningful EHR user and wage index less than or equal to 1 (update = 2.0)		Hospital is NOT a meaningful EHR user and wage index less than or equal to 1 (update = 1.325)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
[1] National	Not Applicable	Not Applicable	$3,795.42	$2,326.23	$3,770.30	$2,310.83

[1] For FY 2022, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

b. The table titled ''TABLE 1D.—CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2022'' is corrected to read as follows:

TABLE 1D—CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2022

	Rate
National	$472.59

C. Correction of Errors in the Appendices

1. On pages 45576 through 45578, the table titled ''Table I.—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2022'' is corrected to read as follows:

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Table I.—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2022

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2022 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2022 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2022 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Imputed Floor Wage Index (6)[7]	Application of the Frontier State Wage Index and Outmigration Adjustment (7)[8]	All FY 2022 Changes (8)[9]
All Hospitals	3,195	2.5	0.0	0.0	0.0	0.0	0.2	0.1	2.6
By Geographic Location:									
Urban hospitals	2,459	2.5	0.0	0.0	-0.1	0.0	0.2	0.1	2.6
Rural hospitals	736	2.2	0.1	0.2	1.3	-0.2	0.0	0.1	2.8
Bed Size (Urban):									
0-99 beds	634	2.4	0.0	0.1	-0.6	0.1	0.2	0.3	2.7
100-199 beds	754	2.5	0.0	0.0	-0.2	0.2	0.2	0.2	2.6
200-299 beds	427	2.5	0.0	0.1	0.2	0.0	0.2	0.1	2.4
300-499 beds	421	2.5	0.0	0.0	0.1	0.0	0.1	0.1	2.6
500 or more beds	223	2.5	0.0	-0.1	-0.3	0.0	0.2	0.0	2.6
Bed Size (Rural):									
0-49 beds	311	2.1	0.1	0.3	0.7	-0.1	0.0	0.2	4.3
50-99 beds	253	2.1	0.1	0.2	0.8	-0.1	0.0	0.2	2.4
100-149 beds	94	2.1	0.1	0.2	1.3	-0.2	0.0	0.0	2.5
150-199 beds	39	2.3	0.0	0.2	1.6	-0.2	0.0	0.1	2.6
200 or more beds	39	2.3	0.0	0.3	2.0	-0.3	0.0	0.0	2.8
Urban by Region:									
New England	112	2.5	0.0	-1.0	0.8	3.7	0.6	0.1	2.7
Middle Atlantic	304	2.5	0.0	-0.2	0.3	-0.4	0.5	0.2	2.5
East North Central	381	2.5	0.0	-0.2	-0.2	-0.4	0.0	0.0	2.4
West North Central	160	2.4	-0.1	0.2	-0.6	-0.3	0.0	0.6	2.7
South Atlantic	402	2.5	0.0	0.3	-0.5	-0.3	0.2	0.0	2.9
East South Central	144	2.5	0.0	0.1	-0.3	-0.3	0.0	0.0	2.5
West South Central	364	2.5	0.0	-0.3	-0.5	-0.3	0.0	0.0	2.3
Mountain	172	2.4	0.0	0.2	0.1	-0.1	0.0	0.2	2.6
Pacific	370	2.4	-0.1	0.5	0.2	0.4	0.0	0.1	2.5
Puerto Rico	50	2.5	-0.5	-0.3	-1.0	0.2	0.0	0.1	1.7
Rural by Region:									
New England	19	2.3	0.0	-0.4	1.3	-0.3	0.2	0.0	3.4
Middle Atlantic	50	2.2	0.1	0.3	1.0	-0.2	0.0	0.0	2.6
East North Central	113	2.2	0.1	0.1	0.9	-0.1	0.0	0.0	2.2
West North Central	89	2.1	0.0	0.1	0.3	-0.1	0.0	0.2	2.8
South Atlantic	114	2.2	0.1	1.1	1.6	-0.2	0.0	0.0	3.0
East South Central	144	2.3	0.1	-0.1	1.8	-0.3	0.0	0.1	2.6
West South Central	135	2.2	0.1	0.0	2.8	-0.3	0.0	0.0	3.0

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2022 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2022 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2022 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Imputed Floor Wage Index (6)[7]	Application of the Frontier State Wage Index and Outmigration Adjustment (7)[8]	All FY 2022 Changes (8)[9]
Mountain	48	1.9	0.0	0.6	-0.1	-0.1	0.0	0.8	1.9
Pacific	24	2.1	0.0	-0.1	1.1	-0.1	0.0	0.0	5.2
By Payment Classification:									
Urban hospitals	1,983	2.5	0.0	0.0	-0.6	0.2	0.2	0.1	2.6
Rural areas	1,212	2.4	0.0	0.0	0.9	-0.3	0.1	0.1	2.6
Teaching Status:									
Nonteaching	2,031	2.4	0.0	0.2	0.1	0.1	0.1	0.1	2.7
Fewer than 100 residents	907	2.5	0.0	0.0	0.1	-0.1	0.2	0.2	2.5
100 or more residents	257	2.4	0.0	-0.1	-0.2	0.0	0.2	0.0	2.6
Urban DSH:									
Non-DSH	502	2.5	0.0	0.0	-0.6	0.0	0.3	0.2	2.6
100 or more beds	1,227	2.5	0.0	0.0	-0.6	0.2	0.2	0.1	2.6
Less than 100 beds	348	2.5	0.0	0.1	-0.5	0.2	0.1	0.2	2.7
Rural DSH:									
SCH	265	2.0	0.0	0.1	0.2	0.0	0.0	0.1	2.5
RRC	608	2.4	0.0	0.0	1.0	-0.3	0.1	0.1	2.6
100 or more beds	30	2.4	0.1	-0.1	0.1	-0.4	0.0	0.0	1.5
Less than 100 beds	215	2.3	0.1	0.3	1.0	-0.3	0.0	0.2	3.2
Urban teaching and DSH:									
Both teaching and DSH	679	2.5	0.0	-0.1	-0.6	0.1	0.3	0.1	2.6
Teaching and no DSH	74	2.5	0.0	-0.1	-0.9	0.6	0.4	0.2	2.4
No teaching and DSH	896	2.5	0.0	0.2	-0.5	0.4	0.1	0.1	2.6
No teaching and no DSH	334	2.5	0.0	0.1	-0.6	-0.2	0.3	0.3	2.6
Special Hospital Types:									
RRC	523	2.5	0.0	0.0	1.0	-0.4	0.1	0.1	2.6
SCH	305	2.0	0.0	0.1	0.1	0.0	0.0	0.0	2.5
MDH	153	2.1	0.1	0.0	0.0	-0.2	0.1	0.1	2.6
SCH and RRC	154	2.1	0.0	0.1	0.5	-0.1	0.0	0.0	2.2
MDH and RRC	27	2.2	0.0	0.0	0.7	-0.2	0.1	0.0	2.2
Type of Ownership:									
Voluntary	1,881	2.5	0.0	-0.1	0.1	0.0	0.2	0.1	2.6
Proprietary	828	2.5	0.0	0.1	-0.1	0.1	0.1	0.1	2.6
Government	486	2.4	0.0	0.2	-0.3	-0.1	0.0	0.0	2.5
Medicare Utilization as a Percent of Inpatient Days:									
0-25	643	2.5	0.0	0.1	-0.6	-0.2	0.0	0.0	2.5
25-50	2,110	2.5	0.0	0.0	0.1	0.0	0.2	0.1	2.6
50-65	367	2.4	0.0	-0.1	0.2	0.3	0.3	0.2	2.2
Over 65	50	2.3	0.1	0.3	-0.7	-0.3	0.3	0.1	3.7

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2022 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2022 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2022 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Imputed Floor Wage Index (6)[7]	Application of the Frontier State Wage Index and Outmigration Adjustment (7)[8]	All FY 2022 Changes (8)[9]
FY 2022 Reclassifications:									
All Reclassified Hospitals	934	2.4	0.0	0.0	1.2	-0.3	0.1	0.1	2.6
Non-Reclassified Hospitals	2,261	2.5	0.0	0.0	-0.9	0.2	0.2	0.2	2.6
Urban Hospitals Reclassified	749	2.4	0.0	0.0	1.1	-0.3	0.1	0.1	2.5
Urban Non-Reclassified Hospitals	1,723	2.5	0.0	0.0	-1.1	0.3	0.3	0.1	2.6
Rural Hospitals Reclassified Full Year	300	2.2	0.1	0.2	2.0	-0.2	0.0	0.0	2.5
Rural Non-Reclassified Hospitals Full Year	423	2.2	0.1	0.2	0.0	-0.2	0.0	0.2	3.3
All Section 401 Reclassified Hospitals	532	2.4	0.0	0.0	0.8	-0.3	0.1	0.1	2.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	2.3	0.1	0.0	2.4	-0.3	0.2	0.0	3.1

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2019, and hospital cost report data are from reporting periods beginning in FY 2018 and FY 2017.

[2] This column displays the payment impact of the hospital rate update and other adjustments, including the 2.0 percent update to the national standardized amount and the hospital-specific rate (the estimated 2.7 percent market basket update reduced by 0.7 percentage point for the productivity adjustment), and the 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the changes to the Version 39 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2019 MedPAR data as the best available data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 1.000107 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wage index data using FY 2018 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000715.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2022 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2022. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.986741.

[6] This column displays the effects of the rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index is 0.992868.

[6] This column displays the effects of the imputed rural floor for all-urban states provided for under section 1886(d)(3)(E)(iv) of the Act. This is not a budget neutral policy.

[8] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[9] This column shows the estimated change in payments from FY 2021 to FY 2022. This column includes the effects of the continued policy of increasing the wage index for hospitals with a wage index value below the 25th percentile wage index (that is, the lowest quartile wage index adjustment), the extended transition policy to place a 5-percent cap on any decrease in a hospital's wage index from its final wage index in FY 2021 (that is, the 5-percent cap), and the associated budget neutrality factors. This column reflects the budget neutrality factor of 0.998029 for the lowest quartile wage index adjustment and the budget neutrality factor of 0.999859 for the 5-percent cap for FY 2022.

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2. On page 45579, third column, first paragraph, line 23, the figure "1.000712" is corrected to read "1.000715".

3. On page 45580, lower three-fourths of the page, first column, third full paragraph, line 6, the figure ''0.986737'' is corrected to read ''0.986741''.

4. On pages 45582 and 45583, the table titled ''Table II.—Impact Analysis of Changes for FY 2022 Acute Care Hospital Operating Prospective Payment System (Payments Per Discharge)'' is corrected to read as follows:

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2022 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals	Estimated average FY 2021 payment per discharge	Estimated average FY 2022 payment per discharge	FY 2022 changes
	(1)	(2)	(3)	(4)
All Hospitals	3,195	13,109	13,448	2.6
By Geographic Location:				
Urban hospitals	2,459	13,454	13,800	2.6
Rural hospitals	736	9,901	10,178	2.8
Bed Size (Urban):				
0–99 beds	634	10,723	11,011	2.7
100–199 beds	754	11,015	11,305	2.6
200–299 beds	427	12,251	12,551	2.4
300–499 beds	421	13,496	13,847	2.6
500 or more beds	223	16,568	16,992	2.6
Bed Size (Rural):				
0–49 beds	311	8,556	8,921	4.3
50–99 beds	253	9,419	9,644	2.4
100–149 beds	94	9,789	10,033	2.5
150–199 beds	39	10,519	10,788	2.6
200 or more beds	39	11,465	11,784	2.8
Urban by Region:				
New England	112	14,858	15,253	2.7
Middle Atlantic	304	15,432	15,814	2.5
East North Central	381	12,838	13,150	2.4
West North Central	160	13,121	13,475	2.7
South Atlantic	402	11,710	12,049	2.9
East South Central	144	11,290	11,576	2.5
West South Central	364	11,806	12,072	2.3
Mountain	172	13,698	14,054	2.6
Pacific	370	17,230	17,664	2.5
Puerto Rico	50	8,491	8,637	1.7
Rural by Region:				
New England	19	13,990	14,463	3.4
Middle Atlantic	50	9,736	9,988	2.6
East North Central	113	10,361	10,592	2.2
West North Central	89	10,638	10,932	2.8
South Atlantic	114	9,032	9,302	3
East South Central	144	8,732	8,955	2.6
West South Central	135	8,292	8,540	3
Mountain	48	12,134	12,359	1.9
Pacific	24	13,865	14,588	5.2
By Payment Classification:				
Urban hospitals	1,983	12,673	13,003	2.6
Rural areas	1,212	13,796	14,148	2.6
Teaching Status:				
Nonteaching	2,031	10,677	10,963	2.7
Fewer than 100 residents	907	12,388	12,694	2.5
100 or more residents	257	18,938	19,437	2.6
Urban DSH:				
Non-DSH	502	11,749	12,054	2.6
100 or more beds	1,227	13,015	13,355	2.6
Less than 100 beds	348	9,559	9,820	2.7
Rural DSH:				
SCH	265	11,906	12,203	2.5
RRC	608	14,380	14,747	2.6
100 or more beds	30	12,115	12,298	1.5
Less than 100 beds	215	7,778	8,025	3.2
Urban teaching and DSH:				
Both teaching and DSH	679	14,116	14,483	2.6
Teaching and no DSH	74	12,825	13,127	2.4
No teaching and DSH	896	10,850	11,137	2.6
No teaching and no DSH	334	10,824	11,110	2.6
Special Hospital Types:				

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2022 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2021 payment per discharge (2)	Estimated average FY 2022 payment per discharge (3)	FY 2022 changes (4)
RRC	523	14,478	14,859	2.6
SCH	305	12,053	12,356	2.5
MDH	153	9,169	9,404	2.6
SCH and RRC	154	12,475	12,746	2.2
MDH and RRC	27	10,622	10,853	2.2
Type of Ownership:				
Voluntary	1,881	13,321	13,667	2.6
Proprietary	828	11,473	11,769	2.6
Government	486	14,109	14,466	2.5
Medicare Utilization as a Percent of Inpatient Days:				
0–25	643	15,158	15,535	2.5
25–50	2,110	12,926	13,268	2.6
50–65	367	10,773	11,010	2.2
Over 65	50	8,132	8,431	3.7
FY 2022 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	934	13,592	13,944	2.6
Non-Reclassified Hospitals	2,261	12,772	13,102	2.6
Urban Hospitals Reclassified	749	14,261	14,619	2.5
Urban Nonreclassified Hospitals	1,723	12,851	13,187	2.6
Rural Hospitals Reclassified Full Year	300	10,087	10,341	2.5
Rural Nonreclassified Hospitals Full Year	423	9,610	9,929	3.3
All Section 401 Reclassified Hospitals	532	14,968	15,343	2.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	9,149	9,429	3.1

5. On page 45584, bottom third of the page, third column, partial paragraph:

a. Line 7, the figure ''$151 million'' is corrected to read ''$158 million''.

b. Line 10, the figure ''$50 million'' is corrected to read ''$57 million''.

c. Lines 15 and 16, the phrase ''for which we are approving new technology add-on payments'' is corrected to read ''for which we are approving or conditionally approving new technology add-on payments''.

6. On page 45585:

a. Top third of the page:

(1) In the untitled table, the third and fourth column headings and the entries at rows 6 and 9 are corrected to read as follows:

Technology name	Estimated cases	FY 2022 NTAP amount	Estimated FY 2022 total impact	Pathway (QIDP, LPAD, or breakthrough device)
* * * * * * *				
Fetroja (HABP/VABP)	379	$8,579.84	$3,251,759.36	QIDP.
* * * * * * *				
Recarbrio (HABP/VABP)	928	9,576.51	8,887,001.28	QIDP.
* * * * * * *				

(2) Following the first untitled table, second column, partial paragraph, last line, the figure ''$498 million'' is corrected to read ''$514 million''.

b. Middle third of the page, in the untitled table, the third and fourth column headings and the entries at rows 2 and 4 are corrected to read as follows:

Technology name	Estimated cases	FY 2022 NTAP amount	Estimated FY 2022 total impact
* * * * * * *			
Abecma	484	$272,675.00	$131,974,700.00

Technology name	Estimated cases	FY 2022 NTAP amount	Estimated FY 2022 total impact
* * * * *	*	*	*
Tecartus	15	259,350.00	3,890,250.00
* * * * *	*	*	*

7. On pages 45587 and 45588, the table titled ''Modeled Uncompensated Care Payments for Estimated FY 2022 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)—from FY 2021 to FY 2022'' is corrected to read as follows:

BILLING CODE 4120–01–P

Modeled Uncompensated Care Payments for Estimated FY 2022 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2021 to FY 2022					
	Number of Estimated DSHs (1)	FY 2021 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2022 Final Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2021 - FY 2022 ($ in millions) (4)	Percent Change** (5)
Total	**2,365**	**8,290**	**7,192**	**-1098**	**-13.24%**
By Geographic Location					
Urban Hospitals	1,900	7,803	6,789	-1014	-12.99
Large Urban Areas	989	4,829	4,146	-683	-14.15
Other Urban Areas	911	2,974	2,643	-331	-11.12
Rural Hospitals	465	487	403	-84	-17.28
Bed Size (Urban)					
0 to 99 Beds	325	290	245	-45	-15.49
100 to 249 Beds	818	1,898	1,603	-294	-15.50
250+ Beds	757	5,615	4,940	-675	-12.02
Bed Size (Rural)					
0 to 99 Beds	352	269	218	-51	-18.97
100 to 249 Beds	100	166	141	-26	-15.53
250+ Beds	13	52	45	-7	-14.16
Urban by Region					
New England	92	227	186	-40	-17.79
Middle Atlantic	230	983	819	-163	-16.62
South Atlantic	313	864	800	-64	-7.44
East North Central	98	405	354	-51	-12.58
East South Central	312	2,027	1,759	-268	-13.2
West North Central	126	498	439	-59	-11.92
West South Central	241	1,637	1,434	-204	-12.44
Mountain	132	333	299	-34	-10.32
Pacific	315	723	607	-116	-15.99
Puerto Rico	41	107	93	-14	-13.01
Rural by Region					
New England	8	15	15	0	-1.27
Middle Atlantic	21	15	12	-3	-17.92
South Atlantic	65	58	43	-15	-25.28
East North Central	28	31	23	-8	-25.87
East South Central	83	135	117	-18	-13.01
West North Central	124	102	85	-18	-17.22
West South Central	107	105	88	-17	-15.92
Mountain	24	19	14	-5	-25.92
Pacific	5	7	5	-2	-25.68
By Payment Classification					
Urban Hospitals	1,506	5,470	4,773	-697	-12.74
Large Urban Areas	850	3,614	3,125	-489	-13.52
Other Urban Areas	656	1,855	1,648	-208	-11.21
Rural Hospitals	859	2,820	2,419	-401	-14.23
Teaching Status					
Nonteaching	1,370	2,444	2,116	-328	-13.4
Fewer than 100 residents	742	2,865	2,494	-371	-12.94
100 or more residents	253	2,980	2,581	-399	-13.39
Type of Ownership					
Voluntary	1,422	4,556	3,981	-574	-12.61
Proprietary	575	1,217	1,076	-141	-11.56

Modeled Uncompensated Care Payments for Estimated FY 2022 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2021 to FY 2022					
	Number of Estimated DSHs (1)	FY 2021 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2022 Final Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2021 - FY 2022 ($ in millions) (4)	Percent Change** (5)
Government	368	2,517	2,134	-383	-15.21
Medicare Utilization Percent* **					
0 to 25	554	3,388	2,940	-448	-13.22
25 to 50	1,602	4,707	4,098	-609	-12.94
50 to 65	187	189	150	-39	-20.85
Greater than 65	22	6	4	-2	-32.86

Source: Dobson | DaVanzo analysis of 2013 and 2018 Hospital Cost Reports.

*Dollar uncompensated care payments calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, uncompensated care payments are estimated to be $8,290 million in FY 2021 and $7,192 million in FY 2022.

** Percentage change is determined as the difference between Medicare uncompensated care payments modeled for this FY 2022 IPPS/LTCH PPS final rule (column 3) and Medicare uncompensated care payments modeled for the FY 2021 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare uncompensated care payments modeled for the FY 2021 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.

***Hospitals with missing or unknown Medicare utilization are not shown in table.

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8. On page 45588, lower half of the page, beginning with the second column, first full paragraph, line 1 with the phrase ''Rural hospitals, in general, are projected to experience'' and ending in the third column last paragraph with the phrase ''15.22 percent. All'' the paragraphs are corrected to read as follows:

''Rural hospitals, in general, are projected to experience larger decreases in uncompensated care payments than their urban counterparts. Overall, rural hospitals are projected to receive a 17.28 percent decrease in uncompensated care payments, which is a greater decrease than the overall hospital average, while urban hospitals are projected to receive a 12.99 percent decrease in uncompensated care payments, similar to the overall hospital average.

By bed size, smaller rural hospitals are projected to receive the largest decreases in uncompensated care payments. Rural hospitals with 0–99 beds are projected to receive an 18.97 percent payment decrease, and rural hospitals with 100–249 beds are projected to receive a 15.53 percent decrease. In contrast, larger rural hospitals with 250+ beds are projected to receive a 14.16 percent payment decrease. Among urban hospitals, the smallest urban hospitals, those with 0–99 and 100–249 beds, are projected to receive a decrease in uncompensated care payments that is greater than the overall hospital average, at 15.49 and 15.50 percent, respectively. In contrast, the largest urban hospitals with 250+ beds are projected to receive a 12.02 percent decrease in uncompensated care payments, which is a smaller decrease than the overall hospital average.

By region, rural hospitals are expected to receive larger than average decreases in uncompensated care payments in all Regions, except for rural hospitals in New England, which are projected to receive a decrease of 1.27 percent in uncompensated care payments, and rural hospitals in the East South Central Region, which are projected to receive a smaller than average decrease of 13.01 percent. Regionally, urban hospitals are projected to receive a more varied range of payment changes. Urban hospitals in the New England, Middle Atlantic, and Pacific Regions are projected to receive larger than average decreases in uncompensated care payments. Urban hospitals in the South Atlantic, East North Central, West North Central, West South Central, and Mountain Regions, as well as hospitals in Puerto Rico are projected to receive smaller than average decreases in uncompensated care payments. Urban hospitals in the East South Central Region are projected to receive an average decrease in uncompensated care payments.

By payment classification, although hospitals in urban areas overall are expected to receive a 12.74 percent decrease in uncompensated care payments, hospitals in large urban areas are expected to see a decrease in uncompensated care payments of 13.52 percent, while hospitals in other urban areas are expected to receive a decrease in uncompensated care payments of 11.21 percent. Rural hospitals are projected to receive the largest decrease of 14.23 percent.

Nonteaching hospitals are projected to receive a payment decrease of 13.4 percent, teaching hospitals with fewer than 100 residents are projected to receive a payment decrease of 12.94 percent, and teaching hospitals with 100+ residents have a projected payment decrease of 13.39 percent. All of these decreases closely approximate the overall hospital average. Proprietary and voluntary hospitals are projected to receive smaller than average decreases of 11.56 and 12.61 percent respectively, while government hospitals are expected to receive a larger payment decrease of 15.21 percent. All''.

9. On page 45589, first column, first partial paragraph, the phrase ''hospitals with less than 50 percent Medicare utilization are projected to receive decreases in uncompensated care payments consistent with the overall hospital average percent change, while hospitals with 50–65 percent and greater than 65 percent Medicare utilization are projected to receive larger decreases of 20.79 and 32.81 percent, respectively.'' is corrected to read as follows: ''hospitals with less than 50 percent Medicare utilization are projected to receive decreases in uncompensated care payments consistent with the overall hospital average percent change, while hospitals with 50–65 percent and greater than 65 percent Medicare utilization are projected to receive larger decreases of 20.85 and 32.86 percent, respectively.''

10. On page 45598, third column, last paragraph, lines 21 through 23, the sentence ''The estimated percentage increase for both rural reclassified and nonreclassified hospitals is 1.4 percent.'' is corrected to read ''The estimated percentage increase for rural reclassified hospitals is 1.3 percent, while the estimated percentage increase for rural nonreclassified hospitals is 1.4 percent.''

11. On pages 45599 and 45600, the table titled ''TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE [FY 2021 PAYMENTS COMPARED TO FY 2022 PAYMENTS]'' is corrected to read as follows:

BILLING CODE 4120–01–P

TABLE III.--COMPARISON OF TOTAL PAYMENTS PER CASE [FY 2021 PAYMENTS COMPARED TO FY 2022 PAYMENTS]				
	Number of Hospitals	Average FY 2021 Payments/ Case	Average FY 2022 Payments/ Case	Change
All hospitals	3,195	981	990	0.9
By Geographic Location:				
Urban Hospitals	2,459	1,014	1,023	0.9
Rural areas	736	673	683	1.5
Bed Size (Urban)				
0-99 beds	634	803	813	1.2
100-199 beds	754	860	871	1.3
200-299 beds	427	939	949	1.1
300-499 beds	421	1,020	1,029	0.9
500 or more beds	223	1,215	1,221	0.5
Bed Size (Rural)				
0-49 beds	311	568	577	1.6
50-99 beds	253	626	634	1.3
100-149 beds	94	666	675	1.4
150-199 beds	39	737	750	1.8
200 or more beds	39	797	810	1.6
By Region:				
Urban by Region				
New England	112	1,104	1,121	1.5
Middle Atlantic	304	1,129	1,134	0.4
South Atlantic	402	889	902	1.5
East North Central	381	966	975	0.9
East South Central	144	863	869	0.7
West North Central	160	989	994	0.5
West South Central	364	927	929	0.2
Mountain	172	1,023	1,032	0.9
Pacific	370	1,304	1,314	0.8
Rural by Region				
New England	19	937	953	1.7
Middle Atlantic	50	651	662	1.7
South Atlantic	114	623	637	2.2
East North Central	113	681	687	0.9
East South Central	144	630	636	1.0
West North Central	89	701	709	1.1
West South Central	135	602	616	2.3
Mountain	48	765	773	1.0
Pacific	24	869	876	0.8
By Payment Classification:				
Urban hospitals	1,983	982	995	1.3
Rural areas	1,212	980	981	0.1
Teaching Status:				
Non-teaching	2,031	817	828	1.3
Fewer than 100 Residents	907	941	949	0.9

TABLE III.--COMPARISON OF TOTAL PAYMENTS PER CASE [FY 2021 PAYMENTS COMPARED TO FY 2022 PAYMENTS]				
	Number of Hospitals	Average FY 2021 Payments/ Case	Average FY 2022 Payments/ Case	Change
100 or more Residents	257	1,358	1,365	0.5
Urban DSH:				
Non-DSH	502	904	915	1.2
100 or more beds	1,227	1,008	1,022	1.4
Less than 100 beds	348	728	737	1.2
Rural DSH:				
Sole Community (SCH/EACH)	265	751	750	-0.1
Referral Center (RRC/EACH)	608	1,030	1,031	0.1
100 or more beds	30	895	875	-2.2
Less than 100 beds	215	559	567	1.4
Urban teaching and DSH:				
Both teaching and DSH	679	1,075	1,090	1.4
Teaching and no DSH	74	981	993	1.2
No teaching and DSH	896	866	878	1.4
No teaching and no DSH	334	859	870	1.3
Special Hospital Types:				
Non special status hospitals	152	781	775	-0.8
RRC/EACH	523	1,061	1,063	0.2
SCH/EACH	305	758	758	0.0
Medicare-dependent hospitals (MDH)	153	610	615	0.8
SCH, RRC and EACH	154	807	815	1.0
MDH, RRC and EACH	27	687	694	1.0
Type of Ownership:				
Voluntary	1,881	993	1,002	0.9
Proprietary	828	896	905	1.0
Government	486	1,031	1,035	0.4
Medicare Utilization as a Percent of Inpatient Days:				
0-25	643	1,119	1,125	0.5
25-50	2,110	972	981	0.9
50-65	367	797	804	0.9
Over 65	50	586	596	1.7
2022 Reclassifications by the Medicare Classification Review Board:				
All Reclassified Hospitals	934	987	993	0.6
All Nonreclassified Hospitals	2,261	977	988	1.1
Urban Hospitals Reclassified	749	1,039	1,042	0.3
Urban Nonreclassified Hospitals	1,723	995	1,008	1.3
Rural Hospitals Reclassified Full Year	300	695	704	1.3
Rural Nonreclassified Hospitals Full Year	423	641	650	1.4
All Section 401 Reclassified Hospitals	532	1,073	1,072	-0.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	662	672	1.5

12. On page 45610:

a. Second column, first partial paragraph:

(1) Line 1, the figure ''$2.293'' is corrected to read ''$2.316''.

(2) Line 11, the figure ''$0.65'' is corrected to read ''$0.68''.

b. Third column, last full paragraph, last line, the figure ''$2.293'' is corrected to read ''$2.316''.

13. On page 45611, the table titled ''Table V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2021 TO FY 2022'' is corrected to read as follows:

Category	Transfers
Annualized Monetized Transfers.	$2.316 billion.
From Whom to Whom.	Federal Government to IPPS Medicare Providers.

List of Subjects in 42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

As noted in section II.B. of the preamble, the Centers for Medicare & Medicaid Services is making the following correcting amendments to 42 CFR part 413:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Amend § 413.24 by:
■ a. In paragraph (f)(5)(i) introductory text, removing the phrase ''except as provided in paragraph (f)(5)(i)(E) of this section:'' and adding in its place the phrase ''except as provided in paragraphs (f)(5)(i)(A)(*2*)(*ii*) and (f)(5)(i)(E) of this section:''; and
■ b. Revising paragraph (f)(5)(i)(A).

The revision reads as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(5) * * *

(i) * * *

(A) *Teaching hospitals.* For teaching hospitals, the Intern and Resident Information System (IRIS) data.

(*1*) *Data format.* For cost reporting periods beginning on or after October 1, 2021, the IRIS data must be in the new XML IRIS format.

(*2*) *Resident counts.* (*i*) Effective for cost reporting periods beginning on or after October 1, 2021, the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the provider's cost report.

(*ii*) For cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022, the cost report is not rejected if the requirement in paragraph (f)(5)(i)(A)(*2*)(*i*) of this section is not met.

* * * * *

Karuna Seshasai,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2021–22724 Filed 10–19–21; 8:45 am]

BILLING CODE 4120–01–C

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket No. 17–97; FCC 20–136; FRS 52215]

Call Authentication Trust Anchor

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces the effective date of an information collection associated with a rule contained in the Commission's *Call Authentication Trust Anchor,* Second Report and Order (Order). This document is consistent with the Commission's *Call Authentication Trust Anchor,* Second Report and Order (Order) which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of that rule.

DATES: The amendment to 47 CFR 64.6306(e) (instruction 11), published November 17, 2020 (85 FR 73360), and delayed indefinitely, is effective October 20, 2021. This final rule is effective October 20, 2021.

FOR FURTHER INFORMATION CONTACT: For further information, please contact Alexander Hobbs, Competition Policy Division, Wireline Competition Bureau at (202) 418–7433 or by email at *Alexander.Hobbs@fcc.gov.*

SUPPLEMENTARY INFORMATION: On June 4, 2021, the Commission announced OMB approval of § 64.6306(e) in a **Federal Register** publication, at 86 FR 29952. This document now announces the effective date of § 64.6306(e). In the Order and the text of § 64.6306(e), the Commission directed the Wireline Competition Bureau to set the compliance date for this rule. On September 3, 2021, the Bureau released a Public Notice, DA 21–1103, setting the date by which voice service providers granted an exemption from the Commission's caller ID authentication rule must file implementation verification certifications and associated supporting statements. Voice service providers must file all certifications and associated supporting statements electronically in WC Docket No. 20–68, Exemption from Caller ID Authentication Requirements, in ECFS, no later than October 4, 2021. We therefore modify the text of § 64.6306(e), previously published at 85 FR 73360, to incorporate this compliance date announced by the Bureau.

If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Nicole Ongele, Federal Communications Commission, Room 3.310, 45 L Street NE, Washington, DC 20002. Please include the OMB Control Number, 3060–1285, in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (*e.g.,* Braille, large print, electronic files, audio format, etc.), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), or (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received final OMB approval on May 13, 2021, for the information collection requirements contained in the modifications to the Commission's rules in 47 CFR part 64 and modifying the language of § 64.6306(e) to conform to the compliance date adopted by the Wireline Competition Bureau in DA 21–1103.

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–1285.

The foregoing is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1285.
OMB Approval Date: May 13, 2021.
OMB Expiration Date: May 31, 2024.

Title: Compliance with the Non-IP Call Authentication Solution Rules; Robocall Mitigation Database; Certification to Verify Exemption from Caller ID Authentication Implementation Mandate.

Form Number: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 6,535 respondents; 6,535 responses.

Estimated Time per Response: .5 hours–3 hours.

Frequency of Response: Recordkeeping requirement and on-occasion reporting requirement.

Obligation to Respond: Mandatory and required to obtain or retain benefits. The statutory authority for this information collection is contained in sections 227(b), 227(e) and 251(e) of the Communications Act of 1934.

Total Annual Burden: 15,520 hours.

Total Annual Cost: No Cost.

Nature and Extent of Confidentiality: The Commission will consider the potential confidentiality of any information submitted, particularly where public release of such information could raise security concerns (*e.g.,* granular location information). Respondents may request materials or information submitted to the Commission or to the Administrator be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: On October 1, 2020, the Commission released the *Order,* FCC 20–136, published at 85 FR 73360, November 17, 2020, adopting final rules—containing information collection requirements—designed to promote caller ID authentication technology. The rules implement the Pallone-Thune Telephone Robocall Abuse Criminal Enforcement and Deterrence Act (TRACED Act), promoting the deployment of caller ID authentication technology, and combatting the practice of illegal caller ID spoofing. In doing so, the *Order* adopts rules governing intermediate providers and caller ID authentication in non-IP networks, implements the exceptions and extensions established by the TRACED Act and prohibits line-item charges for caller ID authentication.

List of Subjects in 47 CFR Part 64

Common carriers.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

For the reasons set forth in the preamble, the Federal Communications Commission amends part 64 of title 47 of the Code of Federal Regulations as follows:

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 § 64.6306 by revising paragraph (e) to read as follows:

§ 64.6306 Exemption.

* * * * *

(e) *Implementation verification.* All voice service providers granted an exemption under paragraphs (a) and (b) of this section shall file an additional certification consistent with the requirements of paragraph (c) of this section on or before October 4, 2021 that attests to whether the voice service provider fully implemented the STIR/SHAKEN authentication framework because it completed all necessary network upgrades to its network infrastructure to enable the authentication and verification of caller identification information for all SIP calls exchanged with STIR/SHAKEN–enabled partners by June 30, 2021. The Wireline Competition Bureau, after issuing a Public Notice seeking comment on the certifications, will, not later than four months after the deadline for filing of the certifications, issue a Public Notice identifying which voice service providers achieved complete implementation of the STIR/SHAKEN authentication framework.

[FR Doc. 2021–22545 Filed 10–19–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 210210–0018; RTID 0648–XB284]

Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 610 in the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for pollock in Statistical Area 610 in the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the annual 2021 total allowable catch of pollock for Statistical Area 610 in the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), October 15, 2021, through 2400 hours, A.l.t., December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Allyson Olds, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The annual 2021 total allowable catch (TAC) of pollock in Statistical Area 610 of the GOA is 18,477 metric tons (mt) as established by the final 2021 and 2022 harvest specifications for groundfish in the GOA (86 FR 10184, February 19, 2021).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the annual 2021 TAC of pollock in Statistical Area 610 of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 18,377 mt and is setting aside the remaining 100 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 610 of the GOA.

While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was 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, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for pollock in Statistical Area 610 of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of October 14, 2021.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 15, 2021.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–22853 Filed 10–15–21; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 86, No. 200
Wednesday, October 20, 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.

FARM CREDIT ADMINISTRATION

12 CFR Part 628

RIN 3052–AD42

Risk Weighting of High Volatility Commercial Real Estate (HVCRE) Exposures

AGENCY: Farm Credit Administration.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Farm Credit Administration (FCA or we) is extending the comment period on its proposed rule that would revise the regulatory capital requirements for Farm Credit System (FCS or System) institutions to define and establish a risk-weight for high volatility commercial real estate (HVCRE) exposures. FCA is extending the comment period for an additional 61 days, until January 24, 2022, so interested parties will have additional time to provide comments on the proposed rule.

DATES: The comment period for the proposed rule published on August 26, 2021 (86 FR 47601) is extended from November 24, 2021, to January 24, 2022.

ADDRESSES: For accuracy and efficiency reasons, please submit comments by email or through FCA's website. We do not accept comments submitted by facsimiles (fax), as faxes are difficult for us to process and achieve compliance with section 508 of the Rehabilitation Act of 1973. Please do not submit your comment multiple times via different methods. You may submit comments by any of the following methods:

- *Email:* Send us an email at *reg-comm@fca.gov.*
- *FCA website: http://www.fca.gov.* Click inside the ''I want to . . .'' field near the top of the page; select ''comment on a pending regulation'' from the dropdown menu; and click ''Go.'' This takes you to an electronic public comment form.
- *Mail:* Kevin J. Kramp, Director, Office of Regulatory Policy, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

You may review copies of comments we receive on our website at *http://www.fca.gov.* Once you are on the website, click inside the ''I want to . . .'' field near the top of the page; select ''find comments on a pending regulation'' from the dropdown menu; and click ''Go.'' This will take you to the Comment Letters page where you can select the regulation for which you would like to read the public comments.

We will show your comments as submitted, including any supporting data provided, but for technical reasons we may omit items such as logos and special characters. Identifying information that you provide, such as phone numbers and addresses, will be publicly available. However, we will attempt to remove email addresses to help reduce internet spam. You may also review comments at our office in McLean, Virginia. Please call us at (703) 883–4056 or email us at *reg-comm@fca.gov* to make an appointment.

FOR FURTHER INFORMATION CONTACT:

Technical information: Ryan Leist, *LeistR@fca.gov,* Senior Accountant, or Jeremy R. Edelstein, *EdelsteinJ@fca.gov,* Associate Director, Finance and Capital Markets Team, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4414, TTY (703) 883–4056, or *ORPMailbox@fca.gov;* or *Legal information:* Jennifer A. Cohn, *CohnJ@fca.gov,* Assistant General Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (720) 213–0440, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: On August 26, 2021, FCA published a proposed rule in the **Federal Register** that would update FCA's regulatory capital requirements to reflect the increased risks that exposures to certain acquisition, development or construction loans pose to System institutions. The proposed rule would also ensure that the System's capital requirements are comparable to the Basel III framework and the standardized approach the Federal banking regulatory agencies have adopted, with deviations as appropriate to accommodate the different operational and credit considerations of the System.

The comment period is currently scheduled to close on November 24, 2021. *See* 86 FR 47601. FCA is extending the comment period for an additional 61 days, until January 24, 2022, so interested parties will have additional time to provide comments on the proposed rule in consideration of other rulemakings that are also open for public comment.

Dated: October 15, 2021.

Dale Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2021–22826 Filed 10–19–21; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 1

RIN 0991–AC29

[HHS–OS–2020–0008; HHS–OS–2021–0001]

Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or the Department) is proposing to repeal two final rules: ''Department of Health and Human Services Good Guidance Practices,'' published in the **Federal Register** of December 7, 2020; and ''Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions,'' published in the **Federal Register** of January 14, 2021.

DATES: To be assured consideration, comments must be received at the address provided below, no later than 11:59 p.m. November 19, 2021.

ADDRESSES: You may submit comments through the Federal eRulemaking Portal: *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet

search engines. No deletions, modifications, or redactions will be made to comments received. Inspection of Public Comments: All comments received before the close of the comment period will be available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.* Follow the search instructions on that website to view the public comments.

FOR FURTHER INFORMATION CONTACT: Daniel J. Barry, Acting General Counsel, 200 Independence Avenue SW, Washington, DC 20201. Email: *GoodGuidance@hhs.gov.* Telephone: 877–696–6775.

SUPPLEMENTARY INFORMATION:

I. Overview of the Proposed Rule

HHS is proposing to repeal two rules that were issued in December 2020 and January 2021 to implement Executive Orders (E.O.s) issued on October 9, 2019. One rule relates to guidance document procedures and the other relates to civil administrative enforcement and adjudication procedures. The Department codified both rules collectively in 45 CFR part 1.

On January 20, 2021, the President, under a new administration, revoked both E.O.s that served as the basis for these rules and directed agencies to promptly take steps to rescind any rules and policies implementing or enforcing the revoked E.O.s, as appropriate and consistent with applicable law. Accordingly, the Department has reconsidered these rules and now believes that they create unnecessary hurdles that hinder the Department's ability to issue guidance, bring enforcement actions, and take other appropriate actions that advance the Department's mission. The Department continues to abide by its longstanding commitment to follow applicable principles of due process and administrative law, as a matter of policy; however, upon further reflection, we now conclude that these rules significantly burden the Department and are inconsistent with the policies and goals of the current Administration. Both rules created a single set of procedures for guidance documents and civil enforcement for the entire Department, which we believe is contrary to the efficient and effective administration of the wide array of programs by the Department, given the diversity of those programs. For these reasons, as discussed in greater detail in this document, and consistent with the President's January 20, 2021, directive, we are proposing to repeal both rules.

II. History of the Rulemaking

On October 9, 2019, the White House issued two E.O.s: Executive Order 13891, ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' 84 FR 55235 (Oct. 15, 2019) (E.O. 13891) and Executive Order 13892, ''Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication,'' 84 FR 55239 (Oct. 15, 2019) (E.O. 13892). These E.O.s served as the basis for two rules promulgated by the Department in December 2020 and January 2021: ''Department of Health and Human Services Good Guidance Practices,'' 85 FR 78770 (Dec. 7, 2020) (GGP rule or the HHS GGP final rule, effective January 6, 2021), and ''Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions,'' 86 FR 3010 (Jan. 14, 2021) (the Civil Enforcement rule, effective January 12, 2021). The Department codified both rules collectively in 45 CFR part 1. Shortly after the rules became effective, on January 20, 2021, the President, under a new administration, issued Executive Order 13992, which revoked both E.O.s that served as the basis for these rules. 86 FR 7049 (Jan. 25, 2021).

A. Revoked Executive Orders

E.O. 13891, ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' required agencies to treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract; take public input on guidance documents into account; and make all guidance documents available on a single website. 84 FR 55235. E.O. 13892, ''Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication,'' imposed a number of procedural hurdles on agencies engaged in civil administrative enforcement or adjudication. 84 FR 55239. As noted, both of these E.O.s have since been rescinded. 86 FR 7049.

However, prior to the rescission of these E.O.s, and consistent with the directive in E.O. 13891, the Department published the GGP rule. Although E.O. 13892 did not require rulemaking, the Department also published a final rule to implement E.O. 13892, the Civil Enforcement rule.

B. GGP Rule

On August 20, 2020, consistent with the requirements of E.O. 13891, HHS published a notice of proposed rulemaking entitled ''Department of Health and Human Services Good Guidance Practices,'' the stated purpose of which was to ''promote the appropriate issuance and use of guidance documents . . .'' 85 FR 51396. The rule's stated intent was to increase accountability, improve the fairness of guidance issued by the Department, guard against unlawful regulation through guidance, and safeguard the important principles underlying the United States administrative law system. *Id.*

The major provisions of the HHS GGP proposed rule were: (1) A requirement that each guidance document issued by the Department generally include certain information, including a statement that the guidance does not have the force and effect of law and is not binding unless specifically incorporated into a contract; (2) heightened procedures for ''significant guidance documents,'' including a period of notice and comment, a requirement for HHS Secretary (Secretary) approval on a non-delegable basis, and a requirement for submission to the Office of Information and Regulatory Affairs (OIRA) for review under Executive Order 12866; (3) creation of a repository for all guidance documents along with a provision stating that guidance documents not in the repository are not effective and will be considered rescinded; and (4) procedures for the public to petition the Department to withdraw or modify any particular guidance document.

HHS proposed that its new requirements for guidance would apply to all components of the Department except for the Food and Drug Administration (FDA). 85 FR 51396. The preamble to the HHS GGP proposed rule explained that FDA already operates under a set of GGP regulations, *see* 21 CFR 10.115, as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 371(h); no other agency within HHS functions under a similar set of regulations or statutory

provisions. 85 FR 51396. FDA's GGP regulations have been in effect for more than two decades. *See* 21 CFR 10.115. The preamble also explained that FDA would be proposing amendments to its GGP regulations to address E.O. 13891 separately. 85 FR 51396.

The Department followed the notice of proposed rulemaking with a correction on August 26, 2020. 85 FR 52515. The correction changed certain dates by which documents would be required to be in the guidance repository or else be deemed rescinded.

During the comment period for the notice of proposed rulemaking, the Department received nearly 90 comments on the proposed rule. 85 FR 78771. The comments are available at *https://www.regulations.gov/document/HHS-OS-2020-0008-0001/comment.*

The Department issued the HHS GGP final rule on December 7, 2020. 85 FR 78770. In response to public comment and the Department's further consideration of the policies addressed in the rule, the HHS GGP final rule made several changes to the proposed rule. First, in addition to the requirement in the proposed rule that the Secretary approve, on a non-delegable basis, all significant guidance documents, the final rule added the requirement that the Secretary approve, on a non-delegable basis, all non-significant guidance documents that the Secretary determines would implicate a policy matter of priority to the Secretary; potentially create a serious inconsistency; or otherwise interfere with an action taken or planned by another HHS agency or the Office of the Secretary. *Id.* at 78786.

Second, the HHS GGP final rule added more detail on what information the Department needs to provide when responding to a petition to amend or withdraw guidance, including a statement on whether the Department agrees or disagrees with the petition and its rationale. 85 FR at 78787.

Third, although FDA had been excluded from the scope of the HHS GGP proposed rule, the final rule included FDA within its scope. 85 FR at 78785. The preamble to the HHS GGP final rule explained that one commenter had urged HHS to amend FDA's good guidance practices regulations to be consistent with the requirements in the HHS GGP proposed rule. 85 FR 78771. HHS agreed with this comment, and then explained that, because the FDA regulations had not yet been amended to address E.O. 13891, FDA would be included in the HHS GGP final rule until the Secretary issued a final rule amending FDA's separate GGP regulations. *Id.*[1]

The Department codified the GGP rule in 45 CFR 1.1 through 1.5.

C. Civil Enforcement Rule

On January 14, 2021, HHS issued a final rule entitled ''Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions.'' 86 FR 3010 (Jan. 14, 2021). The Civil Enforcement rule, which was issued as a procedural rule without notice-and-comment rulemaking, stated that it was intended to provide regulated parties with greater transparency and fairness in administrative actions and to be consistent with the requirements of E.O. 13892. 86 FR 3010. The Department stated that ''[t]he rule is designed to ensure accountability, fairness of how the Department uses guidance, proper use of guidance documents, and opportunities for third parties to be heard, and to safeguard the important principles underlying the United States administrative law system.'' 86 FR 3011.

The rule contains a number of provisions, including the following: (1) A requirement that the agency avoid unfair surprise by only applying standards and practices in a civil enforcement action that have been publicly stated; (2) a requirement that if the agency relies on a decision to assert new or expanded claims of jurisdiction, it must publish the initial decision in the **Federal Register** or the Department's guidance repository before the conduct over which the jurisdiction is sought occurs; and (3) a requirement that the Department give parties—before the agency takes a civil enforcement action—written notice of its initial legal and factual determinations, an opportunity to respond in writing and in certain cases orally, and a written response to the affected entity (when timely requested).

The Department codified the Civil Enforcement rule in 45 CFR part 1, by revising §§ 1.1 and 1.2, and adding §§ 1.6 through 1.9.

III. Legal Authority

The legal authority for this proposed rule is 5 U.S.C. 301. That provision states in relevant part that ''[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.'' Both the HHS GGP final rule and Civil Enforcement rule relied on the same authority.

IV. Discussion of Proposed Rule

This proposed rule, if finalized as proposed, would repeal both the GGP rule and the Civil Enforcement rule, codified collectively in 45 CFR part 1. 45 CFR part 1 would be reserved. This repeal is consistent with the policies of the Biden-Harris Administration as reflected in at least three E.O.s issued by President Biden. First, Executive Order 13992, which is titled ''Revocation of Certain Executive Orders Concerning Federal Regulation,'' 86 FR 7049 (Jan. 25, 2021) (E.O. 13992), revoked both EOs 13891 and 13892 and directed agencies to promptly take steps to rescind any orders, rules, regulations, guidelines, policies, or portions thereof, implementing or enforcing the revoked EOs, as appropriate and consistent with applicable law. As explained in Section II, History of the Rulemaking, the Department drafted the HHS GGP final rule and Civil Enforcement rule in direct response to the revoked EOs; hence, the department has reconsidered these rules and has determined it is appropriate to rescind these rules in accordance with section 3 of E.O. 13992.

Further, E.O. 13992 states that it is the policy of the current Administration to use available tools to confront the urgent challenges facing the nation, including the coronavirus disease 2019 (COVID–19) pandemic, economic recovery, racial justice, and climate change. *Id.* E.O. 13992 explained that to tackle these challenges effectively, executive departments must be equipped with the flexibility to use robust regulatory action to address national priorities. *Id.* The order also stated that it was revoking ''harmful policies and directives that threaten to frustrate the Federal Government's ability to confront these problems'' and was empowering agencies to use appropriate regulatory tools to achieve these goals. *Id.* As explained in greater detail in this document, the Department concludes that both the HHS GGP final rule and Civil Enforcement rule inappropriately constrict the Department's ability to efficiently interpret and enforce regulations. Thus, both rules are inconsistent with the policy expressed in E.O. 13992 Sec 1, and we are proposing that they be rescinded.

Second, the E.O. titled ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' 86 FR 7009 (Jan. 25, 2021) (E.O. 13985), states that it is

[1] In fact, the Department did not issue a proposed or final rule to amend FDA's GGP regulations to address E.O. 13891 before January 20, 2021, when E.O. 13891 was revoked.

the policy of the Biden-Harris Administration for the Federal Government to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. The E.O. directed agencies to recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity. *Id.* Further, both the HHS GGP final rule and the Civil Enforcement rules have a disproportionate effect on marginalized and vulnerable historically underserved communities, because they make it harder for agencies to take action to protect public health or remove bad actors from the market, which in turn harms those who need HHS services the most. For the GGP rule, commenters serving underserved communities explained that programs like Medicaid and CHIP rely on guidance to run the program effectively, and the effectiveness of the program directly affects the children, older adults, people with disabilities, and families these programs serve. Thus, a rule that hinders the publication of guidance may in turn harm the programs and the populations served, who rely on guidance documents to clarify program coverage requirements and have fewer resources to determine, for example, how and why guidance may be rescinded. Further, commenters pointed out that agency specific websites, such as Medicaid.gov, provide easy access to all the applicable guidance. While the rule did not preclude agencies from maintaining topical websites that contain agency specific guidance, it is much easier for organizations with limited resources serving marginalized communities to check the topical websites for new guidance than to check the repository to determine how and why and whether guidance may have been rescinded.

Third, the E.O. titled ''Strengthening Medicaid and the Affordable Care Act,'' 86 FR 7793 (Feb. 2, 2021) (E.O. 14009), states that it is the policy of the Biden-Harris Administration for the Federal Government to protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American. The E.O. directs HHS, among others, to examine its regulations, policies, and the like to ensure that they are consistent with the policy of providing high quality and accessible health care for all, and do not undermine protections for people with pre-existing conditions under the ACA, reduce coverage under or otherwise undermine Medicaid or the ACA, or undermine the Health Insurance Marketplace or the individual, small group, or large group markets for health insurance in the United States. Because HHS frequently issues guidance to clarify policies and beneficiary protections under Medicaid, the additional regulatory hurdles and confusion created by the HHS GGP final rule would likely undermine those goals by impeding and delaying the issuance of Medicaid guidance.

In addition to being inconsistent with this Administration's E.O.s, these rules created a single set of procedures for guidance documents and civil enforcement for the entire Department, which is incompatible with the efficient and effective administration of a Department as large and diverse as HHS. The Department's mission is to enhance the health and well-being of all Americans, and it accomplishes that mission through the work of many individual agencies, including the Administration for Children and Families (ACF), the Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), FDA, the Indian Health Service (IHS), the National Institutes of Health (NIH), and the Office for Civil Rights (OCR). Each of HHS's agencies plays a critical role in protecting and advancing public health by, for example, confronting the COVID–19 pandemic; administering and overseeing the Medicaid and Medicare programs and Affordable Care Act marketplace; providing federal health services to more than two million American Indians and Alaska Natives; taking action to protect consumers from unapproved, misbranded, or adulterated human or animal medical products or tobacco products; investigating, detaining, and recalling contaminated foods; addressing medical product shortages; enforcing age-restrictions or other controls around access to certain regulated products; and quickly distributing grant funds that help vulnerable populations, low-income families, elderly Americans, Indian tribes, and persons with disabilities to receive key resources, especially during the COVID–19 pandemic. Each agency within HHS serves the overall mission but does so in unique ways, often addressing different stakeholders and using specialized regulatory tools.

The imposition of these uniform requirements interferes with agencies' established practices and has disrupted agencies' relationships with stakeholders. FDA also faces a separate challenge with the GGP rule of simultaneously implementing two distinct GGP regulatory frameworks—its own, and that of the HHS GGP final rule—which is particularly inopportune at a time when rapid scientific advancements, as well as ongoing efforts to address the COVID–19 pandemic, warrant that FDA retain the ability to issue and revise guidance documents in a timely manner. As discussed in greater detail in Section A.1, like FDA, other HHS agencies rely on this flexibility to issue timely guidance and quickly share valuable information with stakeholders. Further, as discussed in section B, HHS agencies have developed their own processes for civil administrative enforcement that are unique to the specific requirements of each program. Accordingly, the Department no longer believes that a one-size-fits-all approach to Department guidance or civil administrative enforcement is appropriate and has concerns that the rules, imposing one set of requirements for its vastly different HHS agencies, may hinder the agencies' abilities to efficiently address public health issues, including but not limited to public health emergencies.

In light of the reasons explained in this section, the Department has taken a renewed and critical look at the HHS GGP and Civil Enforcement rules and has concluded that both rules frustrate the Department's ability to efficiently direct and operate in the interest of public health and are inconsistent with the policies and goals of the current Administration. The rules make Department operations more cumbersome and burdensome, impeding the Department's ability to quickly communicate its regulatory interpretations, policies, and recommendations, and use robust tools such as circulars, bulletins, advisories and other guidance documents to protect and advance the national public health and to promote the Department's mission. Accordingly, for the reasons previously stated, as well as specific concerns with each rule discussed in this section, HHS is proposing to repeal both rules in their entirety and remove 45 CFR part 1.

As a procedural matter, we have chosen to engage in notice-and-comment rulemaking for both rules. The Civil Enforcement rule was issued without notice and comment under the Administrative Procedure Act (APA), 5 U.S.C. 553, because the Department determined that it was a rule of agency organization, procedure, or practice. 86 FR 3010. The requirements for notice and comment prior to finalization also do not apply to regulations that involve ''a matter relating to agency

management or personnel.'' 5 U.S.C. 553(a)(2). Because the Department issued the Civil Enforcement rule without going through notice-and-comment rulemaking, HHS could repeal the Civil Enforcement rule without prior notice and comment based on the well-established principle ''that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance.'' *Perez* v. *Mortg. Bankers Ass'n,* 575 U.S. 92, 101 (2015). Similarly, although the Department chose to issue the GGP rule through notice-and-comment rulemaking, we note that generally the HHS GGP final rule involves matters relating to agency procedure and practice that did not require notice-and-comment rulemaking before promulgation. We also note that other departments and agencies have recently rescinded similar rules, and most have proceeded without notice-and-comment rulemaking at both the initial rulemaking and repeal stage. Nevertheless, to ensure transparency and public participation, and because the provisions of the two rules are codified in the same part of the Code of Federal Regulations with some overlapping and related provisions, the Department has opted in its discretion—for substantive and procedural clarity—to proceed with notice-and-comment rulemaking to repeal both rules together and in their entirety.

A. GGP Rule (45 CFR 1.1 Through 1.5)

1. Department-Wide Concerns Regarding the HHS GGP Final Rule

The Department is proposing to repeal the HHS GGP final rule for the following interrelated reasons: (1) It delays or prevents the issuance of guidance documents, which provide valuable information to stakeholders and the general public, including historically underserved populations; (2) it imposes uniform, inflexible requirements on agencies that do not adequately account for the agencies' different operations and are likely to cause confusion among regulated entities and members of the public; (3) it mandates the use of a guidance repository and provides for the rescission of guidance absent any active policy consideration by the agency, which may lead the public to believe that certain active policies are rescinded; and (4) it diverts limited agency resources that the Department now believes are better directed elsewhere.

Delay or Prevent Issuance of Guidance Documents. The procedures required in § 1.3 for the issuance of guidance documents have the potential to delay or impede the issuance of a significant portion of HHS guidance documents that play an important part in effective communication with stakeholders and enhance public health. For example, the rule establishes substantial, time-consuming, and resource-intensive requirements for the issuance of ''significant guidance documents.'' *See* 45 CFR 1.3(b). Required procedures for significant guidance documents include submitting such documents to the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) for review prior to publication, providing a public notice-and-comment process, generating an agency response to major concerns raised during the comment period, complying with applicable requirements for significant regulatory actions as set forth in Executive Orders, and obtaining approval by the Secretary on a non-delegable basis. *Id.* Each of these steps takes considerable time, effort, and Department resources to accomplish. Moreover, under the rule, all of these steps are required in *combination* before a significant guidance can be finalized.

As a matter of the policy, the Department is no longer convinced that these burdens are justified for non-binding agency guidance documents. The additional procedures provide little value, because the Department already has all the tools it needs to ensure adequate public notice and participation in the guidance process, and a one size fits all approach of the procedures fails to accommodate the range of guidance practices of HHS operational divisions. Moreover, the net effects of this requirement are serious burdens on the Department and an overall process that could unduly extend the time needed to promulgate significant guidance. This result is particularly concerning if the definition of significant guidance is construed to apply to a large number of guidance documents, in light of the potential cumulative effects.

The GGP rule imposes additional steps on the process of issuing non-significant guidance as well. For non-significant guidance, § 1.3 requires Secretarial approval under certain circumstances, which could delay the issuance of these guidance documents by drawing on the Secretary's finite time and resources. Further, this requirement could delay even non-significant guidance that do not require Secretarial approval because the process requires the Secretary to make an affirmative decision on whether a document requires Secretarial approval.

The Department has determined that the delay or non-issuance of guidance documents could have substantial negative consequences for the public, including for regulated entities. Guidance holds an important—and legally distinct—place in the Department's regulatory toolbox: It provides an approach to communicating the Department's policies and interpretations that can be more immediate and clearer than case-by-case adjudication, as well as faster and more flexible than legislative rulemaking. Through guidance, traditionally, the Department has been able to quickly and responsively communicate its agencies' non-binding current thinking regarding legal interpretations, recommendations, and policies. Guidance can be helpful, for example, to provide information relevant to a subset of regulated entities, address technical issues, give current examples, and keep pace with rapid advancements in science and technology. While this pathway has been important in a wide array of contexts, it is essential in areas of uncertainty, confusion, or rapid scientific or technological development, where clarity is needed to protect the public health and foster industry confidence and business investments.

Timely guidance is particularly important to parties that are subject to Department regulation. Guidance can assist regulated industries by helping guard against unequal treatment, unnecessary costs, and unnecessary risk. For example, for medical product developers who are engaged in expensive, multi-year development programs with the ultimate objective of finding a proper path to satisfy FDA's approval standards, guidance documents can provide recommendations on how to satisfy regulatory requirements and can describe how FDA staff applies those requirements to particular types of situations. This allows developers to design and invest in their product development strategy with more clarity and more confidence. The timely issuance of FDA guidance documents helps to accelerate the development and availability of innovative new products (or competitors to products already on the market) by: Encouraging particular methodologies, such as clinical trial models, to identify evidence that helps expedite product review; giving advice on how emerging technologies and breakthrough drugs and devices can meet FDA requirements for approval or clearance; and explaining FDA processes and procedures, including processes for premarket review, so developers can navigate those processes more quickly.

Having a robust, efficient guidance system has been especially critical during the COVID–19 emergency. FDA COVID–19-related guidance documents have addressed shortages of essential products including gowns, masks, gloves, and ventilators; the development of vaccines and drug products to prevent and treat COVID–19; recommendations for validating COVID–19 tests and evaluating the impact of viral mutations on COVID–19 tests; and even COVID–19-related effects on the food supply chain. The expeditious publication of the Office of Civil Rights guidance related to the Health Insurance Portability and Accountability Act (HIPAA) during the COVID–19 pandemic also served to communicate critical information to health care providers and the public about sharing and accessing protected health information. In the context of Federal financial assistance, guidance allowed the agency to issue grant funds quickly, which has been essential to providing states and tribes with information on permissible uses of funds to help vulnerable families, refugees, and foster children during the COVID–19 pandemic. For example, ACF's Children's Bureau used a guidance document to provide information to states on how they could use supplemental funding under the Child Abuse Prevention and Treatment Act and the Community-Based Child Abuse Prevention program provided by the American Rescue Plan Act. By issuing guidance quickly, Children's Bureau was able to, shortly after the passage of the law, provide states with information on how to apply for the funds and use them so that the funds could be used to promote the safety and well-being of children during the on-going pandemic.

The Department expressed a contrary assessment in the final rule, concluding that the benefits of receiving stakeholder input generally outweigh any administrative costs or incremental delays. 85 FR 78778. The Department also pointed to the exceptions process for significant guidance documents under § 1.3(b)(2)(ii), under which HHS could elect not to conduct a comment period if it were to find that notice and public comment are impracticable, unnecessary, or contrary to the public interest. *Id.* The Department considered this exceptions process to be sufficient to preserve flexibility during public health emergencies. *Id.*

As a matter of policy, the Department is no longer convinced that the benefits of receiving stakeholder input outweigh any administrative costs or incremental delays in the case of public health emergencies. The Department now disagrees that the exceptions process for significant guidance documents provides sufficient flexibility for the Department to respond to public health emergencies. To rely on the exception under § 1.3(b)(2)(ii), the Department would still need to make findings that public comment would be impracticable, unnecessary, or contrary to the public interest and incorporate the findings and a statement of the reasons into the guidance document. Even if the exceptions could be met during a public health emergency, these additional processes would still need to be followed and would still consume time and resources in a situation where time and resources are limited. In addition, the unprecedented nature of the COVID–19 pandemic has underscored the need for the Department to be able to act quickly during public health emergencies.

Retaining the HHS GGP final rule, with its relative lack of flexibility and procedural burdens that go far beyond what is needed for a transparent and inclusive guidance process, unduly hampers the Department's mission, particularly at this critical time. While the Department is aware that the GGP rule permits significant guidance documents to be exempted from applicable requirements ''if the Secretary [of HHS] and the Administrator of OIRA agree that exigency, safety, health, or other compelling cause warrants the exemption,'' the documents may be exempted only if several burdensome conditions are met. Specifically, for exemption, the Secretary and Administrator must come to the described agreement, the Secretary ''must make this finding,'' and ''the significant guidance document must incorporate the finding and a brief statement of reasons in support.'' *See* 45 CFR 1.3(b)(4). Thus, even where this pathway is taken, as a matter of policy HHS is now concerned that the procedural burdens of the rule may inappropriately delay guidance during an emergency.

The Department has reconsidered the relative merits of an efficient, flexible guidance process and weighed them against the processes finalized in the HHS GGP final rule. Ultimately, the Department favors an approach that is consistent with the Administrative Procedure Act (APA), which exempts non-binding documents like interpretive rules and general statements of policy from notice-and-comment rulemaking requirements.[2]

Confusing and Unhelpful Uniform Standards. As mentioned previously in this document, the GGP rule imposes identical requirements on agencies with different legal authorities and mechanisms for achieving their mission. This attempt to fit vastly different documents into one rubric is unnecessary, counterproductive, and likely to confuse the public about the role of different documents. HHS now believes that more flexibility is appropriate in light of the different roles and responsibilities of the agencies within the Department.

For example, § 1.3(a)(3)(i) of the GGP rule requires every guidance document to bear the following statement: ''The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.'' Although the Department previously concluded that this statement is unlikely to be confusing, 85 FR 78778, upon reconsideration, the Department is now concerned that this universal statement is not appropriate for and cannot cover the range of HHS documents that fall within the definition of ''guidance document'' under § 1.2(a). A better approach would be for each agency to provide information that is appropriate to the agency's stakeholders and the expected uses of the particular document, while acknowledging the document's non-binding nature under the APA. An FDA guidance document may discuss enforcement priorities, for example, and any standard guidance statement for FDA guidance should account for that. An ACF document providing guidance on the requirements of a regulation can indicate that its provisions may become incorporated into the terms and conditions of a grant agreement, which has contractual aspects that bind both the government and the grantee.

Furthermore, the Department is concerned that the required statement that incorporation of provisions of a guidance document into a contract would render the guidance binding may be confusing to the public. While the terms of the contract may be binding, that is, the contractual parties must

[2] *See, e.g., American Hosp. Ass'n* v. *Bowen,* 834 F.2d 1037, 1045 (D.C. Cir. 1987) (''The reading of the [section] 553 exemptions that seems most consonant with Congress' purposes in adopting the APA is to construe them as an attempt to preserve agency flexibility in dealing with limited situations where substantive rights are not at stake.'').

follow the guidance due to the contract terms, the guidance itself remains non-binding. The GGP rule's required statement suggests, to the contrary, that the nature of the guidance is altered by the contract.

The Department is similarly concerned about the ambiguity of the term ''contract,'' especially as it relates to assistance agreements, such as grants and cooperative agreements. While it is understood that assistance agreements have contractual aspects, in several other contexts the Department draws a clear legal and programmatic distinction between contracts and assistance agreements. For example, the Federal Grants and Cooperative Agreement Act, 31 U.S.C. 6301–6308, distinguishes between grants and contracts by explaining that agencies should use contracts for the direct benefit of the Federal Government, and agencies should use grants when the principal purpose of an agreement is the transfer of anything of value for a public purpose. Nevertheless, both contracts and grants require entering into an agreement that binds both parties to its terms, including terms found in guidance documents. The undefined nature of such a key term in a required disclaimer term could create uncertainty and confusion within the Department and among the public.

Like the disclaimer on guidance documents, the definition of ''guidance'' in 45 CFR 1.2 is vague and overly broad and could lead to confusion over the type of documents subject to the rule's requirements. ''Guidance'' is defined, in part, as a ''Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation.'' *See* 45 CFR 1.2(a). In addition, the preamble to the HHS GGP proposed rule provided that ''guidance may come in a variety of forms, including, but not limited to, letters, memoranda, circulars, bulletins, advisories, and preambles and may include video, audio, and Web-based formats.'' 85 FR 51396. Contrary to the previous conclusion that this definition is not confusing, 85 FR 78772, upon reconsideration, this broad definition and understanding could be read to encompass an entire range of documents not intended to serve as guidance, such as resolution documents, agreements and case closure letters, and memoranda published on Department agency websites to inform and educate the general public and regulated entities about agency enforcement activities.

HHS has rejected the alternative approach of addressing these problems by revising the rule. It would be difficult to establish definitions, standard descriptors, policies, and procedures that are clear and that are workable across the Department's many components. As a matter of policy, we now believe it is much better to allow flexibility in approach. With the repeal of this rule, the agencies would be able to develop policies, practices, and rules, consistent with applicable law and as appropriate to their context, and they would be able to update these over time as warranted. This more decentralized approach is also consistent with the revocation of E.O. 13891, which had taken a relatively centralized and standardized approach.

Repository. 45 CFR 1.4 provides for a repository that includes all Department guidance documents. Section 1.4(a)(2) of the rule deems any guidance document not in the repository rescinded. Although the Department plans to maintain a guidance document repository, it now considers the provisions of the HHS GGP final rule governing the repository to be inappropriate and unnecessary, particularly with respect to the rescission requirement for documents not in the repository.

Although the Department previously concluded that the automatic rescission of guidance documents not included in the repository would improve transparency and decrease confusion, 85 FR 78781, upon reconsideration, the Department now has serious reservations about that conclusion. The rescission requirement creates additional burdens among stakeholders by causing confusion about which guidance documents have been rescinded, superseded, or otherwise become obsolete. Even if a guidance document is posted on an HHS website, it is rescinded by the GGP rule if it is not in the repository, *see* § 1.4(a)(3)(ii); rescission can occur simply because a guidance is not uploaded to or is removed from the repository due to human error or technical failures, even if it is publicly available elsewhere. The Department acknowledged in the preamble to the final rule that accidental rescission can occur in this manner. CMS has since encountered difficulties, particularly when establishing automatic processes for publishing guidance documents in the repository. These difficulties have required time and resources to address, and at times CMS has had to resort to a cumbersome manual process to publish the guidance documents. A concern is that, if any document is omitted from the repository, even inadvertently, as a result of using the manual approach, it is rescinded.

The Department also questions whether this rescission approach is consistent with the APA. The APA requires that an agency consider relevant factors and make policy choices based on those factors.[3] It is not clear that rescission of a policy due to human error, oversight, or a technical failure meets these standards. In addition, the Department is concerned that serious questions and problems would arise if a guidance document is ''rescinded'' under the GGP rule, even for a finite period of time, when the guidance in question continues to reflect agency interpretations and policies. In that event, regulated entities would face a high degree of uncertainty as to the Department's current thinking—whether the current thinking is still the same as described in the rescinded guidance or has changed significantly—particularly in light of the possibility that the guidance may have been unintentionally rescinded because of human error or technical failure.

The GGP rule also does not address the situation in which guidance documents are in the repository, but a regulated entity cannot access or view them—for example, due to flaws in the repository search function. For such documents, individuals may incorrectly believe that documents are missing from the HHS repository, and therefore believe that guidance has been rescinded and/or no longer represents the Department's policy or interpretation. In that event, again, regulated entities would risk taking actions based on a misunderstanding of the Department's current interpretations and policies. Or, more likely, regulated entities may have the added burden of inquiring with the agency about whether the guidance is in the repository, either informally or by petition, which would consume time and resources for both the requestor and the Department.[4] The Department is also concerned that this structure may

[3] *See Motor Vehicle Mfrs. Ass'n* v. *State Farm,* 463 U.S. 29, 43 (1983) (courts ''consider whether the [agency's rescission] decision was based on a consideration of the relevant factors'') (citations and internal quotations omitted); *F.C.C.* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009) (''[T]he agency must show that there are good reasons for the new policy.'').

[4] Several commenters noted that they have no trouble finding current guidance without the repository. One commenter pointed out Medicaid guidance can easily be accessed through the ''Federal Policy guidance'' tab on *Medicaid.gov* website. Another commenter suggested that guidance documents on topical web pages was more helpful than the repository, which was not indexed.

cause regulated entities to restructure their compliance processes and operations, which could be quite costly. With all these possible concerns in mind, the Department invites stakeholders to comment on their experience with the repository. Although we no longer think automatic rescission is appropriate, the Department intends to retain the repository and is interested in stakeholders' experience using it. Specifically, the Department is interested in knowing whether stakeholders have been able to easily find the guidance applicable to them in the repository and how the Department can improve its usability and utility.

As noted earlier in this section, the Department believes that there is value in an online guidance database, and currently plans to retain a guidance document repository. However, upon reconsideration, the Department does not see a need to establish this administrative tool by regulation. Particularly in light of the experience of the COVID–19 pandemic, the Department now believes that flexibility is preferable to rigid requirements. The Department's current understanding has also been reinforced upon observing the technical challenges associated with a centralized repository. The Department believes that the better approach would be to engage with the individual agencies to develop the most efficient and user-friendly repository system that has the flexibility to change with improving technology and experience, and not to be constrained by regulatory requirements. If the proposed repeal of the HHS GGP final rule is finalized, the Department currently intends for the repository at *www.hhs.gov/guidance* to remain active, but the additional requirements imposed by the GGP rule (*e.g.,* that removal from the repository would affect rescission of a guidance) would be removed. We propose the automatic rescission requirement will have no effect on the status of guidance documents regardless of when they were issued. If the HHS GGP final rule is repealed as proposed, guidance documents will remain validly issued regardless of whether they were ever inadvertently not included in the repository. HHS will seek to ensure the repository is as complete and up to date as possible.

Unnecessary Diversion of Resources. Other aspects of the HHS GGP final rule also raise concerns because they divert agency resources without providing adequate compensating benefit, or are simply unnecessary. Although the Department previously believed that the petition process would not unduly strain HHS resources and delay the issuance of new guidance documents, 85 FR 78783, we now have serious policy reservations about this allocation of resources. The Department has now determined that the petition process concerning the withdrawal or modification of guidance documents, established in § 1.5—which requires written responses from the Department on a short timeframe regardless of the petition's subject matter or merits or of competing public health priorities—is unnecessary and burdensome. This process allows a petitioner to petition for hundreds of guidance documents to be rescinded at once or allows one or many petitioners to re-petition regarding a single guidance document multiple times. Further, many agencies have well-established petition processes that are already in use by stakeholders seeking changes to or rescission of existing guidance, and there are equally well-established processes for stakeholders wishing to challenge agency decisions (including those involving applicability of a guidance) that are unique to the agency and the communities with whom the agency works. These processes include citizen petitions related to FDA guidance and the appeals process at 42 CFR part 498 for facilities that disagree with decisions involving application of guidance governing Medicare eligibility and participation. Further, many stakeholders are in regular communication with agencies and express their comments, suggestions, or concerns with guidance in their formal and informal discussions with agency employees. It is not necessary, in the Department's view, to require an expedited response to all guidance-related concerns, some of which may warrant extensive review and consideration.

The GGP rule also contains generalized statements related to the role and effect of guidance that are not necessary and could cause confusion. For example, § 1.3(a)(1) states, ''[u]nder the Administrative Procedure Act, the Department may not issue any guidance document that establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute.'' To the extent that provisions such as this one seek to capture a current understanding of principles established by the APA, the Department has reconsidered that effort and now sees little benefit in it. It is unnecessary because the APA governs agency conduct concerning guidance without the need for agency regulations.

If HHS were to finalize this proposed rule to repeal the HHS GGP final rule, appropriate parameters and procedures for guidance documents issued by HHS agencies would remain in place. Repealing the HHS GGP final rule would not change the existing state of the law on the non-binding effect of guidance documents or whether they lack the force and effect of law. Nor would such repeal permit an agency to use guidance documents to establish or change policies where rulemaking is otherwise required, or to require outside parties to take or refrain from taking certain actions that are not addressed by statute or regulation. *See generally Azar* v. *Allina Health Servs.,* 139 S. Ct. 1804 (2019) (finding that Medicare-related guidance cannot create additional burdens beyond those included in statute or regulation). The Department would retain appropriate internal procedures for approval of the issuance of guidance documents and would continue to make guidance documents available to the public. Further, OIRA would continue to review guidance documents in appropriate circumstances, as it did before the issuance of E.O. 13891. Stakeholders could still petition the Department to take certain actions related to guidance documents under their general rights to communicate with and to seek redress from the Federal Government. In summary, the Department no longer believes that the provisions of the HHS GGP final rule are warranted.

2. Conflict With FDA Good Guidance Practices

The HHS GGP final rule also presents implementation problems for FDA. If HHS were not already proposing to repeal the rule in its entirety, HHS would have proposed to amend 45 CFR part 1 to remove FDA from the scope of that regulation. Indeed, it is also possible that, if the exclusion of FDA from 45 CFR part 1 can proceed separately on a faster track, the Department may choose to finalize that part of the repeal in advance of finalizing other aspects of this rulemaking.

As noted, FDA, unlike the other divisions of HHS, has long operated under a statutory provision concerning guidance and has its own GGP regulations, which address FDA's practices related to guidance documents, including practices and procedures for issuing, revising, and implementing guidance documents. FDA adopted its GGP regulations over 20 years ago at the conclusion of a public process that began in the 1990s. In May 1995, the Indiana Medical

Device Manufacturers Council submitted a citizen petition to FDA requesting, among other things, that FDA establish greater controls over the initiation, development, and issuance of guidance documents to ensure the appropriate level of meaningful public participation. In response to this petition, and after an opportunity for public comment, in February 1997, FDA published a guidance document on GGPs. 62 FR 8961 (Feb. 27, 1997). On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115). Section 405 of FDAMA added section 701(h) to the FD&C Act, which codified certain parts of the 1997 FDA GGP guidance document. In response to FDAMA, FDA issued a proposed rule on February 14, 2000, 65 FR 7321, to amend its administrative regulations to codify its policies and procedures for developing, issuing, and using guidance documents, including those set forth in section 701(h) of the FD&C Act. FDA issued a final rule establishing the GGP regulation on September 19, 2000. 65 FR 56468.

FDA currently issues its guidance documents consistent with section 701(h) of the FD&C Act (21 U.S.C. 371(h)) and 21 CFR 10.115, which include procedures for the following:

- Public participation in the development of guidance documents, including to propose topics for guidance, submit drafts of proposed guidance for consideration, comment on most guidance documents before implementation, and comment on revising or rescinding any guidance documents at any time after issuance;
- For most guidance documents, publication of a notice in the **Federal Register** announcing the guidance document's availability;
- Public availability of guidance documents, both on *FDA.gov*, and, upon request, in hard copy;
- Standard elements of guidance documents, including elements to make clear the non-binding effect of guidance documents, to identify the Center or Office issuing the guidance, and to identify the activities to which the guidance applies;
- Approval of guidance documents; and,
- An appeals process if FDA does not follow its GGP regulation or if an FDA employee treats a guidance document as binding.

FDA also operates under longstanding regulations regarding citizen petitions. *See* 21 CFR 10.30, 10.31. For years, stakeholders have submitted petitions under FDA's regulations that suggest that the agency take certain actions on guidance documents, particularly to amend guidance.

The Department is concerned that the HHS GGP final rule establishes standards and processes that overlap with but are distinct from those in section 701(h) of the FD&C Act, FDA's GGP regulation, and/or FDA's regulation governing citizen petitions. For example, section 701(h) of the FD&C Act and 45 CFR 1.3(b)(4) contain different standards for dispensing with prior public participation for certain guidance documents. Having two sets of regulations governing FDA guidance practices, as well as two sets of regulations governing citizen petitions related to FDA guidance documents, creates practical difficulties and confusion. For these reasons as well as the general concerns with the GGP rule discussed in this document, the Department no longer believes that this regulatory overlay on the FDA guidance processes adds value.

In addition, the application of the HHS GGP final rule to FDA guidance presents problems that were not considered or addressed at the time the Department made the decision to extend the rule to apply to FDA. For guidance documents erroneously rescinded based on their absence from the repository, the Department believed that rescission could be remedied simply through issuing the guidance consistent with ''the procedures in [the HHS] rule.'' 85 FR 78781. However, FDA has its own statutory mandate and regulations requiring promulgation of guidance through a notice and comment process in most cases. Therefore, if a guidance document is erroneously rescinded under § 1.4(a)(2) of the HHS GGP final rule, FDA would need to consider how to repromulgate its guidance in a manner consistent not only with the HHS GGP final rule, but also with its own statute and regulations. Repealing the HHS GGP final rule—and in particular, removing FDA from the scope of 45 CFR part 1—is important to stabilize and clarify the regulatory regime for FDA guidance documents, including the process for submitting citizen petitions related to FDA guidance documents. As discussed in this section, the Department now believes that any procedures going beyond those set forth in FDA's current regulations—such as those for significant guidance documents—are unwarranted for FDA guidance. In addition, it is inefficient and confusing for regulated entities as well as FDA staff to toggle back-and-forth between HHS and FDA GGP rules to try to figure out what the requirements are.[5]

B. Civil Enforcement Rule (45 CFR 1.1–1.2, 1.6–1.9)

The Department is proposing to repeal the Civil Enforcement rule because the rule: (1) Creates unnecessary hurdles and roadblocks in agency actions, likely to the detriment of the public; (2) conflicts with and undermines current agency processes; and (3) diverts critical Department resources.

Creates Unnecessary Hurdles. The processes and procedures set forth in the Civil Enforcement rule create unnecessary hurdles and roadblocks for agency actions, to the detriment of the public health and other national priorities. Section 1.9 requires the Department to follow certain steps before taking civil enforcement actions, including providing parties with an initial notice of the agency's legal and factual determinations, an opportunity to object or respond, and the Department's ''written response'' to the affected party's objections. The Department previously anticipated that existing HHS procedures already satisfied the requirements established in § 1.9. 86 FR 3012. Upon reconsideration, as a matter of policy, the Department now finds that the Civil Enforcement rule creates a rigid, burdensome, and resource-intensive path for Department staff, which is unnecessary when other tools in use, such as information negotiation, could be more efficient and effective.

Section 1.7(a) prohibits the Department from applying ''standards or practices'' in a civil enforcement action that have not been ''publicly stated.'' That new restriction on the Department's authority is inconsistent with settled case law,[6] and it could interfere with the Department's ability to enforce new laws and address

[5] The FDA GGP rule is an example of an agency developing procedures uniquely suited to its mission and statutory authorities. Trying to impose processes that were tailored to FDA upon all other agencies within the Department, or trying to force FDA to conform to a process for the entire Department, would create additional burdens and confusion.

[6] *See SEC* v. *Chenery Corp.,* 332 U.S. 194, 203 (1947) (''[P]roblems may arise in a case which the administrative agency could not reasonably foresee. . . . Hence, we refuse to say that the Commission, which had not previously been confronted with the problem of management trading during reorganization, was forbidden from utilizing this [adjudicatory] proceeding for announcing and applying a new standard of conduct''); *Martin* v. *Occupational Safety & Health Rev. Comm'n,* 499 U.S. 144, 154 (1991) (''Within traditional agencies . . . adjudication operates as an appropriate mechanism not only for factfinding, but also for the exercise of delegated lawmaking powers, including lawmaking by interpretation.'').

emerging threats, particularly through the use of adjudicatory proceedings.

Overall, through provisions such as these, the rule could impede and delay civil enforcement actions, as well as depress the overall number of actions, given finite Departmental resources. Slower and fewer enforcement actions could not only leave more bad actors in the market, but could embolden them, ultimately undermining the public interest.

Although § 1.9 includes an exception for actions involving ''a serious threat to health, safety, or similar emergency,'' 86 FR 3013, the discretionary exception does not address fraudulent actors who drain the Department's resources when allowed to remain in Departmental programs. For example, it is not in the public interest for an HHS agency such as CMS to take fewer enforcement actions against providers and suppliers who fraudulently bill patients and harm the Medicare trust funds. Delayed action against fraudulent billing would allow further diversion of taxpayer dollars and loss of program funding, forcing divisions to reprioritize program resources. Additionally, the exception does not alleviate the burden on the Department, because the process, including the Department's written response to the party's objections, must still be followed ''as soon as practicable.'' 86 FR 3013. Finally, analyzing whether a particular action falls into the exceptions set forth in § 1.9(c) would itself require an expenditure of time and resources that could delay actions needed to be taken on a time-sensitive basis.

Conflict with Existing Processes. Although the Department previously concluded that the requirements set forth in the final rule would facilitate smoother operations, 86 FR 3013, upon reconsideration, the Department is now concerned that the requirements in §§ 1.6 through 1.9 may create conflict and cause confusion to Department staff and the public with respect to existing agency processes and regulations. The various agencies under the HHS umbrella each have procedural regulations, some of which have been specifically designed to govern a particular type of proceeding. *See, e.g.,* 21 CFR part 17 (procedures governing hearings concerning the imposition of civil money penalties by FDA); 42 CFR part 488 (CMS and State Agency survey, certification, and enforcement procedures for Medicare providers and suppliers); 42 CFR part 498 (Appeals procedures for determinations that affect participation in the Medicare Program); 45 CFR part 160, subpart E (Procedures governing hearings challenging the imposition of civil monetary penalties in HIPAA cases). The procedures required under the Civil Enforcement rule do not adequately account for these pre-existing, agency-specific procedures, nor do they account for the differences between agencies within the Department. Instead, the Civil Enforcement rule dictates an overlay of new, and in some cases redundant, requirements. These requirements may conflict with or diverge from the existing procedures established to provide parties notice and an opportunity to be heard. This overlay creates confusion for both HHS agencies and regulated parties and could delay or prevent civil enforcement.[7]

The procedural regulations already established within HHS comply with principles of due notice, fairness, and transparency. Parties that are subject to civil administrative enforcement actions and adjudications under the existing procedures established prior to the Civil Enforcement rule are routinely provided with sufficient notice of the action, adequately informed of laws and regulations to which they are subject to, fully instructed on contesting or appealing agency determinations prior to actions of legal consequence, and protected from unfair surprise. The Civil Enforcement rule did not provide any evidence to the contrary. Thus, overall, the Department has not identified grounds to justify the expenditure of resources on compliance with the rule, particularly given that such expenditure would divert resources from other important Department activities, as explained in the next subsection.

Diverts Resources. Further, the Civil Enforcement rule could require the expenditure of significant resources to respond to spurious challenges to valid enforcement actions and adjudications. The rule is likely to invite opportunistic litigation not only because parties will have new procedural grounds to object to agency actions, but also because many of the provisions in § 1.9 are opaque and susceptible to multiple interpretations. The additional time and resources that would be needed to address and defend against such challenges would significantly impede the Department's ability to take enforcement actions and would divert resources from mission-critical activities.

In summary, the Civil Enforcement rule deprives the Department and its agencies of necessary flexibility in determining when and how best to conduct civil administrative enforcement actions and adjudications based on particular facts and circumstances. The Civil Enforcement rule also unduly restricts the Department's ability to take timely action to enhance the health and well-being of all Americans.

C. Reliance Interests

In issuing this proposed rule, the Department has considered reliance interests that may have accrued in connection with 45 CFR part 1. As an initial matter, the Department doubts that any serious reliance interests have accrued. Both the HHS GGP and Civil Enforcement final rules became effective only a couple of weeks before the change in Administration and before the E.O.s on which they relied were revoked. They have been in place for only a few months, most of which time followed that revocation. It is unlikely that serious reliance has developed in that short amount of time. *Cf. Clark-Cowlitz Joint Operating Agency* v. *FERC,* 826 F.2d 1074, 1084 (D.C. Cir. 1987) (finding limited reliance interest where rule was in place for only six months, among other things). Under these circumstances, it is likely that regulated entities would have anticipated that the rules would be reconsidered and potentially rescinded, particularly after the revocation of E.O.s 13891 and 13892 on January 20, 2021. Indeed, other departments and agencies have already repealed rules issued pursuant to those E.O.s.[8]

[7] Further, we note that if the GGP rule is not repealed as part of this rulemaking, the limitations on use of guidance documents in 45 CFR 1.6(b), which were added as part of the Civil Enforcement rulemaking, may raise additional questions regarding the appropriate scope and use of guidance documents—especially in light of potentially conflicting directives in the HHS GGP final rule.

[8] As of May 28, 2021, over 10 other departments and agencies have repealed such rules. *See* Tennessee Valley Authority Final Rule, '''Promoting the Rule of Law Through Improved Agency Guidance' Regulations; Rescission,'' 86 FR 28488 (May 27, 2021) (rescinding rule on guidance); Environmental Protection Agency Final Rule, ''EPA Guidance; Administrative Procedures for Issuance and Public Petitions; Rescission,'' 86 FR 26842 (May 18, 2021) (rescinding rule on guidance); National Endowment for the Humanities and National Foundation on the Arts and the Humanities Final Rule, ''Processes and Procedures for Issuing Guidance Documents,'' 86 FR 26184 (May 13, 2021) (rescinding rule on guidance); U.S. Office of Government Ethics Final Rule, ''Removal of U.S. Office of Government Ethics Guidance Documents Regulations'' 86 FR 25801 (May 11, 2021) (rescinding rule on guidance); Railroad Retirement Board Final Rule, 86 FR 22866 (Apr. 30, 2021) (rescinding rule on guidance); Social Security Administration Final Rule, ''Rescission of Rules on Improved Agency Guidance Documents'' 86 FR 20631 (Apr. 21, 2021) (rescinding regulations on guidance); Department of Interior Final Rule, ''Procedures for Issuing Guidance Documents,'' 86 FR 19786 (Apr. 15, 2021) (rescinding regulations on issuing guidance); Council on Environmental

Continued

Moreover, particularly given the timing of the issuance of these rules, it is difficult to see how the procedures or principles set forth in these rules would translate to a stakeholder making concrete changes in public or business decisions or practices that would implicate serious reliance interests. As explained in this document, consistent with the largely procedural nature of the rules, the rules codify steps that the agency would take in certain circumstances, such as when issuing guidance or prior to civil administrative enforcement actions, but they do not on their own change the substantive requirements governing regulated entities or related property interests. Finally, the Department considers the policies reflected in this proposed rule to advance the public interest. To the extent that any serious reliance interests are at stake, the Department believes that the public interests in efficient issuance of guidance and adequate civil administrative enforcement actions outweigh any such individual reliance interests. However, we invite parties to use the comment period for this proposed rule to explain why they believe they would be adversely affected by this proposed policy change and explain how they would need to adjust their practices, as appropriate.

V. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

E.O. 12866, ''Regulatory Planning and Review,'' and E.O. 13563, ''Improving Regulation and Regulatory Review,'' direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select regulatory approaches that maximize net benefits.

In both the HHS GGP proposed and final rules, OMB determined that the rulemaking was not an economically significant regulatory action under these E.O.s. 85 FR 51399; 85 FR 78784. OMB made a similar finding with respect to the Civil Enforcement rule. 86 FR 3013. The preambles to these rules maintained that the rules primarily described procedural changes that would require Department expenditures to implement. Although the preambles theorized that stakeholders might eventually benefit from greater transparencies and efficiencies from these procedural changes, the rules did not identify any benefits that were likely to be immediately realized. *See* 85 FR 78784; 86 FR 3013.

In the current rulemaking, the Department is proposing to repeal two recent final rules, effective on January 6, 2021, and January 12, 2021, which would remove all of 45 CFR part 1. If finalized, this rulemaking would restore the status quo that existed just prior to the January 2021 effective dates. The Department may then take further action as needed to undo any minimal actions taken since those effective dates to implement the rules' procedural directives. Consistent with the conclusions reached in the preambles of the HHS GGP final rule and Civil Enforcement rule, and for the additional reasons described in this section, OMB finds that this rulemaking is a significant regulatory action under E.O.s 12866 and 13453. The Office of Management and Budget (OMB) has reviewed this rule as consistent with E.O. 12866 and 13453.

B. Regulatory Flexibility Act

The Department has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.* The RFA requires an agency to describe the impact of a proposed rulemaking on small entities by providing an initial regulatory flexibility analysis, unless the agency determines that the proposed rule will not have a significant economic impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a) and 605(b). The Department considers a proposed or final rule to have a significant economic impact on a substantial number of small entities if it has at least a three percent impact on revenue of at least five percent of small entities. The Department anticipates that, if finalized, this rule would restore the status quo just prior to the respective January 6, 2021, and January 12, 2021, effective dates of the HHS GGP final rule and the Civil Enforcement rule, and undo changes, if any, to procedures followed by the Department during the interim period. This proposed rule would repeal two rules that the Department concluded, and the Secretary certified, would not result in a significant impact on a substantial number of small entities. Further, the Department believes that any effects associated with future regulatory actions, including any positive or negative impacts to small entities, should be attributable to those regulatory actions rather than to this proposed rule, if it is finalized as proposed. As a result, the Department has determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on the operations of a substantial number of small entities.

C. Executive Order 13132 (Federalism)

E.O. 13132, ''Federalism,'' establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has Federalism implications. The Department has determined that this proposed rule would not impose such costs or have any Federalism implications.

D. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

HHS has analyzed this proposed rule in accordance with the principles set forth in 13175. HHS has tentatively determined that the proposed 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. In accordance with the Department's Tribal consultation policy, the Department solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

E. National Environmental Policy Act

HHS had determined that this proposed rule would not have a significant impact on the environment.

F. Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, 44 U.S.C. 3501–3521; 5 CFR part 1320, appendix

Quality Final Rule, ''Guidance Document Procedures Rescission,'' 86 FR 19149 (Apr. 13, 2021) (rescinding regulations on issuing guidance); U.S. Agency for International Development (USAID) Final Rule, ''Procedures for the Review and Clearance of USAID's Guidance Documents; Rescission'' 86 FR 18444 (Apr. 9, 2021) (rescinding regulations on issuing guidance); Department of Transportation Final Rule, ''Administrative Rulemaking, Guidance, and Enforcement Procedures,'' 86 FR 17292 (Apr. 2, 2021) (removing regulations regarding issuing guidance and conducting enforcement actions, among other things); Pension Benefit Guaranty Corporation Final Rule, ''Rescission of Pension Benefit Guaranty Corporation Rule on Guidance,'' 86 FR 17066 (Apr. 1, 2021) (rescinding rule on issuing guidance); Department of Energy Notice of Proposed Rulemaking, ''Procedures for the Issuance of Guidance Documents,'' 86 FR 16114 (Mar. 26, 2021) (proposing to rescind final rule on issuing guidance); Department of Energy Final Rule, ''Procedures for the Issuance of Guidance Documents,'' 86 FR 14807 (Mar. 19, 2021) (further delaying effective date of final rule on issuing guidance in order to conduct rulemaking to withdraw the rule); Department of Labor Final Rule, ''Rescission of Department of Labor Rule on Guidance,'' 86 FR 7237 (Jan. 27, 2021) (rescinding rule on issuing guidance).

A.1, the Department has reviewed this proposed rule and has determined that it proposes no new collections of information.

List of Subjects in 45 CFR Part 1

Government employees, Guidance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, and under the authority of 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR, subtitle A, subchapter A, by removing part 1.

PART 1—[REMOVED AND RESERVED]

■ 1. Remove and reserve part 1.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–22503 Filed 10–19–21; 8:45 am]

BILLING CODE 4150–26–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 23

[Docket No. DOT–OST–2021–0113]

Petition for Rulemaking; Airport Concession Disadvantaged Business Enterprise (ACDBE) Program

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of grant of a petition for rulemaking.

SUMMARY: This notification grants the petition for rulemaking submitted by the Airports Council International-North America (ACI–NA) requesting that DOT initiate rulemaking to revise and update agency rules pertaining to Participation of Disadvantaged Business Enterprise in Airport Concessions.

DATES: October 20, 2021.

ADDRESSES: National External Operations and Policy Programs, Federal Aviation Administration, 800 Independence Avenue SW, Room 1030, Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Gene E. Roth, Director, National External Operations and Policy Programs, Federal Aviation Administration, 800 Independence Avenue SW, Room 1030, Washington, DC 20591, email *gene.e.roth@faa.gov*, telephone 202–913–7502; or Marc Pentino, Associate Director, Disadvantaged Business Enterprise Programs Division, Departmental Office of Civil Rights, Office of the Secretary, 1200 New Jersey Avenue SE, Washington, DC 20590, email *marc.pentino@dot.gov*, telephone 202–366–6968.

SUPPLEMENTARY INFORMATION:

Background

On June 30, 2021 ACI–NA submitted a petition for rulemaking requesting that DOT begin the process necessary to initiate a rulemaking to revise and update 49 CFR part 23. Specifically, ACI–NA requested that a number of regulatory issues important to airports be addressed to modernize the ACDBE program, including the definition of concession, the requirements for ACDBE program submittals, and the treatment of long-term exclusive agreements.

DOT plans to initiate a rulemaking to update DOT's Disadvantaged Business Enterprise (DBE) and ACDBE regulations to alleviate burdens for lower-tiered recipients and aviation sponsors to have a DBE program, remove the ACDBE program requirement for non-hub primary airports, modernize the definition of ''regular dealer'' to reflect changing material handling practices in the field, enhance current requirements to ease the burden on prime contractors in finding competitive and qualified DBE subcontractors, adjust the DBE and ACDBE program personal net worth cap for inflation, formalize guidance establishing successful COVID–19 flexibilities, allow qualified DBEs to work on large multiyear projects, and make technical corrections and other necessary updates. For additional information, see the Department's Spring 2021 Unified Agenda, available at *https://www.reginfo.gov/public/do/eAgendaMain*. Select Department of Transportation from the drop-down menu for the current agenda, and then select RIN 2105–AE98.

Conclusion

Having received this petition for rulemaking related to 49 CFR part 23, DOT has decided that ACI–NA's petition merits further consideration through the rulemaking process and hereby grants its petition for rulemaking using the existing RIN 2105–AE98.

The granting of the petition from ACI–NA, however, does not indicate that a final rule will be issued as requested by ACI–NA. The determination of whether to issue a rule and the content of the rule is made after the study of the requested action and the various alternatives in the course of the rulemaking proceeding, in accordance with statutory criteria.

Signed in Washington, DC, on October 13, 2021.

Irene B. Marion,

Director, Departmental Office of Civil Rights, Department of Transportation.

[FR Doc. 2021–22626 Filed 10–19–21; 8:45 am]

BILLING CODE P

Notices

Federal Register
Vol. 86, No. 200
Wednesday, October 20, 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

Food Safety and Inspection Service

[Docket No. FSIS–2021–0024]

National Advisory Committee on Microbiological Criteria for Foods

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: This notice is announcing a public meeting of the full Committee and Subcommittees from November 17, 2021 to November 19, 2021. The Committee will discuss the following two new charges: Enhancing *Salmonella* Control in Poultry Products and *Cyclospora cayetanensis* Contamination.

DATES: The full Committee will hold an open meeting on Wednesday, November 17, 2021 from 9:00 a.m. to 12:00 p.m. EST. The Subcommittees on Enhancing *Salmonella* Control in Poultry Products and *Cyclospora cayetanensis* Contamination, will hold concurrent open Subcommittee meetings on Wednesday, November 17, 2021 from 1:00 p.m. to 5:00 p.m.; Thursday November 18, 2021 from 1:00 p.m. to 4:00 p.m. EST.; and Friday, November 19, 2021 from 10:00 a.m. to 12:00 p.m. EST.

ADDRESSES: The Committee meetings will be held virtually. Attendees must pre-register at *https://ems8.intellor.com?do=register&t=1&p=841219* to receive a link for the meeting, dial-in number, access code, and unique Attendee ID for the Wednesday November 17, 2021 plenary meeting. There will be an opportunity to provide oral comments during the public meeting. Speakers are limited to three minutes during the public comment period. Attendees must notify FSIS during registration of their wish to speak at the meeting. FSIS will do its best to accommodate all registered persons who request to provide oral comments. Attendees should also indicate if they are interested in attending any of the Subcommittee meetings so FSIS can provide links for those meetings.

The NACMCF charges to be presented will be available at: *https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-notices.*

Agenda: FSIS will finalize an agenda on or before the meeting date and post it on FSIS' website at *https://www.fsis.usda.gov/news-events/events-meetings.*

Please note that the meeting agenda is subject to change due to the time required to present and discuss new charges; thus, sessions could end earlier or later than anticipated. Please plan accordingly if you would like to attend this meeting. Also, the official transcript of the November 17, 2021 full Committee meeting, when it becomes available, will be available on FSIS' website at *https://www.fsis.usda.gov/news-events/events-meetings.*

FOR FURTHER INFORMATION CONTACT: Persons with additional questions should contact Dr. Evelyne Mbandi: Phone: (202) 690–6537; Email: *NACMCF@usda.gov.* Sign Language Interpretation: Persons requiring a sign language interpreter or other special accommodations should notify Dr. Mbandi by November 3, 2021.

SUPPLEMENTARY INFORMATION:

Background

The NACMCF was established in 1988, in response to a recommendation of the National Academy of Sciences for an interagency approach to microbiological criteria for foods, and in response to a recommendation of the U.S. House of Representatives Committee on Appropriations, as expressed in the Rural Development, Agriculture, and Related Agencies Appropriation Bill for fiscal year 1988. The charter for the NACMCF is available for viewing on FSIS' website at *https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf.* The NACMCF provides scientific advice and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services on public health issues relative to the safety and wholesomeness of the U.S. food supply, including development of microbiological criteria and review and evaluation of epidemiological and risk assessment data and methodologies for assessing microbiological hazards in foods. The Committee also provides scientific advice and recommendations to the Centers for Disease Control and Prevention and the Departments of Commerce and Defense. Ms. Sandra Eskin, Deputy Under Secretary for Food Safety, USDA, is the Committee Chair; Dr. Susan T. Mayne, Director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN), is the Vice-Chair; and Mr. John J. Jarosh, FSIS, is the Director of the NACMCF Secretariat and Designated Federal Officer. Charges reviewed and approved by NACMCF Executive Committee deliberations will be made available by FSIS to the public prior to the Plenary Session on FSIS' website.

Disclaimer: NACMCF documents and comments posted on FSIS' website are electronic conversions from a variety of source formats. In some cases, document conversion may result in character translation or formatting errors. The original document is the official, legal copy. To meet the electronic and information technology accessibility standards in Section 508 of the Rehabilitation Act, NACMCF may add alternate text descriptors for non-text elements (graphs, charts, tables, multimedia, etc.). These modifications only affect the internet copies of the documents. Copyrighted documents will not be posted on FSIS' website, but will be available for inspection in the FSIS Docket Room. FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-notices.* FSIS also will make copies of this publication available through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This

service is available at: *https://www.fsis.usda.gov/news-events/news-press-releases/news-feeds-subscriptions.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

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Dated: October 15, 2021.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2021–22829 Filed 10–19–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest Advisory Board

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of intent to re-establish the charter for the Black Hills National Forest Advisory Board.

SUMMARY: The U.S. Department of Agriculture, Forest Service intends to reestablish the Charter of the Black Hills National Forest Advisory Board (Board). The purpose of the Board is to obtain advice and recommendations on a broad range of forest issues such as forest plan revisions or amendments, forest health including fire management and mountain pine beetle infestations, travel management, forest monitoring and evaluation, recreation fees, and site-specific projects having forest wide implications.

FOR FURTHER INFORMATION CONTACT: Scott Jacobson, Committee Coordinator, USDA, Black Hills National Forest, by telephone: 605–440–1409, fax: 605–673–9208, or email: *scott.j.jacobson@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: USDA 16565—Black Hills National Forest Advisory Board is a non-scientific program advisory Board established by the Secretary of Agriculture in 2003 to provide advice and counsel to the U.S. Forest Service, Black Hills National Forest, in the wake of increasingly severe and intense wildfires and mountain pine beetle epidemics.

The purpose of the Board is to provide advice and recommendations on a broad range of forest issues such as forest plan revisions or amendments, travel management, forest monitoring and evaluation, and site-specific projects having forest-wide implications. The Board also serves to meet the needs of the Recreation Enhancement Act of 2005 as a recreation resource advisory committee (RRAC) for the Black Hills of South Dakota. The Board provides timely advice and recommendations to the Regional Forester through the Forest Supervisor regarding programmatic forest issues and project-level issues that have forest-wide implications for the Black Hills National Forest.

The Board meets approximately ten times a year, with one meeting being a field trip, held in August, and focusing on both current issues and the educational value of seeing management strategies and outcomes on the ground. This Board has been established as a truly credible entity and a trusted voice on forest management issues and is doing often astonishing work in helping to develop informed consent for forest management.

For years, the demands made on the Black Hills National Forest have resulted in conflicts among interest groups, resulting in both forest-wide and site-specific programs being delayed due to appeals and litigation. The Board provides a forum to resolve these issues to allow for the Black Hills National Forest to move forward in its management activities.

Significant Contributions

The Board's most significant accomplishments include:

1. A 2004 report on the Black Hills Fuels Reduction Plan, a priority following the major fires including the 86,000 acre Jasper Fire in 2000;

2. A 2004 initial Off-Highway Vehicle Travel Management Subcommittee report;

3. A report on their findings regarding the thesis, direction, and assumptions of Phase II of the Forest Plan produced in 2005;

4. The Invasive Species Subcommittee Report in 2005 covering recommendations to better stop invasive species from infiltrating the Forest;

5. A final Travel Management Subcommittee Report in 2006 in which the Board made 11 recommendations regarding characteristics of a designated motor vehicle trail system, the basis for initial work to prepare the Motor Vehicle Use Map in 2010–2011;

6. The Mountain Pine Beetle Response Project in 2012 covering landscape scale treatments on portions of 248,000 acres of ponderosa pine stands at high risk for infestation;

7. The Board's annual work to attract funding through grants based on the Collaborative Landscape Forest Restoration Program (CFLRP), a program of the Secretary of Agriculture to encourage the collaborative, science-based ecosystem restoration of priority forest landscapes;

8. Recommendations for implementing the Black Hills Resilient Landscape (BHRL) project that proposed landscape vegetation treatment on 1,098,0000 acres;

9. A recommendation to develop a non-motorized Trail Strategy for various users across the Forest;

10. A recommendation on mineral withdrawal action in Research Natural

Areas (RNA) and Botanical Areas (BA) on the Black Hills National Forest;

11. A letter to the Secretary and the Chief of the Forest Service to work, restore, and maintain open space for wildlife habitat and recreation needs like snowmobile trails; and

12. Annual reports to the Secretary detailing the Board's activities, issues, and accomplishments.

The reestablishment of the Board is deemed to be among the most effective public involvement strategies in the Forest Service and continues to lead by example for Federal, State, and local government agencies working to coordinate and cooperate in the Black Hills of South Dakota and Wyoming.

Background

Pursuant to the Federal Advisory Committee Act (5 U.S.C. App. II); notice is hereby given that the Secretary of Agriculture intends to re-establish the charter of the Black Hills National Forest Advisory Board. The Board provides advice and recommendations on a broad range of forest issues and, in accordance with the Federal Lands Recreation Enhancement Act (Pub. L. 108–447 (FLREA)), more specifically will provide advice and recommendations on Black Hills National Forest recreation fee issues (serving as the RRAC for the Black Hills National Forest). The Board membership consists of individuals representing commodity interests, amenity interests, and State and local government.

The Board has been determined to be in the public interest in connection with the duties and responsibilities of the Black Hills National Forest. National forest management requires improved coordination among the interests and governmental entities responsible for land management decisions and the public that the agency serves.

Advisory Committee Organization

The Board consists of 16 members that are representative of the following interests (this membership is similar to the membership outlined by the Secure Rural Schools and Community Self Determination Act for Resource Advisory Committees (16 U.S.C. 500, *et seq.*)):

1. Economic development;
2. Developed outdoor recreation, off-highway vehicle users, or commercial recreation;
3. Energy and mineral development;
4. Forest products industry;
5. Grazing or other permit holders;
6. Nationally recognized environmental organization;
7. Regionally recognized environmental organization;
8. Dispersed recreation;
9. Archaeological, cultural, and historical interests;
10. Nationally or regionally recognized sportsmen's groups, such as anglers or hunters;
11. State, county, local-elected or South Dakota or Wyoming appointed office holders (3 positions);
12. Tribal government elected or appointed officials;
13. State Natural Resource Agency, South Dakota; and
14. State Natural Resource Agency, Wyoming.

No individual who is currently registered as a Federal lobbyist is eligible to serve as a member of the Committee. The Committee will meet approximately nine times and will attend at least one summer field tour as determined by the Designated Federal Officer (DFO).

The members of the Board will elect and determine the responsibilities of the Chairperson and the Vice-Chairperson. In the absence of the Chairperson, the Vice-Chairperson will act in the Chairperson's stead. The Forest Supervisor of the Black Hills National Forest serves as the Designated Federal Officer (DFO) under sections 10(e) and (f) of the Federal Advisory Committee Act (5 U.S.C. App. II).

Members will serve without compensation but may be reimbursed for travel expenses while performing duties on behalf of the Board, subject to approval by the DFO.

Equal opportunity practices are followed in all appointments to the Board in accordance with USDA policies. To ensure that the recommendations of the Board have taken into account the needs of diverse groups served by the Black Hills National Forest, membership shall include, to the extent practicable, individuals with demonstrated ability to represent the needs of men and women of all racial and ethnic groups, and persons with disabilities.

Dated: October 15, 2021.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2021–22872 Filed 10–19–21; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Texas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meetings.

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 (FACA) that the Texas Advisory Committee (Committee) will hold a series of meetings via Webex on Wednesday, November 3, 2021 and Wednesday, December 8, 2021 at 12:00 p.m. Central Time for the purpose of discussing their first Committee topic.

DATES: These meetings will be held on:

- Wednesday, November 3, 2021, from 12:00 p.m.–1:00 p.m. CT
- Wednesday, December 8, 2021, from 12:00 p.m.–1:00 p.m. CT

Public Webex Registertion Link:

- Wednesday, November 3rd: *https://tinyurl.com/s6ww7mkh*
- Wednesday, December 8th: *https://tinyurl.com/npynfny9*

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer (DFO) at *bpeery@usccr.gov* or by phone at (202) 701–1376. Persons with hearing impairments 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 entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012 or email Brooke Peery (DFO) at *bpeery@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkoAAA.*

Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Introductions
II. Discussion

III. Public Comment
IV. Adjournment

Dated: October 15, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–22848 Filed 10–19–21; 8:45 am]

BILLING CODE 6335–01–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 virtual press conference.

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 virtual press conference via Webex at 10:00 a.m. ET on Wednesday, December 1, 2021. The Committee will present the findings and recommendations from its report on Bail Reform.

DATES: The meeting will take place on Wednesday, December 1, 2021, at 10:00 a.m. ET.

ADDRESSES:

Online Registration (Audio/Visual): https://tinyurl.com/3e8tka58.

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: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, 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. 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 details found through registering at the web link above. To request additional accommodations, please email *bdelaviez@usccr.gov* at least ten (10) days prior to the meeting.

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 Coordination 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 Coordination Unit at the above email or street address.

Agenda

I. Opening Statement and Presentation by Chair
II. Roundtable with Invited Guests
III. Q&A with Press
IV. Adjourn

Dated: Friday, October 15, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–22871 Filed 10–19–21; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the New Mexico Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meetings.

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 New Mexico Advisory Committee (Committee) will hold a series of meetings via videoconference on Tuesday, November 9, 2021 at 10:00 a.m. and Thursday, December 16, 2021 at 11:00 a.m. Mountain Time for the purpose of discussing their first Committee topic.

DATES: These meetings will be held on:

- Tuesday, November 9, 2021, from 10:00 a.m.–11:00 a.m. MT
- Thursday, December 16, 2021, from 11:00 a.m.–12:00 p.m. MT

Public Registration Link:

- Tuesday, November 9: *https://tinyurl.com/h32z5jvk*
- Thursday, December 16: *https://tinyurl.com/3xwbsmwx*

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer (DFO), at *bpeery@usccr.gov* or (202) 701–1376

SUPPLEMENTARY INFORMATION: Members of the public may listen to the discussion. This meeting is available to the public through the public registration link listed above. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. 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. Persons with hearing impairments 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 mailed to the Regional Programs Unit Office, U.S. Commission on Civil Rights, 300 N. Los Angeles St., Suite 2010, Los Angeles, CA 90012 or emailed to Brooke Peery at *bpeery@usccr.gov*

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 at: *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlGAAQ*.

Please click on the ''Meeting Details'' and ''Documents'' links. Persons interested in the work of this Committee are also directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit office at the above email or street address.

Agenda

I. Welcome and Introductions
II. Discussion
III. Public Comment
IV. Adjournment

Dated: October 15, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–22847 Filed 10–19–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–50–2021]

Foreign-Trade Zone (FTZ) 265—Conroe, Texas; Authorization of Production Activity; LUC Urethanes, Inc. (Wheels, Rollers and Friction Pads for Industrial Machinery and Material Conveyance), Conroe, Texas

On June 17, 2021, the City of Conroe, Texas, grantee of FTZ 265, submitted a notification of proposed production activity to the FTZ Board on behalf of LUC Urethanes, Inc., within FTZ 265, in Conroe, Texas.

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 35472–35473, July 6, 2021). On October 15, 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.

Dated: October 15, 2021.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2021–22870 Filed 10–19–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

United States Travel and Tourism Advisory Board: Meeting of the United States Travel and Tourism Advisory Board

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The United States Travel and Tourism Advisory Board (Board or TTAB) will hold a meeting on Friday, November 5, 2021. The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry. The purpose of the meeting is for Board members to discuss and potentially adopt recommendations for the Secretary in the areas of (1) five-year goals for international arrivals and spending; (2) top issues facing the sector related to climate change; (3) actions to accelerate vaccination; and (4) actions to provide for employment in the sector. The final agenda will be posted on the Department of Commerce website for the Board at *https://www.trade.gov/ttab-meetings* at least two days prior to the meeting.

DATES: Friday, November 5, 2021, 2:00 p.m.–3:00 p.m. EDT. The deadline for members of the public to register for the meeting or to submit written comments for dissemination prior to the meeting is 5:00 p.m. EDT on Tuesday, November 2, 2021.

ADDRESSES: The meeting will be held virtually. The access information will be provided by email to registrants. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted by email to *TTAB@trade.gov*.

FOR FURTHER INFORMATION CONTACT: Jennifer Aguinaga, the United States Travel and Tourism Advisory Board, National Travel and Tourism Office, U.S. Department of Commerce; telephone: 202–482–2404; email: *TTAB@trade.gov*.

SUPPLEMENTARY INFORMATION: *Public Participation:* The meeting will be open to the public and will be accessible to people with disabilities. Any member of the public requesting to join the meeting is asked to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted but may not be possible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Members of the public wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EDT on Tuesday, November 2, 2021, for inclusion in the meeting records and for circulation to the members of the Board.

In addition, any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Jennifer Aguinaga at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EDT on Tuesday, November 2, 2021, to ensure transmission to the Board prior to the meeting. Comments received after that date and time will be transmitted to the Board but may not be considered during the meeting. Copies of Board meeting minutes will be available within 90 days of the meeting.

This Notice is published pursuant to the Federal Advisory Committee Act, as amended (FACA), 5 U.S.C., App., § 9(c). It has been determined that the Committee is necessary and in the public interest. The Committee was established pursuant to Commerce's authority under 15 U.S.C. 1512, established under the FACA, as amended, 5 U.S.C. App., and with the concurrence of the General Services Administration.

Jennifer Aguinaga,

Designated Federal Officer, United States Travel and Tourism Advisory Board.

[FR Doc. 2021–22648 Filed 10–19–21; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB513]

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of webconference.

SUMMARY: The North Pacific Fishery Management Council (Council) Bering Sea Fishery Ecosystem Plan Local Knowledge, Traditional Knowledge, and Subsistence Taskforce (LKTKS) will be held November 8, 2021 and on November 10, 2021.

DATES: The meeting will be held on Monday, November 8, 2021, from 8:30 to 12 p.m. and on Wednesday, November 10, 2021, from 8:30 a.m. to 2:30 p.m. Alaska Time.

ADDRESSES: The meeting will be a webconference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/2652.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave, Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions

for attending the meeting are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Kate Haapala Council staff; phone: (907) 271–2809 and email: *kate.haapala@noaa.gov*. For technical support please contact our administrative staff; email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Monday, November 8, 2021 and Wednesday, November 10, 2021

The agenda will include: (a) Updates on work from Climate Change Taskforce; (b) Norton Sound Red King Crab case study; (c) protocol development; and (d) other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2652* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2652.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2652* by 5 p.m. Alaska time on Friday, November 5, 2021. An opportunity for oral public testimony will also be provided during the meeting.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 15, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–22865 Filed 10–19–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB507]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will host a Seminar Series presentation on Red Porgy distribution changes via webinar on November 9, 2021.

DATES: The webinar presentation will be held on Tuesday, November 9, 2021, from 1 p.m. until 2:30 p.m.

ADDRESSES:

Meeting address: The presentation will be provided via webinar. The webinar is open to members of the public. Information, including a link to webinar registration will be posted on the Council's website at: *https://safmc.net/safmc-meetings/other-meetings/* as it becomes available.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8439 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The Council will host a presentation from South Carolina Department of Natural Resources on Red Porgy (*Pagrus pagrus*) distribution changes. A question and answer session will follow the presentation. Members of the public will have the opportunity to participate in the discussion. The presentation is for informational purposes only and no management actions will be taken.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 15, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–22863 Filed 10–19–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB515]

Pacific 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 Pacific Fishery Management Council's (Pacific Council) Ad Hoc Marine Planning Committee (MPC) will hold an online meeting. This meeting is open to the public.

DATES: The online meeting will be held Wednesday, November 10, 2021, 9 a.m. to 4 p.m., Pacific Standard Time (PST) or until business for the day has been completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Mr. Kerry Griffin, Staff Officer, Pacific Council; telephone: (503) 820–2409; email: *kerry.griffin@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Pacific Council's MPC will consider information and develop a report for the Pacific Council's November 15–22, 2021 meeting. Topics for the MPC's online meeting will include the NOAA Aquaculture Opportunity Areas and the United States Coast Guard's Port Access Route Study. The MPC may consider other information relevant to aquaculture or offshore wind energy planning and development as appropriate.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 15, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–22867 Filed 10–19–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB471]

South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a webinar meeting of its Executive Committee (partially closed session).

DATES: The Executive Committee meeting will be held from 1 p.m. until 2 p.m. on Wednesday, November 10, 2021.

ADDRESSES: The meeting will be held via webinar. Webinar registration is required. See **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8440 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: Meeting information, including the webinar link, agenda, and briefing book materials will be posted on the Council's website at: *http://safmc.net/safmc-meetings/council-meetings/.* Written comments may be directed to John Carmichael, Executive Director, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405 or electronically via the Council's website at *http://safmc.net/safmc-meetings/council-meetings/.* After Friday, November 3, 2021, comments must be submitted through the Council's online form on the website.

Agenda items include:

1. Council activity schedules for 2022
2. Council budget for 2022 (partially closed session)

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 15, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–22861 Filed 10–19–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB499]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 77 HMS Hammerhead Sharks Data Webinar III.

SUMMARY: The SEDAR 77 assessment of the Atlantic stocks of hammerhead sharks will consist of a stock identification (ID) process, data webinars/workshop, a series of assessment webinars, and a review workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 77 HMS Hammerhead Sharks Data webinar III has been scheduled for Tuesday, November 9, 2021, from 11 a.m. until 2 p.m. EST.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Registration is available online at: *https://attendee.gotowebinar.com/register/4373361793622080523.*

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4371; email: *Kathleen.Howington@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 77 HMS Hammerhead Shark Data Webinar III are as follows: Discuss data issues or concerns and discuss the logistics for the upcoming data workshop.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues

arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 15, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–22862 Filed 10–19–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB511]

Caribbean Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Caribbean Fishery Management Council's (Council) Outreach and Education Advisory Panel (OEAP) will hold a 2-day public virtual meeting in November to discuss the items contained in the agenda in the **SUPPLEMENTARY INFORMATION.**

DATES: The OEAP virtual meeting will be held on November 9, 2021, from 12 p.m. to 3 p.m. and on November 10, 2021, from 12 p.m. to 3 p.m.

ADDRESSES: You may join the OEAP public virtual meeting (via Zoom) from a computer, tablet or smartphone by entering the following address:

Join OEAP Zoom Meeting
https://us02web.zoom.us/j/84039986774?pwd=SUhDc1hXeFloQWF3ajVtL2ZHRGN3Zz09
Meeting ID: 840 3998 6774
Passcode: 179728
One tap mobile
+17879667727,,84039986774#,,,,*179728# Puerto Rico
+19399450244,,84039986774#,,,,*179728# Puerto Rico

Dial by your location
+1 787 966 7727 Puerto Rico
+1 939 945 0244 Puerto Rico
+1 787 945 1488 Puerto Rico
+1 669 900 6833 US (San Jose)
+1 929 205 6099 US (New York)
+1 253 215 8782 US (Tacoma)
+1 301 715 8592 US (Washington DC)
+1 312 626 6799 US (Chicago)
+1 346 248 7799 US (Houston)
Meeting ID: 840 3998 6774
Passcode: 179728

FOR FURTHER INFORMATION CONTACT: Diana Martino, phone: (787) 226–8849; Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918–1903.

SUPPLEMENTARY INFORMATION:

Tentative Agenda

November 9, 2021

12 p.m.–1 p.m.

—Call to Order
—Adoption of Agenda
—Outreach and Education Advisory Panel Chair's Report
—Updates:
  —Recipe Book
  —Illustrated Booklet on Ecosystem Based Fishery Management (EBFM)
  —Final Products on St. Thomas/St. John Marine Protected Areas (MPAs)
  —Calendar 2022 on U.S. Caribbean MPAs
  —Marine Resources Education Program
  —Outreach & Education Products Approved by the Caribbean Fishery Management Council: Illustrated Booklets (3), Bulletin Boards with Fisheries Information for Fish Markets/Restaurants and Signs on MPAs

1 p.m.–1:10 p.m.

—Break

1:10 p.m.–3 p.m.

—Issues/Activities in U.S.V.I. and P.R.
  —Wilson Santiago/P.R.
  —Nicole Greaux/St. Thomas
  —Mavel Maldonado/St. Croix
—Status of Marine Protected Areas in Territorial Jurisdiction
  —Presentations by Liaisons on their Respective Areas
—Outreach and Education Recommendations on MPAs

November 10, 2021

12 p.m.–1 p.m.

—Update Status of Fishery Ecosystem Plan
  —Outreach and Education Strategies to Support the Plan
  —Request for young Fishers Education Strategies to Recruit New Fishers—Vanessa Ramírez

1 p.m.–1:10 p.m.

—Break

1:10 p.m.–3 p.m.

—CFMC Facebook, Instagram and YouTube Communications with Stakeholders
—Other Business

The order of business may be adjusted as necessary to accommodate the completion of agenda items. The meeting will begin on November 9, 2021 at 12 p.m. and will end on November 10, 2021, at 3 p.m. Other than the start time, interested parties should be aware that discussions may start earlier or later than indicated. In addition, the meeting may be extended from, or completed prior to the date established in this notice.

Special Accommodations

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: October 15, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–22864 Filed 10–19–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB520]

Fisheries of the Gulf of Mexico and South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 79 Data webinar for Gulf of Mexico and South Atlantic mutton snapper.

SUMMARY: The SEDAR 79 assessment process of Gulf of Mexico and South Atlantic mutton snapper will consist of a Data Workshop, and a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 79 Data webinar will be held November 8, 2021, from 10 a.m.

until 12 p.m. Eastern Time. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net*.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion during the Data webinar are as follows:

Panelists will review the data sets being considered for the assessment.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 15, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–22868 Filed 10–19–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB514]

Pacific 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 Pacific Fishery Management Council's (Pacific Council) Groundfish Management Team (GMT) will hold a webinar meeting to discuss items on the Pacific Council's November 2021 meeting agenda. The meeting is open to the public.

DATES: The online meeting will be held on Monday, November 8, 2021, beginning at 1 p.m. and ending at 4 p.m. Pacific Standard Time, or when business for the day is completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Todd Phillips, Staff Officer, Pacific Council; telephone: (503) 820–2426.

SUPPLEMENTARY INFORMATION: The primary purpose of the GMT webinar is to prepare for the Pacific Council's November 2021 meeting. The GMT will discuss and may develop recommendations on groundfish management and administrative items on the Pacific Council's November 2021 agenda. A detailed agenda for the webinar will be available on the Pacific Council's website prior to the meeting. The GMT may also address other assignments relating to groundfish management.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 15, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–22866 Filed 10–19–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Administrative Suspension of Table Rock Lake Oversight Committee

AGENCY: Department of Defense (DoD).

ACTION: Administrative suspension of Federal Advisory Committee.

SUMMARY: The DoD is publishing this notice to announce it is administratively suspending the Table Rock Lake Oversight Committee (''the Committee'') on September 7, 2021.

FOR FURTHER INFORMATION CONTACT: Jim Freeman, DoD Advisory Committee Management Officer, 703–692–5952.

SUPPLEMENTARY INFORMATION: The DoD, pursuant to section 1185(c) of the Water Infrastructure Improvements for the Nation Act (''the WIIN Act'') (Pub. L. 114–322) and in accordance with the Federal Advisory Committee Act (5 U.S.C., Appendix), established the Committee on July 10, 2019. After careful consideration, the DoD determined that the Committee's stated objectives are accomplished and administratively suspended the Committee effective September 7, 2021, pending rescission of Section 1185(c) of the WIIN Act. Information concerning the Committee, to include contact information for the Committee's Designated Federal Officer can be found at *https://www.facadatabase.gov/FACA/FACAPublicPage.*

Dated: October 15, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–22859 Filed 10–19–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Amendment of Department of Defense Federal Advisory Committees; Defense Business Board

AGENCY: Department of Defense (DoD).

ACTION: Charter amendment of Federal Advisory Committee.

SUMMARY: The DoD is publishing this notice to announce that it is amending the charter for the Defense Business Board (DBB).

FOR FURTHER INFORMATION CONTACT: Jim Freeman, DoD Advisory Committee Management Officer, 703–692–5952.

SUPPLEMENTARY INFORMATION: The DBB's charter is being amended in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix) and 41 CFR 102–3.50(d). The charter and contact information for the DBB's Designated Federal Officer (DFO) are found at *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation.*

The DBB provides the Secretary of Defense and Deputy Secretary of Defense with independent advice and actionable recommendations to address critical matters and challenges to accelerate adoption of effective and efficient business processes and functions, organizational management constructs, and business and organizational cultural changes within the DoD in response to specific tasking from the Secretary of Defense or the Deputy Secretary of Defense (''the DoD Appointing Authority''). The DBB examines and advises on DoD executive management, innovative business processes, and governance from private, public, and academic sector perspectives. The DBB is composed of no more than 20 members who meet one of more of the following criteria: (a) Proven track record of sound judgement in leading or governing large, complex public or private-sector organizations, including academia; (b) significant management-level (executive level managers that are titled ''chief'' followed by their function) global business or academic experience including, but not limited to the areas of executive management, corporate strategy, governance, business process improvement and innovation, global business services/shared services, audit and finance, supply chain and logistics, human resources/talent management, data/analytics management and use, real property management, organizational design and optimization, energy and climate, or technology; (c) demonstrated performance in developing new business theories, innovation, and concepts; (d) career as a distinguished academic or researcher in business at an accredited college or institute of higher education; or (e) a proven track record as an innovative leader in small and minority owned businesses.

Individual members are appointed according to DoD policy and procedures, and serve a term of service of one-to-four years with annual renewals. One member will be appointed as Chair of the DBB. No member, unless approved according to DoD policy and procedures, may serve more than two consecutive terms of service on the DBB, or serve on more than two DoD Federal advisory committees at one time.

DBB members who are not full-time or permanent part-time Federal civilian officers or employees, or active duty members of the Uniformed Services, are appointed as experts or consultants, pursuant to 5 U.S.C. 3109, to serve as special government employee members. DBB members who are full-time or permanent part-time Federal civilian officers or employees, or active duty members of the Uniformed Services are appointed pursuant to 41 CFR 102–3.130(a), to serve as regular government employee members.

All DBB members are appointed to provide advice based on their best judgment without representing any particular point of view and in a manner that is free from conflict of interest. Except for reimbursement of official DBB-related travel and per diem, members serve without compensation.

The public or interested organizations may submit written statements about the DBB's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the DBB. All written statements shall be submitted to the DFO for the DBB, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: October 15, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–22856 Filed 10–19–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Wage Committee (DoDWC); Notice of Federal Advisory Committee Meetings

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of closed Federal Advisory Committee meetings.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meetings of the DoDWC will take place.

DATES:

Tuesday, October 19, 2021 from 10:00 a.m. to 11:00 a.m. and will be closed to the public.

Tuesday, November 2, 2021 from 10:00 a.m. to 12:00 p.m. and will be closed to the public.

Tuesday, November 16, 2021 from 10:00 a.m. to 12:00 p.m. and will be closed to the public.

Tuesday, November 30, 2021 from 10:00 a.m. to 11:00 a.m. and will be closed to the public.

Tuesday, December 14, 2021 from 10:00 a.m. to 12:00 p.m. and will be closed to the public.

Tuesday, January 11, 2022 from 10:00 a.m. to 11:00 a.m. and will be closed to the public.

ADDRESSES: The closed meetings will be held by teleconference.

FOR FURTHER INFORMATION CONTACT: Mr. Karl Fendt, (571) 372–1618 (voice), *karl.h.fendt.civ@mail.mil.* (email), 4800 Mark Center Drive, Suite 05G21, Alexandria, Virginia 22350 (mailing address). Any agenda updates can be found at the DoDWC's official website: *https://wageandsalary.dcpas.osd.mil/BWN/DODWC/.*

SUPPLEMENTARY INFORMATION:

Meeting Announcement: Due to circumstances beyond the control of the Department of Defense and the Designated Federal Officer for the DoDWC, the DoDWC was unable to provide public notification required by 41 CFR 102–3.450(a) concerning its October 19, 2021 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement. These meetings are 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 these meetings is to provide independent advice and recommendations on matters relating to the conduct of wage surveys and the establishment of wage schedules for all appropriated fund and non-appropriated fund areas of blue-collar employees within the DoD.

Agenda

October 19, 2021

Reviewing survey results and/or survey specifications for the following Nonappropriated Fund areas:

1. Any items needing further clarification or action from the previous agenda.
2. Wage Schedule (Wage Change) for the Ventura, California wage area (AC–132).
3. Wage Schedule (Wage Change) for the San Bernardino, California wage area (AC–134).

Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

4. Wage Schedule (Full Scale) for the Albany, Georgia wage area (AC–036).
5. Wage Schedule (Full Scale) for the Northwestern Michigan wage area (AC–071).
6. Wage Schedule (Full Scale) for the Scranton-Wilkes-Barre, Pennsylvania wage area (AC–117).
7. Wage Schedule (Wage Change) for the Little Rock, Arkansas wage area (AC–011).
8. Wage Schedule (Wage Change) for the Boston, Massachusetts wage area (AC–068).
9. Survey Specifications for the Birmingham, Alabama wage area (AC–002).
10. Survey Specifications for the Southern Colorado wage area (AC–023).
11. Survey Specifications for the Hagerstown-Martinsburg-Chambersburg, Maryland wage area (AC–067).
12. Survey Specifications for the Dayton, Ohio wage area (AC–107).
13. Survey Specifications for the Harrisburg, Pennsylvania wage area (AC–114).
14. Survey Specifications for the Wyoming wage area (AC–150).
15. Special Pay—Boston, Massachusetts Special Rates.
16. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

November 2, 2021

Reviewing survey results and/or survey specifications for the following Nonappropriated Fund areas:

1. Any items needing further clarification or action from the previous agenda.
2. Wage Schedule (Full Scale) for the Monterey, California wage area (AC–003).
3. Wage Schedule (Full Scale) for the Kern, California wage area (AC–010).
4. Wage Schedule (Full Scale) for the San Diego, California wage area (AC–054).
5. Wage Schedule (Full Scale) for the Solano, California wage area (AC–059).
6. Wage Schedule (Wage Change) for the Los Angeles, California wage area (AC–130).
7. Wage Schedule (Wage Change) for the Orange, California wage area (AC–131).
8. Wage Schedule (Wage Change) for the Santa Barbara, California wage area (AC–135).
9. Wage Schedule (Wage Change) for the Guam wage area (AC–150).
10. Survey Specifications for the Oklahoma, Oklahoma wage area (AC–052).
11. Survey Specifications for the Harrison, Mississippi wage area (AC–070).
12. Survey Specifications for the Hardin-Jefferson, Kentucky wage area (AC–096).
13. Survey Specifications for the Wayne, North Carolina wage area (AC–107).
14. Survey Specifications for the Cumberland, North Carolina wage area (AC–108).
15. Survey Specifications for the Richland, South Carolina wage area (AC–110).
16. Survey Specifications for the Wichita, Texas wage area (AC–122).
17. Survey Specifications for the Comanche, Oklahoma wage area (AC–123).
18. Survey Specifications for the Craven, North Carolina wage area (AC–164).

Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

19. Survey Specifications for the New York, New York wage area (AC–094).
20. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

November 16, 2021

Reviewing survey results and/or survey specifications for the following Nonappropriated Fund areas:

1. Any items needing further clarification or action from the previous agenda.
2. Wage Schedule (Full Scale) for the York, Maine wage area (AC–139).
3. Wage Schedule (Wage Change) for the Pima, Arizona wage area (AC–013).
4. Wage Schedule (Wage Change) for the Yuma, Arizona wage area (AC–055).
5. Wage Schedule (Wage Change) for the Riverside, California wage area (AC–133).

Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

6. Wage Schedule (Full Scale) for the San Diego, California wage area (AC–017).
7. Wage Schedule (Full Scale) for the San Francisco, California wage area (AC–018).
8. Wage Schedule (Full Scale) for the Pensacola, Florida wage area (AC–034).
9. Wage Schedule (Full Scale) for the Central Illinois wage area (AC–046).
10. Wage Schedule (Full Scale) for the Des Moines, Iowa wage area (AC–054).
11. Wage Schedule (Full Scale) for the Baltimore, Maryland wage area (AC–066).
12. Wage Schedule (Full Scale) for the Buffalo, New York wage area (AC–092).
13. Wage Schedule (Wage Change) for the Los Angeles, California wage area (AC–013).
14. Wage Schedule (Wage Change) for the San Bernardino-Riverside-Ontario, California wage area (AC–016).
15. Wage Schedule (Wage Change) for the Santa Barbara, California wage area (AC–019).
16. Wage Schedule (Wage Change) for the New London, Connecticut wage area (AC–025).

17. Wage Schedule (Wage Change) for the Panama City, Florida wage area (AC–033).

18. Wage Schedule (Wage Change) for the Chicago, Illinois wage area (AC–047).

19. Wage Schedule (Wage Change) for the Las Vegas, Nevada wage area (AC–085).

20. Wage Schedule (Wage Change) for the Portsmouth, New Hampshire wage area (AC–087).

21. Wage Schedule (Wage Change) for the Seattle-Everett-Tacoma, Washington wage area (AC–143).

22. Survey Specifications for the Salinas-Monterey, California wage area (AC–015).

23. Survey Specifications for the Lexington, Mississippi wage area (AC–058).

24. Survey Specifications for the Northern Mississippi wage area (AC–077).

25. Survey Specifications for the Memphis, Tennessee wage area (AC–124).

26. Special Pay—Los Angeles, California Special Rates.

27. Special Pay—San Diego, California Special Rates.

28. Special Pay—New London, Connecticut Special Rates.

29. Special Pay—North Central Power Rate.

30. Special Pay—Southwest Power Rate.

31. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

November 30, 2021

Reviewing survey results and/or survey specifications for the following Nonappropriated Fund areas:

1. Any items needing further clarification or action from the previous agenda.

2. Wage Schedule (Full Scale) for the Hampden, Massachusetts wage area (AC–039).

3. Wage Schedule (Full Scale) for the Middlesex, Massachusetts wage area (AC–138).

4. Wage Schedule (Wage Change) for the Maricopa, Arizona wage area (AC–012).

5. Wage Schedule (Wage Change) for the Kings-Queens, New York wage area (AC–091).

Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

6. Survey Specifications for the Rochester, New York wage area (AC–096).

7. Survey Specifications for the Nashville, Tennessee wage area (AC–125).

8. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

December 14, 2021

Reviewing survey results and/or survey specifications for the following Nonappropriated Fund areas:

1. Any items needing further clarification or action from the previous agenda.

2. Survey Specifications for the Calhoun, Alabama wage area (AC–104).

3. Survey Specifications for the Madison, Alabama wage area (AC–105).

4. Survey Specifications for the Lake, Illinois wage area (AC–145).

5. Survey Specifications for the Douglas-Sarpy, Nebraska wage area (AC–149).

6. Survey Specifications for the Leavenworth, Kansas-Jackson-Johnson, Missouri wage area (AC–086).

7. Survey Specifications for the St. Clair, Illinois wage area (AC–151).

Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

8. Wage Schedule (Full Scale) for the Cocoa Beach-Melbourne, Florida wage area (AC–028).

9. Wage Schedule (Full Scale) for the Davenport-Rock Island-Moline, Iowa wage area (AC–053).

10. Wage Schedule (Full Scale) for the Southwestern Michigan wage area (AC–073).

11. Wage Schedule (Full Scale) for the Philadelphia, Pennsylvania wage area (AC–115).

12. Wage Schedule (Full Scale) for the Eastern South Dakota wage area (AC–121).

13. Wage Schedule (Wage Change) for the Bloomington-Bedford-Washington, Indiana wage area (AC–048).

14. Wage Schedule (Wage Change) for the Fort Wayne-Marion, Indiana wage area (AC–049).

15. Wage Schedule (Wage Change) for the Indianapolis, Indiana wage area (AC–050).

16. Wage Schedule (Wage Change) for the Kansas City, Missouri wage area (AC–080).

17. Wage Schedule (Wage Change) for the St. Louis, Missouri wage area (AC–081).

18. Wage Schedule (Wage Change) for the Southern Missouri wage area (AC–082).

19. Wage Schedule (Wage Change) for the Omaha, Nebraska wage area (AC–084).

20. Wage Schedule (Wage Change) for the Dallas-Ft. Worth, Texas wage area (AC–131).

21. Survey Specifications for the Reno, Nevada wage area (AC–086).

22. Survey Specifications for the Houston-Galveston-Texas City, Texas wage area (AC–133).

23. Special Pay—Omaha, Nebraska Special Rates.

24. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

January 11, 2022

Reviewing survey results and/or survey specifications for the following Nonappropriated Fund areas:

1. Any items needing further clarification or action from the previous agenda.

2. Survey Specifications for the Cumberland, Pennsylvania wage area (AC–092).

3. Survey Specifications for the York, Pennsylvania wage area (AC–093).

4. Survey Specifications for the Honolulu, Hawaii wage area (AC–106).

5. Survey Specifications for the Norfolk-Portsmouth-Virginia Beach, Virginia wage area (AC–111).

6. Survey Specifications for the Hampton-Newport News, Virginia wage area (AC–112).

7. Survey Specifications for the Harford, Maryland wage area (AC–148).

Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

8. Wage Schedule (Full Scale) for the Wilmington, Delaware wage area (AC–026).

9. Wage Schedule (Full Scale) for the Topeka, Kansas wage area (AC–056).

10.Wage Schedule (Full Scale) for the Wichita, Kansas wage area (AC–057).

11. Wage Schedule (Full Scale) for the Biloxi, Mississippi wage area (AC–076).

12. Wage Schedule (Full Scale) for the Roanoke, Virginia wage area (AC–142).

13. Wage Schedule (Wage Change) for the New Orleans, Louisiana wage area (AC–048).

14. Wage Schedule (Wage Change) for the Richmond, Virginia wage area (AC–141).

15. Survey Specifications for the Huntsville, Alabama wage area (AC–004).

16. Survey Specifications for the Syracuse-Utica-Rome, New York wage area (AC–097).

17. Survey Specifications for the North Dakota wage area (AC–103).

18. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b(c)(4), the DoD has determined that the meetings shall be closed to the public. The Under Secretary of Defense for Personnel and

Readiness, in consultation with the DoD Office of General Counsel, has determined in writing that each of these meetings may disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential.

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 DoDWC 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 DoDWC 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: October 15, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–22879 Filed 10–19–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0113]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Consolidated State Performance Report Renewal (Part 1 and Part 2)

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 November 19, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Sarah Newman, 202–453–6956.

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: Consolidated State Performance Report Renewal (Part 1 and Part 2).

OMB Control Number: 1810–0724.

Type of Review: A revision of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 14,653.

Total Estimated Number of Annual Burden Hours: 16,481.

Abstract: The Consolidated State Performance Report (CSPR) is the required annual reporting tool for each State, the Bureau of Indian Education, District of Columbia, and Puerto Rico as authorized under Section 8303 of the Elementary and Secondary Education Act (ESEA), as amended by the Every Student Succeeds Act (ESSA). The CSPR collects data on programs authorized by: Title I, Part A; Title I, Part C; Title I, Part D; Title II, Part A; Title III, Part A; Title IV Part A; Title V, Part A; Title V, Part B, Subparts 1 and 2; and The McKinney-Vento Act. The information in this collection relate to the performance and monitoring activities of the aforementioned programs under ESSA and the McKinney-Vento Act. These data are needed for reporting on GPRA as well as other reporting requirements under ESSA. This submission is a request to update the currently-approved CSPR collection (OMB 1810–0724) for school years 2020–21 and 2021–22. There are two substantive changes to the collection since it was last approved: (1) Questions were added to CSPR Part I on ARP–HCY and (2) the section on the Migrant Education Program (Title I, Part C) was moved from CSPR Part II to CSPR Part I.

Dated: October 15, 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. 2021–22825 Filed 10–19–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2021–SCC–0119]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Income Based Repayment—Notifications

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before November 19, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection

activities, please contact Beth Grebeldinger, 202–377–4018.

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: Income Based Repayment—Notifications.

OMB Control Number: 1845–0114.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 958,240.

Total Estimated Number of Annual Burden Hours: 76,665.

Abstract: The Higher Education Act of 1965, as amended (HEA), established the Federal Family Education Loan (FFEL) Program under Title IV, Part B. Section 493C [20 U.S.C. 1098e] of the HEA authorizes income based repayment for Part B borrowers who have a partial financial hardship. The regulations in 34 CFR 682.215(e)(2) require notifications to borrowers from the loan holders once a borrower establishes a partial financial hardship and is placed in an income based repayment (IBR) plan by the loan holder. The regulations identify information the loan holder must provide to the borrower to continue to participate in an IBR plan. This is a request for extension without change of the current information collection 1845–0114.

Dated: October 15, 2021.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–22850 Filed 10–19–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

DOE/NSF Nuclear Science Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of virtual open meeting.

SUMMARY: This notice announces a meeting of the DOE/NSF Nuclear Science Advisory Committee (NSAC). Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Tuesday, November 16, 2021; 10:00 a.m.–5:15 p.m. (EDT).

ADDRESSES: This meeting is open to the public. This meeting will be held digitally via Zoom. Information to participate can be found on the website closer to the meeting date at: *https://science.osti.gov/np/nsac/meetings*.

FOR FURTHER INFORMATION CONTACT: Brenda L. May, U.S. Department of Energy; SC–36/Germantown Building, 1000 Independence Avenue SW, Washington, DC 20585–1290; Telephone: (301) 903–0536 or email: *brenda.may@science.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The purpose of the Committee is to provide advice and guidance on a continuing basis to the Department of Energy and the National Science Foundation on scientific priorities within the field of basic nuclear science research.

Tentative Agenda

Tuesday, November 16, 2021

- Call to Order, Introductions, Review of the Agenda
- Perspectives from Department of Energy and National Science Foundation
- Update from the Department of Energy and National Science Foundation's Nuclear Physics Office's
- Presentation on DOE NP Diversity Pilot Program
- LEGEND Technical Update
- NEXO Technical Update
- CUPID Technical Update
- Neutrinoless Double Beta Decay Progress and Prospects
- Long Range Plan Discussion
- NSAC Business/Discussions

Public Participation: The meeting is open to the public. Please check the website below for updates and information on how to view the meeting. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of these items on the agenda, you should contact Brenda L. May at *Brenda.May@science.doe.gov.* You must make your request for an oral statement at least five business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of the meeting will be available for review on the U.S. Department of Energy's Office of Nuclear Physics website at: *https://science.osti.gov/np/nsac/meetings.*

Signed in Washington, DC, on October 15, 2021.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2021–22878 Filed 10–19–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River Site

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES:

Monday, November 15, 2021; 1:00 p.m.–5:00 p.m.

Tuesday, November 16, 2021; 9:00 a.m.–2:00 p.m.

ADDRESSES: Holiday Inn—Beach House, 1 South Forest Beach Drive, Hilton Head, SC 29928.

FOR FURTHER INFORMATION: Amy Boyette, Office of External Affairs, U.S.

Department of Energy (DOE), Savannah River Operations Office, P.O. Box A, Aiken, SC 29802; Phone: (803) 952–6120; email: *amy.boyette@srs.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

Monday, November 15, 2021

Chair Update
Agenda Review
Agency Updates
Recommendation 367: *Stakeholder Survey Report*
Presentation on Major Accomplishments at the Savannah River Site
Public Comments
EM SSAB Chairs Recommendations:
- Charge #1: Advisory Board and Site Outreach
- Charge #2: EM SSAB Expectations, Guiding Principles
- Revise Member Appointment Process

Election: Chair and Vice Chair
Tuesday, November 16, 2021
Agenda Review
Presentation on 235–F Deactivation Progress, Engineering Evaluation and Cost Analysis
Presentation on Annual Site Environmental Report
Public Comments
Voting on EM SSAB Chairs Recommendations:
- Charge #1: Advisory Board and Site Outreach
- Charge #2: EM SSAB Expectations, Guiding Principles
- Revise Member Appointment Process

Public Participation: The meeting is open to the public. It will be held strictly following COVID–19 precautionary measures. To provide a safe meeting environment, seating may be limited; attendees should register for in-person attendance by sending an email to *srscitizensadvisoryboard@srs.gov* no later than 4:00 p.m. ET on Thursday, November 11, 2021. The EM SSAB, Savannah River Site, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Amy Boyette at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board via email either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should submit their request to *srscitizensadvisoryboard@srs.gov.* Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. Comments will be accepted after the meeting, by no later than 4:00 p.m. ET on Monday, November 22, 2021. Please submit comments to *srscitizensadvisoryboard@srs.gov.* The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make oral public comments will be provided a maximum of five minutes to present their comments. Individuals wishing to submit written public comments should email them as directed above.

Minutes: Minutes will be available by writing or calling Amy Boyette at the address or telephone number listed above. Minutes will also be available at the following website: *https://cab.srs.gov/srs-cab.html.*

Signed in Washington, DC, on October 15, 2021.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2021–22832 Filed 10–19–21; 8:45 am]

BILLING CODE 6450–01–P

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: CP22–5–000.
Applicants: Destin Pipeline.
Description: Joint Abbreviated Application of Destin Pipeline Company, L.L.C., for a Certificate of Public Convenience and Necessity and Authorization to reacquire capacity under CP22–5. Aplication/Petition/Request | Abandonment of Service or Facility, Application/Petition/Request Certificate of Public Convenience and Necessity Public.
Filed Date: 10/12/2021.
Accession Number: 20211012–5187.
Comment Date: 5 p.m. ET 11/2/21.

Docket Numbers: CP22–7–000.
Applicants: Southern Natural Gas Company.
Description: Application for Authorization of Abandonment for Rate Schedule X–54 of Southern Natural Gas Company, L.L.C. under CP22–7. Application/Petition/Request | Abandonment of Service or Facility Public.
Filed Date: 10/12/21.
Accession Number: 20211012–5650.
Comment Date: 5 p.m. ET 11/2/21.

Docket Numbers: PR21–53–002.
Applicants: Moss Bluff Hub, LLC.
Description: Submits tariff filing per 284.123(b),(e)/: MBH Amendment to PR21–53–000—FERC Housekeeping Items to be effective 10/13/2021.
Filed Date: 10/13/21.
Accession Number: 20211013–5046.
Comments/Protests Due: 5 p.m. ET 10/27/21.

Docket Numbers: RP22–42–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: Compliance filing: Cost & Revenue Study for NEXUS in Compliance with CP16–22–000 to be effective N/A.
Filed Date: 10/13/21.
Accession Number: 20211013–5068.
Comment Date: 5 p.m. ET 10/25/21.

Docket Numbers: RP22–43–000.
Applicants: Arlington Storage Company, LLC.
Description: Compliance filing: Informational Filing Concerning MBR Authority.
Filed Date: 10/13/21.
Accession Number: 20211013–5161.
Comment Date: 5 p.m. ET 10/25/21.

Docket Numbers: RP22–44–000.
Applicants: Stagecoach Pipeline & Storage Company LLC.
Description: Compliance filing: Informational Filing Concerning. MBR Authority.
Filed Date: 10/13/21.
Accession Number: 20211013–5162.
Comment Date: 5 p.m. ET 10/25/21.

Docket Numbers: RP22–45–000.
Applicants: Double E Pipeline, LLC.
Description: § 4(d) Rate Filing: Double E Pipeline, LLC—Tariff Cleanup Filing to be effective 11/15/2021.
Filed Date: 10/13/21.
Accession Number: 20211013–5194.
Comment Date: 5 p.m. ET 10/25/21.

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: October 14, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–22838 Filed 10–19–21; 8:45 am]

BILLING CODE 6717–01–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: EG22–7–000.

Applicants: EnerSmart Chula Vista BESS LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of EnerSmart Chula Vista BESS LLC.

Filed Date: 10/8/21.

Accession Number: 20211008–5318.

Comment Date: 5 p.m. ET 10/29/21.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL00–95–312; EL00–98–284.

Applicants: Investigation of Practices of the California Independent System Operator and the California Power Exchange, San Diego Gas & Electric Company v. Sellers of Energy and Ancillary Services.

Description: Notice of the California Power Exchange Corporation of Wire Transfer Information Provided by Participants for the Final Market Clearing.

Filed Date: 10/8/21.

Accession Number: 20211008–5320.

Comment Date: 5 p.m. ET 10/29/21.

Docket Numbers: EL00–95–313; EL00–98–285.

Applicants: Investigation of Practices of the California Independent System Operator. and the California Power Exchange, San Diego Gas & Electric Company v. Sellers of Energy and Ancillary Services.

Description: Schedule of Final Balances of California Parties and Indicated Attorneys General.

Filed Date: 10/8/21.

Accession Number: 20211008–5321

Comment Date: 5 p.m. ET 10/29/21.

Docket Numbers: EL22–2–001.

Applicants: New York Independent System Operator, Inc.

Description: Compliance filing: Errata to Section 206—ROFR to be effective 10/12/2021.

Filed Date: 10/13/21.

Accession Number: 20211013–5195.

Comment Date: 5 p.m. ET 11/2/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER17–2342–002.

Applicants: Bladen Solar, LLC.

Description: Compliance filing: Bladen MBR Change in Category to be effective 10/14/2021.

Filed Date: 10/13/21.

Accession Number: 20211013–5196.

Comment Date: 5 p.m. ET 11/3/21.

Docket Numbers: ER17–2343–002.

Applicants: Bullock Solar, LLC.

Description: Compliance filing: Bullock MBR Change in Category to be effective 10/14/2021.

Filed Date: 10/13/21.

Accession Number: 20211013–5197.

Comment Date: 5 p.m. ET 11/3/21.

Docket Numbers: ER18–348–002.

Applicants: Shoe Creek Solar LLC.

Description: Compliance filing: Shoe Creek MBR Change in Category to be effective 10/14/2021.

Filed Date: 10/13/21.

Accession Number: 20211013–5198.

Comment Date: 5 p.m. ET 11/3/21.

Docket Numbers: ER21–1506–002.

Applicants: Shaw Creek Solar, LLC.

Description: Refund Report: Shaw Creek Solar, LLC Refund Report of Sellers to be effective N/A.

Filed Date: 10/14/21.

Accession Number: 20211014–5093.

Comment Date: 5 p.m. ET 11/4/21.

Docket Numbers: ER22–100–000.

Applicants: Avista Corporation.

Description: § 205(d) Rate Filing: Avista Corp T1168–1 Amended Construction Agmt BPA Walla Walla Wannapum to be effective 10/15/2021.

Filed Date: 10/14/21.

Accession Number: 20211014–5039.

Comment Date: 5 p.m. ET 11/4/21.

Docket Numbers: ER22–101–000.

Applicants: Otter Tail Power Company.

Description: § 205(d) Rate Filing: Filing of Certificate of Concurrence—NSP OMA to be effective 8/12/2011.

Filed Date: 10/14/21.

Accession Number: 20211014–5041.

Comment Date: 5 p.m. ET 11/4/21.

Docket Numbers: ER22–102–000.

Applicants: NorthWestern Corporation, Southwest Power Pool, Inc.

Description: Compliance filing: NorthWestern Corporation submits tariff filing per 35: Petition of Southwest Power Pool and NorthWestern Corporation.

Filed Date: 10/14/21.

Accession Number: 20211014–5058.

Comment Date: 5 p.m. ET 11/4/21.

Docket Numbers: ER22–103–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3127R5 Montana-Dakota Utilities Co. NITSA NOA to be effective 1/1/2022.

Filed Date: 10/14/21.

Accession Number: 20211014–5062.

Comment Date: 5 p.m. ET 11/4/21.

Docket Numbers: ER22–104–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of ISA, SA No. 5887; Queue No. AF2–045 re: breach to be effective 10/8/2021.

Filed Date: 10/14/21.

Accession Number: 20211014–5063.

Comment Date: 5 p.m. ET 11/4/21.

Docket Numbers: ER22–105–000.

Applicants: Beech Ridge Energy II Holdings LLC.

Description: Tariff Amendment: Notice of Cancellation of Market-Based Rate Tariff to be effective 10/15/2021.

Filed Date: 10/14/21.

Accession Number: 20211014–5076.

Comment Date: 5 p.m. ET 11/4/21.

Docket Numbers: ER22–106–000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Dellsol (Dellwood Solar) LGIA Filing to be effective 9/30/2021.

Filed Date: 10/14/21.

Accession Number: 20211014–5079.

Comment Date: 5 p.m. ET 11/4/21.

Docket Numbers: ER22–107–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2021–10–14 PSC–SMS1–PLGIA–631–0.0.0 to be effective 10/15/2021.

Filed Date: 10/14/21.

Accession Number: 20211014–5092.

Comment Date: 5 p.m. ET 11/4/21.

Docket Numbers: ER22–108–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Attachment X to Modify Minimum Capitalization Requirements to be effective 4/30/2022.

Filed Date: 10/14/21.

Accession Number: 20211014–5096.

Comment Date: 5 p.m. ET 11/4/21.

Docket Numbers: ER22–109–000.

Applicants: Cheyenne Light, Fuel and Power Company.

Description: § 205(d) Rate Filing: Filing of Jurisdictional Agreements to be effective 12/31/9998.

Filed Date: 10/14/21.
Accession Number: 20211014–5099.
Comment Date: 5 p.m. ET 11/4/21.
Docket Numbers: ER22–110–000.
Applicants: Cheyenne Light, Fuel and Power Company.
Description: § 205(d) Rate Filing: Filing of Jurisdictional Agreements to be effective 12/31/9998.
Filed Date: 10/14/21.
Accession Number: 20211014–5104.
Comment Date: 5 p.m. ET 11/4/21.
Docket Numbers: ER22–111–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: Rate Schedule No. 217 Exhibit B Revisions to be effective 12/17/2021.
Filed Date: 10/14/21.
Accession Number: 20211014–5121.
Comment Date: 5 p.m. ET 11/4/21.
Docket Numbers: ER22–99–000.
Applicants: MATL LLP.
Description: § 205(d) Rate Filing: OATT Clarifying L–T Sales Changes to be effective 12/14/2021.
Filed Date: 10/14/21.
Accession Number: 20211014–5006.
Comment Date: 5 p.m. ET 11/4/21.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES22–7–000; ES22–8–000.
Applicants: Entergy New Orleans, LLC, Entergy Louisiana, LLC.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Entergy Louisiana, LLC, et al.
Filed Date: 10/13/21.
Accession Number: 20211013–5219.
Comment Date: 5 p.m. ET 11/3/21.

Take notice that the Commission received the following PURPA 210(m)(3) filings:

Docket Numbers: QM22–4–000.
Applicants: Ohio Edison Company, Cleveland Electric Illuminating Company, Toledo Edison Company, West Penn Power Company, Pennsylvania Power Company, Pennsylvania Electric Company, Jersey Central Power & Light Company, Metropolitan Edison Company, Monongahela Power Company, Potomac Edison Company.
Description: Application of FirstEnergy Utility Companies to Terminate Its Mandatory Purchase Obligation under the Public Utility Regulatory Policies Act of 1978.
Filed Date: 10/13/21.
Accession Number: 20211013–5215.
Comment Date: 5 p.m. ET 11/10/21.

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: October 14, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–22835 Filed 10–19–21; 8:45 am]

BILLING CODE 6717–01–P

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: RP22–23–000.
Applicants: WBI Energy Transmission, Inc.
Description: 2021 Annual Penalty Revenues Credit Report of WBI Energy Transmission, Inc. RP22–23.
Filed Date: 10/1/21.
Accession Number: 20211001–5293.
Comment Date: 5 p.m. ET 10/13/21.

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: October 14, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–22839 Filed 10–19–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or 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. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202)502–8659.

Docket Nos.	File date	Presenter or requester
Prohibited:		
1. P–1494–438	10–12–2021	FERC Staff.[1]
2. P–1494–438	10–13–2021	FERC Staff.[2]
Exempt:		
P–12514–000	10–6–2021	U.S. Congress.[3]

[1] Emailed comments dated 10/11/2021 from Jim Loveland.
[2] Emailed comments dated 10/13/2021 from Tia Triplett.
[3] Congressman James R. Baird.

Dated: October 14, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–22840 Filed 10–19–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ22–1–000]

Oncor Electric Delivery Company LLC; Notice of Filing

Take notice that on October 12, 2021, Oncor Electric Delivery Company LLC submitted its tariff filing: Oncor TFO Tariff Rate Changes, to be effective September 20, 2021.

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. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

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, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, 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.

Comment Date: 5:00 p.m. Eastern Time on November 2, 2021.

Dated: October 14, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–22841 Filed 10–19–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–96–000]

Route 66 Solar Energy Center, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Route 66 Solar Energy Center, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 3, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: October 14, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–22842 Filed 10–19–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12589–028]

Public Service Company of Colorado; 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. *Type of Application:* Non-capacity amendment of license.

b. *Project No.:* 12589–028.

c. *Date Filed:* July 2, 2021.

d. *Applicant:* Public Service Company of Colorado.

e. *Name of Project:* Tacoma Hydroelectric Project.

f. *Location:* The project is located on Cascade Creek in La Planta and San Juan counties, Colorado.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Ms. Christine Johnston, Environmental Analyst, Xcel Energy, 1800 Larimer Street, Suite 1300, Denver, CO 80202, (303) 294–2224.

i. *FERC Contact:* Mr. Korede Olagbegi, (202) 502–6268, *Korede.Olagbegi@ferc.gov*.

j. Deadline for filing comments, motions to intervene, and protests is 30 days from the issuance of this notice. 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/docs-filing/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 send 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 docket number P–12589–028. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person 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 applicant proposes to delete Article 305 and Article 406 from its license, and to modify Article 407, relating to the construction and operation of the Canyon Creek Diversion to supply back-up water to the Tacoma powerhouse. Previously in an order issued November 15, 2012, Commission staff required the applicant, pursuant to Article 305 of its license, to instead construct and operate a flow line from Electra Lake to supply back-up water to the Tacoma powerhouse. Upon further evaluation, the applicant has determined that the need for a back-up water supply is no longer necessary at this time. As such, the applicant proposes to delete Articles 305 and 406, and modify Article 407, all associated with the construction and operation of the Canyon Creek Diversion or the alternative flow line.

l. *Locations of the Applications:* 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 website at *http://www.ferc.gov/docs-filing/elibrary.asp.* 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. Agencies may obtain copies of the application directly from the applicants. 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 FERC at *FERCOnlineSupport@ferc.gov or call toll free,* (866) 208–3676 or TTY, (202) 502–8659.

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, Motions to Intervene, or Protests:* Anyone may submit comments, a motion to intervene, or a protest in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. 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, motions to intervene, or protests must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''MOTION TO INTERVENE'', or ''PROTEST'' 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 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. A copy of all other filings in reference to this application 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: October 14, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–22845 Filed 10–19–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–4–000]

WBI Energy Transmission, Inc.; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on October 5, 2021, WBI Energy Transmission, Inc. (WBI Energy) filed a prior notice request for authorization, in accordance with 18 CFR Sections 157.205(b) and 157.216(b) of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act and WBI Energy's blanket certificate issued in Docket Nos. CP82–487–000, *et al.*, for the abandonment of natural gas storage facilities located at the Baker Storage Field in Fallon County, Montana. WBI Energy is proposing to plug and abandon six natural gas storage wells, to abandon in place the associated storage well pipelines and their associated measurement facilities. The proposed abandonments will have no impact on WBI Energy's existing customers as their abandonment will not change the overall firm withdrawal capabilities of the Baker Storage Field, all as more fully set forth in the request 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 concerning this application should be directed to Andrew Bates, Supervisor, Regulatory Affairs, WBI Energy Transmission, Inc., 1250 West Century Avenue, Bismarck, North Dakota 58503, (701) 530–1576; or email at *andrew.bates@wbienergy.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: 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 three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on December 14, 2021. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[2] any person [3] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[4] and must be submitted by the protest deadline, which is December 14, 2021. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person 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 December 14, 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 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.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). 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. 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.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before December 14, 2021. The filing of a comment alone will not serve to make the filer a party

[1] 18 CFR (Code of Federal Regulations) § 157.9.

[2] 18 CFR 157.205.

[3] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 CFR 157.205(e).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP22–4–000 in your submission.

(1) You may file your protest, motion to intervene, and comments 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 ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [7]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP22–4–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: Andrew Bates, Supervisor, Regulatory Affairs, WBI Energy Transmission, Inc., 1250 West Century Avenue, Bismarck, North Dakota 58503; or email at: *andrew.bates@wbienergy.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.

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.*

Dated: October 14, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–22844 Filed 10–19–21; 8:45 am]

BILLING CODE 6717–01–P

[7] Additionally, 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.

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2020–0520; FRL–9142–01–OGC]

Proposed Stipulated Partial Settlement Agreement, Endangered Species Act Claims

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed stipulated partial settlement agreement; request for public comment.

SUMMARY: In accordance with the Environmental Protection Agency (EPA) Administrator's October 16, 2017, Directive Promoting Transparency and Public Participation in Consent Decrees and Settlement Agreements, notice is hereby given of a proposed stipulated partial settlement agreement in the case of *Natural Resources Defense Council* v. *Wheeler, et al.,* in the United States District Court for the District of Columbia (1:17–CV–02034). The Plaintiff filed its original case on October 3, 2017, alleging that EPA violated the Endangered Species Act (ESA) by failing to consult on the effects to listed species of certain pesticide product registrations containing one of three pesticide active ingredients—acetamiprid (Claim One), dinotefuran (Claim Two), and imidacloprid (Claim Three). EPA and the Natural Resources Defense Council (NRDC) are proposing to resolve this case through a stipulated partial settlement agreement. Defendant-Intervenor takes no position on this agreement.

DATES: Written comments on the proposed stipulated partial settlement agreement must be received by November 19, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2020–0520, 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 Settlement Agreement'' 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: Michele Knorr, Pesticides and Toxic Substances Law Office MC–2333A, Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone (202) 564–5631; email address *knorr.michele@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Settlement Agreement

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2020–0520) contains a copy of the proposed settlement agreement.

The electronic version of the public docket for this action contains a copy of the proposed settlement agreement 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 Settlement Agreement

On October 3, 2017, Plaintiff (a non-governmental environmental organization) filed a complaint in the United States District Court in the District of Columbia asserting three claims against EPA for allegedly violating section 7(a)(2) of the ESA by failing to initiate and reinitiate consultation with the Services. Specifically, Plaintiffs alleged that the EPA failed to consult on the effects to listed species of 95 pesticide product registrations containing one of three pesticide active ingredients—acetamiprid (Claim One), dinotefuran (Claim Two), and imidacloprid (Claim Three). The Court approved, in February 2018, a stipulation of partial dismissal of many products, leaving 59 pesticide product registrations at issue. In January 2021, Plaintiff and EPA reached a stipulated partial settlement agreement in this case where EPA agreed to complete ESA section 7(a)(2) effects determination, compiled into a biological evaluation, for imidacloprid by June 30, 2022, and, as appropriate, request initiation of any ESA section 7(a)(2) consultation with the Services.

After the entry of the stipulated partial settlement agreement for imidacloprid, the parties filed summary judgment motions and cross motions on the remaining claims. Shortly after these filings, the parties began settlement discussions on these remaining claims. The stipulated partial settlement agreement for which EPA is taking comment addresses these two claims. Specially, Paragraph 1 of the stipulated partial settlement agreement states that EPA will by October 2024 complete effects determinations and request initiation of any necessary ESA consultation pursuant to 50 CFR part 402 regarding the potential effects of acetamiprid and dinotefuran on any and all listed species and designated critical habitat.

Consistent with current practice, the agreement would also include statements of EPA's intent to take certain actions in addition to the deadlines associated with specific biological evaluations, including: (1) To complete the draft biological evaluations no later than one year prior to the deadline for the final biological evaluations, as well as to provide notice and a 60-day opportunity for public comment on any such draft, and (2) conduct the effects determinations on a nationwide-scale. Defendant-Intervenor takes no position on this agreement.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed stipulated partial settlement agreement from persons who are not named as parties to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed stipulated partial settlement agreement if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the ESA or the Federal Insecticide, Fungicide, and Rodenticide Act. Unless EPA or the Department of Justice determines that consent should be withdrawn, the terms of the proposed stipulation and stipulated notice of dismissal will be affirmed.

III. Additional Information About Commenting on the Proposed Settlement Agreement

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2020–0520, 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.

Christopher E. Kaczmarek,

Acting Associate General Counsel.

[FR Doc. 2021–22860 Filed 10–19–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2020–0675; FRL–9147–01–ORD]

Availability of the Draft IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA) and Related Compound Ammonium Perfluorobutanoic Acid; Extension of Public Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period; extension.

SUMMARY: The Environmental Protection Agency (EPA) is extending the public comment period for the document titled, ''Availability of the Draft IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA) and Related Compound Ammonium Perfluorobutanoic Acid.'' The original **Federal Register** document announcing the public comment period was published on August 23, 2021.

DATES: The public comment period for the notice published on August 23, 2021 (86 FR 47100), is being extended. The EPA must receive comments on or before Monday, November 8, 2021.

ADDRESSES: The ''Availability of the Draft IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA) and Related Compound Ammonium Perfluorobutanoic Acid'' is available via the internet on IRIS' website at *https://www.epa.gov/iris* and in the public docket at *https://www.regulations.gov,* Docket ID: EPA–HQ–ORD–2020–0675.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202–566–1752; facsimile: 202–566–9744; or email: *Docket_ORD@epa.gov.*

For technical information on the IRIS Toxicological Review of Perfluorobutanoic acid (PFBA) and Related Compound Ammonium Perfluorobutanoic Acid, contact Ms. Vicki Soto, CPHEA; telephone: 202–564–3077; or email: *soto.vicki@epa.gov.* The IRIS Program will provide updates through the IRIS website (*https://www.epa.gov/iris*) and via EPA's IRIS listserv. To register for the IRIS listserv, visit the IRIS website (*https://www.epa.gov/iris*) or visit *https://www.epa.gov/iris/forms/staying-connected-integrated-risk-information-system#connect.*

SUPPLEMENTARY INFORMATION:

How To Submit Technical Comments to the Docket at https://www.regulations.gov

Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2020–0675 for the Perfluorobutanoic Acid (PFBA) and Related Compound Ammonium Perfluorobutanoic Acid IRIS assessment, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: Docket_ORD@epa.gov.*
- *Fax:* 202–566–9744. Due to COVID–19, there may be a delay in processing comments submitted by fax.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. The phone number is 202–566–1752. Due to COVID–19, there may be a delay in processing comments submitted by mail.

For information on visiting the EPA Docket Center Public Reading Room, visit *https://www.epa.gov/dockets.* Due to public health concerns related to COVID–19, the EPA Docket Center and Reading Room may be closed to the public with limited exceptions. The telephone number for the Public Reading Room is 202–566–1744. The public can submit comments via *www.Regulations.gov* or email.

Instructions: Direct your comments to docket number EPA–HQ–ORD–2020–0675 for Perfluorobutanoic Acid (PFBA) and Related Compound Ammonium Perfluorobutanoic Acid. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *www.regulations.gov,* including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information through *www.regulations.gov* or email that you consider to be CBI or otherwise protected. The *www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *www.epa.gov/epahome/dockets.htm.*

Docket: Documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Timothy Watkins,

Acting Director, Center for Public Health & Environmental Assessment.

[FR Doc. 2021–22784 Filed 10–19–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2021–0653; FRL–9072–01–OW]

Notification of Receipt of Safe Drinking Water Act (SDWA) Section 1441 Application Submissions for FY21

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; request for comments.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing receipt of Certification of Need applications pursuant to the Safe Drinking Water Act (SDWA) Section 1441. Three public water systems (PWSs) and one publicly owned treatment works (POTW) submitted these applications. See the **SUPPLEMENTARY INFORMATION** section of this document for their specific concerns about the unavailability of treatment chemical(s) via normal procurement channels. EPA is providing an opportunity for written comments from the public on these SDWA Section 1441 applications, from chemical producers and repackagers that could supply the required liquid oxygen, sulfur dioxide, clarifloc SE- 1371, clarifloc SE 1482, gaseous chlorine, and sodium hypochlorite to the applicants, and from any other interested parties. The applications are available in the docket.

DATES: Comments must be received on or before November 3, 2021.

ADDRESSES: You may send comments, identified by Docket ID Number EPA–HQ–OW–2021–0653, by any of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov (our preferred method). Follow the online instructions for submitting comments.

Mail: U.S. Environmental Protection Agency, EPA Docket Center, Water Docket, Environmental Protection Agency, Mail code: 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand Delivery/Courier (by scheduled appointment only): EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except federal holidays).

Instructions: All submissions received must include the Docket ID No. EPA–HQ–OW–2021–0653 for this announcement. Comments received may be posted without change to *https://www.regulations.gov* including any personal information provided. For detailed instructions on sending comments, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this announcement. 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 delay in processing mail. Hand deliveries and couriers may be received by scheduled appointment only. For further information of EPA Docket Center Services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: For information on SDWA Section 1441 applications contact Gabrielle Minton, Office of Ground Water and Drinking Water, Water Security Division, at (202) 564–8284 or email *minton.gabrielle@epa.gov.* For information on water utility disinfection products contact Steve Allgeier, Office of Ground Water and Drinking Water, Water Security Division, at (513) 569–7131 or email *allgeier.steve@epa.gov.* For more information, visit EPA's website at: *https://www.epa.gov/waterutilityresponse/watersectorsupplychainchemicalshortages.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information

A. System's Report of Need

Two PWSs that submitted Certification of Need applications pursuant to the Safe Drinking Water Act (SDWA) Section 1441 cited receipt of notifications of *force majeure* or unavailability of treatment chemicals via normal procurement channels. The *force majeure* notices were issued due to competing demand for liquid oxygen at hospitals for high-flow oxygen therapy for COVID–19 patients. Additionally, limited or non-cost-effective transportation resources or options have hampered their ability to bring in liquid oxygen from production facilities outside of the region. The applications further stated that after receiving the notices, each of these utilities contacted several additional liquid oxygen suppliers in the region and were informed that none had product that was not already allocated to critical customers, primarily for medical use. These drinking water systems rely on liquid oxygen to produce ozone that is used to disinfect the water, a step necessary to produce safe drinking water as required under the Safe Drinking Water Act and its implementing regulations.

The third PWS and the POTW, operated by the same municipality, have not received *force majeure* notices and have not been placed on reduced allocation at the time the application was submitted. They based their applications for Certifications of Need on concerns regarding limited supply and increased demand on the specified treatment chemicals, as well as ongoing transportation and logistics challenges. The chemicals listed in the applications from this municipality included: Sulfur dioxide, clarifloc SE–1371, clarifloc SE 1482, gaseous chlorine, and sodium hypochlorite.

B. Does this action impose any requirements on public water systems or public treatment works?

This action, when published, will not impose any requirements on regulated entities.

C. Public Participation

Submit your comments, identified by Docket ID No. EPA–HQ–OW–2021–0653, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section of this announcement. Once submitted, comments cannot be edited or removed from the docket. 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. 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.*

Due to public health concerns related to COVID–19, the EPA Docket Center and Reading Room are open to the public by appointment only. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

D. What should I consider as I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

Explain your views as clearly as possible.

Describe any assumptions that you used.

Provide any technical information and/or data you used that support your views.

Provide full references for any peer reviewed publication you used that support your views.

Provide specific examples to illustrate your concerns.

Offer alternatives.

Make sure to submit your comments by the comment period deadline. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Purpose, Background, and Statutory Requirements of This Action

This section briefly summarizes the purpose of this action and the statutory requirements.

A. What is the purpose of this action?

The purpose of this action is to provide notification of the applications received under SDWA Section 1441 and to allow the public to comment on them.

B. Background and Statutory Requirements

Pursuant to SDWA Section 1441, a PWS or POTW may submit an application to the EPA Administrator for a Certification of Need when the amount of a ''chemical or substance necessary to effectively treat water is not reasonably available'' or ''will not be so available when required.'' 42 U.S.C. 300j(a). Upon receipt of the application, EPA must publish an announcement in the **Federal Register**, notify in writing all individuals who could be subject to an order based on the Certification of Need, and provide time for written comment. EPA may waive such requirements when EPA finds for good cause that a waiver is necessary to protect public health. *Id.* at (b)(2). Within 30 days after publishing the announcement in the **Federal Register** or after receipt of the application, if publication is waived, EPA will either issue or deny the Certification of Need. *Id.* at (b)(3). The EPA Administrator has delegated the authority to receive applications for Certifications of Need, issue such certifications, and take other actions under SDWA Section 1441 to the EPA Assistant Administrator for Water.

If EPA issues the certification, the agency will forward it to the Department of Commerce for implementation. 42 U.S.C. 300j(c)(1). Within seven days of EPA issuing the certification, the Department of Commerce will issue an order requiring the manufacturers, producers, processors, distributors, or repackagers of the chemical or substance identified, in the amount and form, per the Certification of Need, that the Department determines to be necessary and appropriate. *Id.* Persons or companies subject to the order will be given a reasonable opportunity to consult with the Department of Commerce with respect to implementation of the order. *Id.*

C. Summary of Applications

EPA has received applications for Certifications of Need, under SDWA Section 1441 authority, from the following public water systems and publicly owned treatment works: Tampa Bay Water (PWSID FL6296139), Regional Surface Water Treatment Plant submitted an application for 99.9% liquid oxygen, 487 tons per month with 5 deliveries per week; City of Tampa (PWSID FL6290327), David L. Tippin Water Treatment Facility submitted an application for 99.9% liquid oxygen, 620 tons per month with daily deliveries; Pinellas County, South Cross Bayou Advanced Water Reclamation Facility (POTW ID FL0040436) submitted an application for Clarifloc SE–1371, 1,100 gallons per month, Clarifloc SE–1482, 11,000 pounds per month, 12.5% Sodium Hypochlorite, 835 gallons per month, Sulfur Dioxide Liquified Gas, 8 tons per month, 100% Gaseous Chlorine, 34 one-ton cylinders per month; and Pinellas County, S.K. Keller Water Treatment Facility (PWSID FL6521405), 12.5% Sodium Hypochlorite, 70,500 gallons per month.

Submitted applications were reviewed by EPA for accuracy, completeness, and basis for need. After the comment period, EPA will determine whether to issue Certifications of Need for each distinct application. If issued, EPA will transmit the certifications to the Department of Commerce Bureau of Industry and Security to implement the certification by issuing an order to contracted suppliers. The orders will require repackagers and/or suppliers to provide the fully contracted chemical allocations to the applicants listed in this **Federal Register** announcement. EPA requests comment on the application submittals as well as feedback from repackagers or suppliers who may be able to assist.

Tampa Bay Water indicates that if they do not have adequate supply of liquid oxygen to operate their ozonation process, they will need to shut down their surface water treatment plant. They can partially offset the loss of the surface water treatment plant production with increased production from groundwater sources. However, the system seeks to resume operation of its normal disinfection process as soon as possible.

The City of Tampa has temporarily switched their primary disinfection from ozonation to chlorination, using sodium hypochlorite. However, according to the City of Tampa, this alteration in treatment makes it challenging to meet other water quality objectives, potentially including compliance with other drinking water standards. Furthermore, the supply of chlorine and sodium hypochlorite is strained in multiple regions of the country, making this emergency solution tenuous.

Upon receipt of the applications from City of Tampa and Tampa Bay Water for Certifications of Need regarding liquid oxygen, EPA contacted their supplier, Matheson Tri-Gas, and was informed by the supplier that the increased demand on liquid oxygen is largely due to the increase in COVID-related hospitalizations and limited and non-cost-effective transportation options, which were the primary factors leading to issuance of force majeure. On August 27, 2021, EPA met with representatives from the Department of Homeland Security, the Sector Risk Management Agency for the Chemical Sector, and representatives from several major producers of liquid oxygen to discuss the risk of cascading impacts should water systems, which depend on a reliable supply of liquid oxygen to produce safe drinking water or treat wastewater, not receive the necessary allocations. As a result, the Chemical Sector Coordinating Council sent a notice to all major domestic liquid oxygen producers requesting that they coordinate with their water sector customers to ensure that adequate supplies of liquid oxygen are delivered to those water sector customers to maintain production of safe drinking water and treatment of wastewater.

D. Additional Background

EPA is also aware that several other water systems that have not submitted applications for a Certification of Need as of the date of this announcement have received force majeure notices and have been placed on reduced allocations, in some cases 0% of the contracted amount. Furthermore, EPA has been informed by suppliers that all non-critical customers of liquid oxygen have been issued force majeure notices and placed on reduced allocation in order to preserve available supplies for medical use and critical infrastructure customers. In some cases, these industrial customers include manufacturers of other treatment chemicals, such as ferric sulfate, and thus, could result in shortages of other water treatment chemicals critical to the provision of safe drinking water and treatment of wastewater. All suppliers

have reported significant challenges due to an inadequate number of qualified drivers with the necessary endorsements and experience to transport and offload liquified oxygen, as well as a limited fleet of cryogenic trucks that are necessary to transport liquid oxygen. EPA continues to work with our federal partners and suppliers to identify actions that can be taken to increase the availability of liquid oxygen to all critical customers.

Pinellas County indicated that if they do not receive a sufficient and reliable supply of the required treatment chemicals used at their drinking water treatment facility, they would not be able to ensure safe drinking water to the communities they serve and may need to shut down their water treatment plant. Under normal circumstances, they could rely on other sources of water from Tampa Bay Water, such as Tampa Bay Water's wellfield. However, Tampa Bay Water is currently in the process of assessing and potentially utilizing their backup sources, which, in turn, would make them unavailable to Pinellas County Utilities. Pinellas County also indicated that if they did not receive a sufficient and reliable supply of the required treatment chemicals to their reclamation facility, they would not have the ability to disinfect the effluent. Pinellas County asserts that this scenario would force the facility to discontinue reclaimed uses of the effluent for irrigation and to discharge water that has not been properly disinfected, leading to a violation of their discharge permit. Additionally, the lack of available irrigation water would put additional burden on the drinking water supply for irrigation purposes. According to Penallas County, exhausting its supplies of sulfur dioxide, specifically, would render the facility unable to dechlorinate plant effluent. In order to discharge plant effluent to local waterbodies, effluent must be properly dechlorinated or the facility will be in violation of their discharge permit. This scenario is of concern particularly during the rainy season and at times with heavy influent. Further, if Pinellas County were to exhaust its supplies of Clarifloc SE–1482 and Clarifloc SE–1371, the facility asserts that it would not have the proper polymers needed for effective sludge thickening and dewatering, causing a backup of solids and treatment and potentially leading to septic conditions with subsequent sludge storage overflow, which could harm the surrounding environment.

At the time of application, Pinellas County had not received a force majeure notice or been placed on reduced allocation. However, given the shortage of related treatment chemicals in the region and the vulnerability in the system's backup supplies, Pinellas County is concerned that there is a risk that they could face a shortage of one or more of the listed chemicals.

Radhika Fox,

Assistant Administrator.

[FR Doc. 2021–22830 Filed 10–19–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreement to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**. Copies of agreement are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011075–082.

Title: Central America Discussion Agreement.

Parties: Crowley Latin America Services, LLC: Dole Ocean Cargo Express, LLC; Great White Fleet Corp.; Great White Fleet Liner Service, Ltd.; King Ocean Services Limited, Inc.; Seaboard Marine Ltd.; and Tropical Shipping & Construction Co., Ltd.

Filing Party: Wayne Rohde, Esq.; Cozen O'Connor.

Synopsis: The amendment would delete or update obsolete language in Articles 6(b), 7 and 8. The Amendment would also update the address of party Dole Ocean Cargo Express, and restate the Agreement.

Proposed Effective Date: 11/26/2021.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1332.

Dated: October 15, 2021.

Rachel E. Dickon,

Secretary.

[FR Doc. 2021–22874 Filed 10–19–21; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; COVID–19 Provider Relief Fund (PRF) Reporting Activities, OMB No. 0906–XXXX—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 19, 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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: COVID–19 Provider Relief Fund (PRF) Reporting Activities, OMB No. 0906–XXXX—New.

Abstract: HRSA administers the PRF, which has disbursed funds to eligible health care providers to support health care-related expenses or lost revenues attributable to the COVID–19 pandemic. Providers who have accepted the Terms and Conditions regarding their PRF payment(s), including the requirement that the provider ''shall submit reports as the Secretary determines are needed to ensure compliance with conditions

that are imposed on this Payment, and such reports shall be in such form, with such content, as specified by the Secretary in future program instructions directed to all Recipients,'' will be using the PRF Reporting Portal to submit information about their use of PRF payments. HRSA is currently operating under the Paperwork Reduction Act, Public Health Emergency (PHE) waiver that was approved by the Office of the Assistant Secretary for Planning and Evaluation on January 14, 2021. In anticipation of the PHE waiver expiring, HRSA is undergoing the OMB clearance process as the data will be collected beyond the PHE.

A 60-day notice was published in the **Federal Register**, 86, FR 40064 (July 26, 2021). There were 11 public comments. Comments were in regards to the accuracy of burden hours, data collection, and/or specific questions, suggestions, or feedback about the PRF program.

Need and Proposed Use of the Information: Recipients of a PRF payment agreed to a set of Terms & Conditions, which, among other requirements, mandate compliance with certain reporting requirements that will facilitate appropriate oversight of recipients' use of funds.

Information collected will allow for (1) assessing whether recipients have met statutory and programmatic requirements, (2) conducting audits, (3) gathering data required to report on findings with respect to the disbursements of PRF payments, and (4) program evaluation. HRSA staff will also use information collected to identify and report on trends in health care metrics and expenditures before and during the allowable period for expending PRF payments.

Likely Respondents: PRF recipients who have received more than $10,000 in aggregate PRF payments during one of the Payment Received Periods outlined below and that agreed to the associated Terms & Conditions are required to submit a report in the PRF Reporting Portal during the applicable Reporting Time Period.

Reporting period	Payment received period (payments exceeding $10,000 in aggregate received)	Reporting time period
Period 1	April 10, 2020, to June 30, 2020	July 1, 2021, to September 30, 2021.
Period 2	July 1, 2020, to December 31, 2020	January 1, 2022, to March 31, 2022.
Period 3	January 1, 2021, to June 30, 2021	July 1, 2022, to September 30, 2022.
Period 4	July 1, 2021, to December 31, 2021	January 1, 2023, to March 31, 2023.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
PRF Reporting Portal, Reporting Period 1 (Providers who received payments April 10, 2020, to June 30, 2020)	126,831	1	126,831	5.6	710,254
PRF Reporting Portal, Reporting Period 2 (Providers who received payments July 1, 2020, to December 31, 2020)	120,536	1	120,536	4.2	506,251
PRF Reporting Portal, Reporting Period 3 (Providers who received payments, January 1, 2021, to June 30, 2021)	19,962	1	19,962	5.6	111,787
PRF Reporting Portal, Reporting Period 4 (Providers who received payments July 1, 2021, to December 31, 2021)	19,962	1	19,962	5.6	111,787
Total	287,291	.....	287,291	.....	1,440,079

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–22831 Filed 10–19–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Sleep Disorders Research Advisory Board.

The meeting will be open to the public, with attendance limited to space

available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sleep Disorders Research Advisory Board.

Date: December 2, 2021.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: The purpose of this meeting is to update the Advisory Board and public stakeholders on the research agenda across NIH for the upcoming fiscal year, and the activities of professional societies.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting—Teleconference and ZoomGov).

Telephone Access: 1–669–254–5252 (Meeting ID: 161 159 8968).

Virtual Access: https://nih.zoomgov.com/j/1611598968?pwd=SVl5OXorOTJkQlhWS1dzVVNmZDk0QT09 (Webinar ID: 161 159 8968 Passcode: 563804).

Contact Person: Marishka Brown, BS, MS, Ph.D., Health Scientist Administrator, National Center on Sleep Disorders Research, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Suite 407B, Bethesda, MD 20892, 301–435–0199, *ncsdr@nih.gov*.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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: *www.nhlbi.nih.gov/meetings/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(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: October 15, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–22828 Filed 10–19–21; 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; Small Business: Computational, Modeling and Biodata Management.

Date: November 12, 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: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 6188, MSC 7804, Bethesda, MD 20892, (301) 435–1267, *belangerm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Shared Instrumentation: Mass Spectrometry (S10).

Date: November 16–17, 2021.

Time: 9:45 a.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: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Endocrinology and Metabolism.

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, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Liliana N. Berti-Mattera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 6158, MSC 7890, Bethesda, MD 20892, (301) 827–7609, *liliana.berti-mattera@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Endocrinology, Metabolism, Nutrition and Reproductive Sciences.

Date: November 17, 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: Baskaran Thyagarajan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 800B, Bethesda, MD 20892, (301) 867–5309, *thyagarajanb2@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

Date: November 17, 2021.

Time: 11:00 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: Eugene Carstea, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7818, Bethesda, MD 20892, (301) 408–9756, *carsteae@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Metabolism and Reproductive Sciences.

Date: November 17, 2021.

Time: 12:00 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: Hui Chen, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, Bethesda, MD 20892, 301–435–1044, *chenhui@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Neuroscience Assays, Diagnostics, Instrumentation, and Interventions.

Date: November 18–19, 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: Thomas Zeyda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1042, *thomas.zeyda@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: October 14, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–22827 Filed 10–19–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Collection of Customer Service, Demographic, and Smoking/Tobacco Use Information From the National Cancer Institute's (NCI) Cancer Information Service (CIS)

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Candace Maynard, Branch Chief, Cancer Information Service Branch, CISB/OCPL, 9609 Medical Center Drive, Rockville, MD 20850, or call non-toll-free number 240–276–6657 or email your request, including your address to: *deatonc@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function 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, including the validity of the methodology and assumptions used; (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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Collection of Customer Service, Demographic, and Smoking/Tobacco use Information from the National Cancer Institute's (NCI) Cancer Information Service (CIS), 0925–0208, Expiration Date 02/28/2022, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) currently collects: (1) Customer service and demographic information from clients of the Cancer Information Service (CIS) in order to properly plan, implement, and evaluate cancer education efforts, including assessing the extent by which the CIS reaches and impacts underserved populations; (2) smoking/tobacco use behavior of individuals seeking NCI's smoking cessation assistance through the CIS in order to provide smoking cessation services tailored to the individual client's needs and track their smoking behavior at follow up. This is a request for OMB to approve a revised submission for an additional three years to provide ongoing customer service collection of demographic information, and collection of brief customer satisfaction questions from NCI Cancer Information Service Clients for the purpose of program planning and evaluation.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 5,818 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Category of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Demographic & Customer Satisfaction Questions (Appendix 1A or 1AB).	Individuals	24,133	1	3/60	1,207
Demographic & Customer Satisfaction Questions (Appendix 1B).	Individuals	58,501	1	2/60	1,950
Smoking Cessation "Intake" Questions (Appendix 1C)	Individuals	2,888	1	6/60	289
Smoking Call Backs (Appendix 1D)	Individuals	2,904	1	4/60	194
VA Call Backs (Appendix 1E)	Individuals	8,166	1	4/60	544
Cancer Info Call Backs (Appendix 1F)	Individuals	2,242	1	4/60	149
Email Intake Form (Appendix 2)	Individuals	8,796	1	10/60	1,466
Demographic & Customer Satisfaction Questions (Appendix 9).	Individuals	578	1	2/60	19
Totals		108,208			5,818

Dated: October 15, 2021.

Diane Kreinbrink,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2021–22875 Filed 10–19–21; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2021–0592]

Recertification of Cool Inlet Regional Citizens' Advisory Council

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.

SUMMARY: The Coast Guard announces the recertification of the Cook Inlet Regional Citizens' Advisory Council (CIRCAC) as an alternative voluntary advisory group for Cook Inlet, Alaska. This certification allows the CIRCAC to monitor the activities of terminal facilities and crude oil tankers under the Cook Inlet Program established by the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990.

DATES: This recertification is effective for the period from September 1, 2021 through August 31, 2022.

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email LT Lauren Bloch, Seventeenth Coast Guard District (dpi), by phone at (907) 463–2812 or email at *Lauren.E.Bloch@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

The Coast Guard published guidelines on December 31, 1992 (57 FR 62600), to assist groups seeking recertification under the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (33 U.S.C. 2732) (the Act). The Coast Guard issued a policy statement on July 7, 1993 (58 FR 36504), to clarify the factors that the Coast Guard would be considering in making its determination as to whether advisory groups should be certified in accordance with the Act, and the procedures which the Coast Guard would follow in meeting its certification responsibilities under the Act.

Most recently, on September 16, 2002 (67 FR 58440), the Coast Guard changed its policy on recertification procedures for regional citizen's advisory council by requiring applicants to provide comprehensive information every three years. For each of the two years between the triennial application procedures, applicants submit a letter requesting recertification that includes a description of any substantive changes to the information provided at the previous triennial recertification. Further, public comment is only solicited during the triennial comprehensive review.

Recertification

By letter dated August 27, 2021, the Commander, Seventeenth Coast Guard District, certified that the CIRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). This recertification terminates on August 31, 2022.

Dated: August 27, 2021.

Nathan A. Moore,

Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.

[FR Doc. 2021–22782 Filed 10–19–21; 8:45 am]
BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0006; OMB No. 1660–0058]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Fire Management Assistance Grant Program

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30 Day notice of renewal and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before November 19, 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.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address *FEMA-Information-Collections-Management@fema.dhs.gov* or Antonio Jones, FMAG Program Specialist, Office of Response & Recovery, FEMA, at *antonio.jones@fema.dhs.gov* or (540) 320–1928.

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on February 24, 2021, at 86 FR 11318 with a 60-day public comment period. Three comments were received during that period and one comment (FEMA–2021–0006–0002) was not germane. The other two comments (FEMA–2021–0006–0003 and FEMA–2021–0006–0004) recommended that FEMA discontinue the Fire Management Assistance Grant Program (FMAGP). FEMA has considered these comments, but declines to make any changes to the FMAGP as a result of it. The FMAGP was established under Section 420 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C 5187, as amended by § 303 of the Disaster Mitigation Act of 2000, which authorizes the President to provide assistance to any state or local government for the mitigation, management, and control of any fire on public or private forest land or grassland that threatens such destruction as would constitute a major disaster. FEMA has implemented this program through 44 CFR part 204. Absent a change to the Stafford Act, FEMA will continue implementing the FMAGP. Moreover, discontinuing this program would negatively impact many Regions and states that receive grant funding under this program for disaster recovery purposes. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Fire Management Assistance Grant Program.

Type of information collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0058.

Form Titles and Numbers: FEMA Form FF–104–FY–21–165 (formerly FEMA Form 078–0–2), Request for Fire Management Assistance Declaration; FEMA Form FF–104–FY–21–167 (formerly FEMA Form 089–0–24),

Request for Fire Management Sub-grant; FEMA Form FF–104–FY–21–166 (formerly FEMA Form 078–0–1), Principal Advisor's Report.

Abstract: The information collection is required to make grant eligibility determinations for the Fire Management Assistance Grant Program. These eligibility-based grants and subgrants provide assistance to any eligible state, tribal government, or local government for the mitigation, management, and control of a fire on public or private forest land or grassland that is threatening such destruction as would constitute a major disaster. The information gathered in the forms is used to determine the severity of the threatening fire, current and forecast weather conditions, and associated factors related to the fire and its potential threat as a major disaster.

Affected Public: State, Tribal, or Local Governments.

Estimated Number of Respondents: 178.

Estimated Number of Responses: 553.

Estimated Total Annual Burden Hours: 811.

Estimated Total Annual Respondent Cost: $68,294.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $630,971.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance 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 proposed 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 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.

Millicent L. Brown,

Senior Manager, Records Management Branch, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2021–22851 Filed 10–19–21; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2021–0038]

Privacy Act of 1974; System of Records

AGENCY: Science & Technology Directorate, U.S. Department of Homeland Security.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the U.S. Department of Homeland Security (DHS) proposes to modify and reissue a current DHS system of records titled, ''DHS/Science & Technology Directorate (S&T)-001 Research, Development, Test, and Evaluation System of Records.'' This system of records allows DHS/S&T to collect and maintain records in support of, or during the conduct of, S&T-funded research, development, test, and evaluation activities. Information is collected for the purpose of furthering S&T's mission to push innovation and development, and the use of high technology in support of homeland security. This modified system will be included in DHS's inventory of record systems.

DATES: Submit comments on or before November 19, 2021. This modified system of records will be effective upon publication. New or modified routine uses will be effective November 19, 2021.

ADDRESSES: You may submit comments, identified by docket number DHS–2021–0038 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Lynn Parker Dupree, Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number DHS–2021–0038. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Maria Petrakis, (202) 254–7748, *STPrivacy@hq.dhs.gov,* S&T Privacy Officer, Science & Technology Directorate, Mail Stop: 0205, U.S. Department of Homeland Security, 245 Murray Lane SW, Washington, DC 20528. For privacy questions, please contact: Lynn Parker Dupree, (202) 343–1717, *Privacy@hq.dhs.gov,* Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, the U.S. Department of Homeland Security (DHS) Science & Technology Directorate (S&T) proposes to modify and reissue a current DHS system of records titled, ''DHS/S&T–001 Research, Development, Test, and Evaluation System of Records.'' S&T's mission is to conduct research, development, testing, and evaluation (RDT&E or RDT&E activities) on topics and technologies related to improving homeland security and combating terrorism. Some RDT&E activities involve the collection of personally identifiable information. This system of records covers records collected in support of, or during the conduct of, DHS/S&T-funded RDT&E activities in support of DHS Components and other partners in the Homeland Security Enterprise. Records can be collected through RDT&E activities such as testing and evaluating a screening technology, obtaining feedback on a technology from volunteer participants, or evaluating analytic tools using publicly available information.

Pursuant to its statutory mandate, S&T engages in both basic and applied RDT&E. Basic research is that RDT&E which is normally conducted without specific applications toward processes or products in mind. For example, S&T researchers often engage in the development of knowledge products (*e.g.,* white papers, literature reviews, peer-reviewed scholarly articles) for distribution to the Homeland Security Enterprise at large. This type of RDT&E is not in response to an external demand signal; rather, individual subject matter experts (SME) use their expertise and experience to advance the science of their respective fields. Because these

knowledge products are shared with external entities, S&T refers to these external entities as S&T's ''customers.'' Applied research is that RDT&E which is conducted to determine the means by which a recognized and specific operational need may be met. For example, if the Transportation Security Administration (TSA) identifies the need for a novel methodology of screening carry-on luggage at airport checkpoints, TSA would task S&T to develop this novel methodology through RDT&E activity. In instances where the RDT&E demand signal originates from outside of S&T, the originator is also referred to as an S&T's ''customer.''

In situations where DHS/S&T-funded RDT&E activities directly involve law enforcement, intelligence personnel, and/or other operational entities, a source-system system of records notice (SORN) is relied upon to cover any records collected that are to be used in operations, to support operational decisions, or any purpose other than RDT&E activities. However, there could be situations, for example, during a human subject testing activity, whereby an individual provides information that indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations, for which such records would be covered by this SORN, and subsequently may be disclosed to external third parties that are charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, described in Routine Use G below.

DHS/S&T is updating this system of records notice for several reasons, to include the maintenance of classified records, correct the citation of the authority which outlines the responsibilities of the Under Secretary for Science & Technology, add additional categories of individuals and categories of records, and modify Routine Uses. Individuals covered by this system of records now include individuals whose names or other identifying information may appear on social media platforms used or accessed by S&T for RDT&E purposes related to public safety, terrorism (including terrorist and targeted violence events), violent or criminal groups, or other topics related to preventing terrorism; counterterrorism; chemical, biological, and related weapons and materials; biomedical and life sciences research; or other homeland security information of interest to DHS/S&T in the performance of RDT&E activities. Additional records added to this system include Social Security number (SSN); social media handle, online user name, or other online identifier; research or other unique identifier; Uniform/Universal Resource Locator (URL); Internet Protocol (IP) address; Media Access Control Address (MAC); and Computer name to account for information collected and maintained related to social media, other publicly available information, and other RDT&E activities. S&T is also updating this SORN to clarify the types of biometric samples and data that may be collected.

DHS/S&T is also updating this SORN to include additional record source categories to include information obtained from publicly available sources, such as social media and the internet; other governmental agencies and entities; critical infrastructure owners and operators; other private sector entities and organizations; and free or fee-based commercial data providers. This SORN also addresses new policies and practices regarding storage, retrieval, retention, and disposal of records.

Further, DHS/S&T is modifying Routine Use ''E'' and adding Routine Use ''F'' to conform to the breach requirements in OMB Memorandum M–17–12. The previous Routine Use ''F'' has been re-lettered as Routine Use ''H,'' the content of the previous Routine Use ''G'' has been modified to conform with current DHS requirements, and Routine Use ''I'' has been added to account for sharing to appropriate governmental agencies or multilateral governmental organizations, with the approval of the Chief Privacy Officer, when DHS is aware of a need to use relevant data for purposes of testing new technology. Subsequent Routine Uses have been renumbered to account for these changes.

Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice.

Consistent with DHS's information sharing mission, information stored in DHS/S&T–001 Research, Development, Test, and Evaluation System of Records may be shared with other DHS Components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, DHS/S&T may share information with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice.

This modified system will be included in DHS's inventory of record systems.

II. Privacy Act

The fair information practice principles found in the Privacy Act underpin the statutory framework governing the means by which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined as U.S. citizens and lawful permanent residents. Similarly, the Judicial Redress Act (JRA) provides a statutory right to covered persons to make requests for access and amendment to covered records, as defined by the JRA, along with judicial review for denials of such requests. In addition, the JRA prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

Below is the description of the DHS/S&T–001 Research, Development, Test, and Evaluation System of Records. In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

U.S. Department of Homeland Security (DHS)/Science & Technology Directorate (S&T)-001 Research, Development, Test, and Evaluation (RDT&E) System of Records.

SECURITY CLASSIFICATION:

Unclassified and Classified.

SYSTEM LOCATION:

Records are maintained at the S&T Directorate Headquarters in Washington, DC, and field offices, and at public or private institutions conducting S&T-funded RDT&E activities.

SYSTEM MANAGER(S):

Under Secretary for Science and Technology, Mail Stop: 0205, U.S. Department of Homeland Security, 245 Murray Lane SW, Washington, DC 20528; (202) 254–7748; *STPrivacy@hq.dhs.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Homeland Security Act of 2002, Public Law 107–296, Sec. 302 (codified at 6 U.S.C. 182) authorizes the S&T to conduct ''basic and applied research, development, demonstration, testing, and evaluation activities that are relevant to any or all elements of the

Department, through both intramural and extramural programs.'' In exercising its responsibility under the Homeland Security Act, S&T is authorized to collect information, as appropriate, to support research and development related to improving the security of the homeland. To the extent an activity meets the definition of research involving human subjects, DHS complies with the regulations set forth in 6 CFR part 46.

PURPOSE(S) OF THE SYSTEM:

Records are collected for the purposes of furthering S&T's mission to push innovation and development and use technology in support of homeland security. The purposes of this system are to:

- Understand the motivations and behaviors of terrorists, individuals that engage in violent or criminal activities, terrorist groups, and groups that engage in violent or criminal activities;
- Understand terrorist incidents and the phenomenon of terrorism and identify trends and patterns in terrorist activities;
- Collect and maintain searchable records of individuals (such as subject matter experts on chemical weapons) and/or their characteristics and professional accomplishments, organized according to categories useful for the conduct of research, including research to determine the efficacy and utility of new or enhanced technologies intended for eventual transition to and use by S&T's customers or to provide scientific and technical expertise in support of emergency preparedness and response;
- Evaluate the performance and utility to the future customer of an experimental homeland security technology or product in a laboratory or ''real-world'' setting;
- Test the accuracy of a research hypothesis (for example, S&T might hypothesize that an individual's behavior changes in a detectable manner when he or she is being deceitful, and then design a research experiment to test that hypothesis);
- Answer a research question (for example, ''Can an experimental screening technology distinguish between threat objects and non-threat objects?'');
- Conduct testing and evaluation of an experimental technology at the request of or on behalf of a customer; and
- Conduct research and development to solve a technical problem for a customer.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals include voluntary participants in S&T-funded RDT&E activities such as field exercises or assessments, voluntary participants in human subjects research (note: All S&T-funded human subjects research is conducted in accordance with 45 CFR 46 and is reviewed by a certified Institutional Review Board); individuals whose names or other identifying information may appear in publicly available documents (*e.g.,* newspapers, academic articles, and websites) or on social media platforms about public safety, terrorism (including terrorist and targeted violence events), counterterrorism, violent or criminal groups, or other topics related to chemical, biological, and related weapons and materials, biomedical and life sciences research, or other homeland security information of interest to DHS/S&T in the performance of RDT&E activities. This system of records also covers individuals whose images, biometrics, physiological features, or other information may be intentionally (with notice to and consent by the individual) or incidentally captured during testing of S&T technologies; subject matter experts who publish articles related to terrorism, counterterrorism, chemical, biological, biomedical and life sciences research; and subject matter experts who voluntarily consent to be included in a database of experts.

CATEGORIES OF RECORDS IN THE SYSTEM:

S&T's RDT&E activities will vary according to the specific project. The information may include an individual's:

- Name;
- SSN;
- User name;
- Online identifier (*e.g.,* social media handle);
- Research or other unique identifier;
- Uniform Resource Locator (URL);
- Internet Protocol (IP) address;
- Media Access Control (MAC) Address;
- Computer name;
- Age;
- Gender;
- Contact information;
- Birthplace;
- Ethnicity;
- Level of education;
- Occupation;
- Institutional or organizational affiliation;
- Publication record (*e.g.,* article and publication titles, dates and sources);
- Medical history and other health-related information;
- Lifestyle information (*e.g.,* caffeine use, tobacco use);
- Publicly available reports of criminal history or violence;
- Video or still images;
- Other images (*e.g.,* infrared thermography, terahertz, millimeter wave);
- Audio recordings;
- Biometric samples (*e.g.,* facial images, speech/voice, fingerprints, deoxyribonucleic acid (DNA), iris, human tissue, or other biometric information);
- Biometric data (*e.g.,* Fingerprint Identification Number, voice and contactless fingerprints, biometric templates, typing cadence, cardiac signature, vascular patterns); and
- Physiological measurements collected using sensors (*e.g.,* heart rate, breathing pattern, electrodermal activity).

RECORD SOURCE CATEGORIES:

Records are obtained from (1) individuals directly; (2) publicly available information (*e.g.,* social media platforms, news media outlets, internet search engines, academic and scientific publications); (3) sensors (*e.g.,* records collected from the individual using sensors, such as a heart rate monitor) or technologies (*e.g.,* cameras, audio recorders, infrared thermography or other images, biometric devices); (4) federal, state, local, territorial, tribal governments and agencies; (5) other domestic agencies; (6) foreign governments and agencies; (7) multinational or nongovernmental organizations; (8) critical infrastructure owners and operators; (9) private sector entities and organizations; and (10) free or fee-based commercial data providers.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including the U.S. Attorneys Offices, or other federal agencies conducting litigation or proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. Any employee or former employee of DHS in his/her official capacity;

3. Any employee or former employee of DHS in his/her individual capacity, only when DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when (1) DHS suspects or has confirmed that there has been a breach of the system of records; (2) DHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DHS (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

F. To another federal agency or federal entity, when DHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the federal government, or national security, resulting from a suspected or confirmed breach.

G. To an appropriate federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

I. To appropriate federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations, with the approval of the Chief Privacy Officer, when DHS is aware of a need to use relevant data for purposes of testing new technology.

J. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information, when disclosure is necessary to preserve confidence in the integrity of DHS, or when disclosure is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent the Chief Privacy Officer determines that release of the specific information in the context of a particular case would constitute a clearly unwarranted invasion of personal privacy.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

DHS/S&T stores records in this system electronically or on paper in secure facilities, typically, in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

S&T may retrieve records by any of the information listed in the Categories of Records above.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

All records are maintained in accordance with the appropriate NARA-approved retention schedules. Different NARA-approved records retention schedules apply to specific RDT&E records, depending on the RDT&E activity. For example, Technical Information Bulletins, Technical Notes, Test and Evaluation Case Files, Test and Evaluation Files, Test and Evaluation Product Packages, Test Procedures and Protocols, and Test Team Assessment Letters fall under DHS Schedule 109–026–003, Scientific and Technological Research and Innovation. DHS/S&T must review Technical Information Bulletins and Technical Notes annually in accordance with N1–563–08–30 and delete or destroy records that have been inactive for five years. Test and Evaluation Case Files and supporting documentation is scheduled to be destroyed at the end of the calendar year five years after the completion of the test, exclusive of Test and Evaluation Final Reports, which are scheduled to be destroyed five years after the tested device, system, or equipment is removed from operation in accordance with N1–563–08–13–7. Test and Evaluation File records, excluding Final Reports, are scheduled to be destroyed at the end of the calendar year five years after completion or cancellation of a project or one year after the responsible office determines the record is no longer needed for legal, audit, administrative or business purposes. Final Reports must be reviewed annually and destroyed or deleted after five years of inactivity, in accordance with N1–563–09–4–4. DHS/S&T destroys Test and Evaluation Product Packages 10 years after the testing and evaluation is completed as required by N1–563–08–13–8.

DHS/S&T retains other RDT&E records on specific topics, issues, or projects in accordance with DHS Schedule 401–000–001a, Subject Files. The Subject Files are permanent and transferred to the National Archives after 10 years, in accordance with N1–563–07–13–11. DHS/S&T retains records involving inventions or patents according to DHS Schedule 105–012–002, Intellectual Property Protection, and N1–563–07–17–9. For trademarks, DHS/S&T destroys the records at the end of the calendar year, 20 years after the date of issuance. For patents, DHS/S&T destroys the records at the end of the calendar year, 40 years after the date of issuance. For copyright, DHS/S&T destroys the records at the end of the calendar year, 150 years after the date of issuance. For trade secrets, DHS/S&T destroys the records at the end of the calendar year, 20 years after the date when developed/discovered or when the trade secret is no longer valuable, whichever is later. Research and Development-related memoranda of understanding or agreement fall within DHS Schedule 105–012–003, Intellectual Property Protection, and are destroyed or deleted three years from when the agreement is terminated under N1–563–09–11–1. Program Evaluation records including Technical Assessments and Legal and Regulatory Compliance Records fall within DHS Schedule 301–092–002, Program

Evaluation, and N1–563–08–30–5. DHS/S&T is required to destroy or delete Technical Assessment project files, excluding Final Reports, at end of the calendar year five years after completion or cancelation of assessment or one year after the responsible office determines the records are no longer needed for legal, audit, administrative, or business purposes. DHS/S&T must destroy Program Evaluation legal and regulatory compliance records when the records are five years old.

Given the scope of RDT&E activities, additional NARA-approved schedules apply to S&T records. Some records are permanent records and other records are temporary records. The records have different disposition instructions based on the applicable records retention schedule.

DHS/S&T also has RDT&E records schedule requests pending, for example, for DHS/S&T National Laboratory research and development files, not used in law enforcement cases, and records that document compliance with standards-organization requirements to carry out test and calibration. Records subject to pending records schedule requests shall be retained until a records retention schedule has been approved by NARA.

Researchers may retain aggregated research data indefinitely, as it may help inform future RDT&E efforts.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DHS/S&T safeguards records in this system according to applicable rules and policies, including all applicable DHS automated systems security and access policies. S&T has imposed strict controls to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system 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.

RECORD ACCESS PROCEDURES:

Individuals seeking access to and notification of any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Component Privacy Officer or Component Freedom of Information Act Officer, whose contact information can be found at *http://www.dhs.gov/foia* under ''Contacts Information.'' If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, U.S. Department of Homeland Security, Washington, DC 20528–0655, or electronically at *https://www.dhs.gov/dhs-foia-privacy-act-request-submission-form.* Even if neither the Privacy Act nor the Judicial Redress Act provide a right of access, certain records about him or her may be available under the Freedom of Information Act.

When an individual is seeking records about himself or herself from this system of records or any other Departmental system of records, the individual's request must conform with the Privacy Act regulations set forth in 6 CFR part 5. The individual must first verify his/her identity, meaning that the individual must provide his/her full name, current address, and date and place of birth. The individual must sign the request, and the individual's signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. An individual may obtain more information about this process at *http://www.dhs.gov/foia.* In addition, the individual should, whenever possible:

- Describe the records sought, including any circumstances or reasons why the Department would have information being requested;
- Identify which component(s) of the Department or Department Headquarters Office he or she believes may have the information;
- Specify the timeline when the individual believes the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS Headquarters Office or component agency may have responsive records;

If the request is seeking records pertaining to another living individual, the request must include a statement from the living individual verifying the identity of the individual, as described in the verification steps above, and provide a statement from the living individual certifying the individual's agreement that records concerning the individual may be released to you.

Without the above information, the component(s) may not be able to conduct an effective search, and the individual's request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

For records covered by the Privacy Act or covered JRA records, individuals may make a request for amendment or correction of a record of the Department about the individual by writing directly to the Department component that maintains the record, unless the record is not subject to amendment or correction. The request should identify each particular record in question, state the amendment or correction desired, and state why the individual believes that the record is not accurate, relevant, timely, or complete. The individual may submit any documentation that would be helpful. If the individual believes that the same record is in more than one system of records, the request should state that and be addressed to each component that maintains a system of records containing the record. Even if neither the Privacy Act nor the Judicial Redress Act provide a right of access, individuals may seek to amend records following the ''Record Access Procedures'' above. DHS/S&T, in its discretion, may choose to make the requested amendment. However, neither this system of records notice, nor DHS/S&T's making a requested amendment, confers to individuals any right to access, contest, or amend records not covered by the Privacy Act or Judicial Redress Act.

NOTIFICATION PROCEDURES:

See ''Record Access Procedures'' above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None. When this system receives a record from another system exempted in that source system under 5 U.S.C. 552a, DHS will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated.

HISTORY:

78 FR 3019 (January 15, 2013).

Lynn Parker Dupree,

Chief Privacy Officer, U.S. Department of Homeland Security.

[FR Doc. 2021–22849 Filed 10–19–21; 8:45 am]

BILLING CODE 9110–9F–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7034–N–60]

30-Day Notice of Proposed Information Collection: Single Family Premium Collection Subsystem—Periodic (SFPCS–P); OMB Control No.: 2502–0536

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* November 19, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. 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/Start* Printed Page 15501PRAMain. 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: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on June 23, 2021. May 7, 2021, at 118 FR 32965.

A. Overview of Information Collection

Title of Information Collection: Single Family Premium Collection Subsystem—Periodic (SFPCS–P).

OMB Approval Number: 2502–0536.

OMB Expiration Date: 2/28/2022.

Type of Request: Revision of a currently approved collection.

Form Number: None.

Description of the need for the information and proposed use: The Single Family Premium Collection Subsystem—Periodic (SFPCS–P) allows the lenders to remit the single-family periodic mortgagee insurance premium (PMIP) using funds obtained from the mortgagor during the collection of the monthly mortgage payment. The SFPCS–P strengthens HUD's ability to manage and process PMIP collections and corrections to submitted data. It also improves data integrity for the Single Family Mortgage Insurance Program and enables FHA to track borrower's insurance PMIP status. Therefore, the FHA approved lenders remit PMIP payments that are required by the authority for this collection of information in 24 CFR 203.264 and 24 CFR 203.269 and to comply with the Federal Credit Reform Act of 1990, 2 U.S.C. 661, *et seq.*

Respondents: Business or other for-profit.

Estimated Number of Respondents: 730.

Estimated Number of Responses: 8,760.

Frequency of Response: 12 per year/monthly.

Average Hours per Response: .15.

Total Estimated Burden: 1,314 hours.

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.

(5) ways to minimize the burden of the collection of information on those who are respond, including the use of automated collection techniques or other forms of information technology.

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.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2021–22852 Filed 10–19–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2021–0101; FXIA16710900000–212–FF09A30000]

Foreign Endangered Species; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA). With some exceptions, the ESA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The ESA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA with respect to any endangered species.

DATES: We must receive comments by November 19, 2021.

ADDRESSES: *Obtaining Documents:* The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *http://www.regulations.gov* in Docket No. FWS–HQ–IA–2021–0101.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: http://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2021–0101.
- *U.S. Mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2021–0101; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2185, via email at *DMAFR@fws.gov,* or via the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment

on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or fax, or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *http://www.regulations.gov,* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *http://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17.

III. Permit Applications

We invite comments on the following endangered species applications.

Applicant: Molly McCargar, New York, NY; Permit No. PER0019092

The applicant requests a permit to import biological specimens noninvasively obtained from wild green sea turtles (*Chelonia mydas*) and hawksbill sea turtles (*Eretmochelys imbricata*) from Costa Rica for scientific research purposes. This notification is for a single import. This notification covers activities that were conducted over a 3-year period.

Applicant: Reid Park Zoological Society, Tucson, AZ; Permit No. PER0017418

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species, to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Common name	Scientific name
Galapagos tortoise	*Geochelone nigra.*
Military macaw	*Ara militaris.*
African elephant	*Loxodonta africana.*
Ring-tailed lemur	*Lemur catta.*
Black and while ruffed lemur.	*Varecia variegata.*
Lion-tailed macaque	*Macaca silenus.*
Lar gibbon	*Hylobates lar.*
African wild dog	*Lycaon pictus.*
Grevy's zebra	*Equus grevyi.*
Baird's tapir	*Tapirus bairdii.*
White rhinoceros	*Ceratotherium simum simum.*

Applicant: Antonin Dvorak, Williamsville, NY; Pet No. PER0013488

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for radiated tortoise (*Astrochelys radiata*) to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Binder Park Zoo, Battle Creek, MI; Permit No. 49623B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species, to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Common name	Scientific name
Bontebok	*Damaliscus pygargus pygargus.*
Cheetah	*Acinonyx jubatus.*
African wild dog	*Lycaon pictus.*
Panamanian golden frog	*Atelopus varius zeteki.*
Red-necked gazelle	*Nanger dama ruficollis.*
Przewalski's horse	*Equus przewalskii.*
Snow leopard	*Uncia uncia.*
Ring-tailed lemur	*Lemur catta.*
Black-and-white ruffed lemur.	*Varecia variegata.*
Red-collared lemur	*Eulemur collaris.*
African lion	*Panthera leo melanochaita.*

Applicant: University of Michigan Herbarium and Museum of Zoology, Ann Arbor, MI; Permit No. PER0019239

The applicant requests the renewal of their permit to export and re-import non-living museum and herbarium specimens of endangered species previously accessioned into the applicant's collection for scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: University of Texas Austin, Department of Integrative Biology, Austin, TX; Permit No. PER0021285

The applicant requests the renewal of their permit to export and re-import non-living museum specimens of endangered species previously accessioned into the applicant's collection for scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice

announcing the permit issuance by searching *http://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *http://www.regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Brenda Tapia,

Supervisor Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2021–22818 Filed 10–19–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–MB–2021–0111; FF09M22000–223–FXMB1231099BPP0; OMB Control Number 1018–0067]

Agency Information Collection Activities; Approval Procedures for Nontoxic Shot and Shot Coatings

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before December 20, 2021.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods:

- *Internet (preferred): http://www.regulations.gov*. Follow the instructions for submitting comments on Docket No. FWS–HQ–MB–2021–0111.
- *Email: Info_Coll@fws.gov*. Please reference Office of Management and Budget (OMB) Control Number 1018–0067 in the subject line of your comments.
- *U.S. Mail:* Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Docket No. FWS–HQ–MB–2021–0111, Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency 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 response.

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 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.

Abstract: The Migratory Bird Treaty Act (MBTA, 16 U.S.C. 703, *et seq.*) prohibits the unauthorized take of migratory birds and authorizes the Secretary of the Interior to regulate take of migratory birds in the United States. Under this authority, we control the hunting of migratory game birds through regulations in 50 CFR part 20. On January 1, 1991, we banned lead shot for hunting waterfowl and coots in the United States.

This is a non-form collection. Regulations at 50 CFR 20.134 outline the application and approval process for new types of nontoxic shot. When considering approval of a candidate material as nontoxic, we must ensure that it is not hazardous in the environment and that secondary exposure (ingestion of spent shot or its components) is not a hazard to migratory birds. To make that decision, we require each applicant to provide information about the solubility and toxicity of the candidate material. Additionally, for law enforcement purposes, a noninvasive field detection device must be available to distinguish candidate shot from lead shot. This information constitutes the bulk of an application for approval of nontoxic shot. The Director uses the data in the application to decide whether to approve a material as nontoxic.

Title of Collection: Approval Procedures for Nontoxic Shot and Shot Coatings (50 CFR 20.134).

OMB Control Number: 1018–0067.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses that produce and/or market approved nontoxic shot types or nontoxic shot coatings.

Total Estimated Number of Annual Respondents: 1.

Total Estimated Number of Annual Responses: 1.

Estimated Completion Time per Response: 3,200 hours.

Total Estimated Number of Annual Burden Hours: 3,200 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: $26,630 ($1,630 application processing fee and $25,000 for solubility testing).

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 authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2021–22805 Filed 10–19–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2021–N197; FXES11130100000–212–FF01E00000]

Endangered Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation and survival of endangered species under the Endangered Species Act of 1973, as amended. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before November 19, 2021.

ADDRESSES: *Document availability and comment submission:* Submit a request for a copy of the application and related documents and submit any comments by one of the following methods. All requests and comments should specify the applicant name and application number (*e.g.,* Dana Ross, PER0001705):

- *Email: permitsR1ES@fws.gov.*
- *U.S. Mail:* Marilet Zablan, Regional Program Manager, Restoration and Endangered Species Classification, Ecological Services, U.S. Fish and Wildlife Service, Portland Regional Office, 911 NE 11th Avenue, Portland, OR 97232–4181.

FOR FURTHER INFORMATION CONTACT: Colleen Henson, Regional Recovery Permit Coordinator, Ecological Services, (503) 231–6131 (phone); *permitsR1ES@fws.gov* (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits would allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes such activities as pursuing, harassing, trapping, capturing, or collecting, in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found in the Code of Federal Regulations (CFR) at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
PER0020873 ..	Hawaii Division of Forestry and Wildlife, Honolulu, HI.	Lanai tree snail (*Partulina semicarinata* and *P. variabilis*), Newcomb's tree snail (*Newcombia cumingi*), Oahu tree snails (*Achatinella* spp.).	Hawaii	Euthanasia of captive diseased snails to prevent pathogen and parasite spread between individuals and identification of parasite/disease causing agent.	Amend.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
PER0020897 ..	U.S. Department of the Navy, Naval Base Guam, Santa Rita, GU.	Green sea turtle or haggan (*Chelonia mydas*), Hawksbill sea turtle or haggan karai (*Eretmochelys imbricata*), Mariana common moorhen or pulatatt (*Gallinula chloropus guami*), Micronesian megapode or sasangat (*Megapodius laperouse*), Nightingale reed warbler or gaga karisu (*Acrocephalus luscinia*), *Eugenia bryanii* (No common name (NCN)), *Hedyotis megalantha* (Paodedu), *Heritiera longipetiolata* (Ufa-halomtano), *Phyllanthus saffordii* (NCN), *Psychotria malaspinae* (Aplokating-palaoan), *Serianthes nelsonii* (Hayun lagu), *Solanum guamense* (Berenghenas halomtano), *Tinospora homosepala* (NCN).	Guam and the Commonwealth of the Northern Mariana Islands.	*Sea turtles:* Harass by survey, monitor nests, capture, handle, measure, tag, biosample, attach transmitters, release, excavate hatched nests, and salvage.. *Mariana common moorhen:* Harass by survey, monitor nests, and salvage. *Micronesian megapode and nightingale reed warbler:* Harass by survey. *Plants:* Remove/reduce to possession by collecting seeds, flowers, and cuttings; propagate; outplant; monitor; conduct whole plant rescue; and salvage.	Amend.
PER0021495 ..	Archipelago Research and Conservation, Kalaheo, HI.	Hawaiian petrel or ua'a (*Pterodroma sandwichensis*).	Hawaii	Harass by adding passive integrated transponder tags to bands.	Amend.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. 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 can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue a permit to an applicant listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Katherine Norman,

Assistant Regional Director—Ecological Services, Pacific Region.

[FR Doc. 2021–22812 Filed 10–19–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLHQ310000.L13100000. PP0000.21X]

Notice Regarding Use of Truck-Mounted Coriolis Meters; Correction

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of correction.

SUMMARY: The Bureau of Land Management (BLM) published a document in the **Federal Register** of August 31, 2021, clarifying its position on the use of truck-mounted Coriolis meters under the Bureau's oil-measurement regulations. The document referenced two incorrect Code of Federal Regulations citations.

FOR FURTHER INFORMATION CONTACT: Amanda Eagle, Production Management Team Lead for the Division of Fluid Minerals, BLM Headquarters Office, 301 Dinosaur Drive, Santa Fe, NM 87508; phone 907–538–2300; email *pmt@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Ms. Eagle. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of August 31, 2021, in FR Doc. 2021–18750:

On page 48760, in the second column, correct line 40 to read ''complying with § 3174.9, which''

On page 48760, in the second column, correct line 42 to read ''components'' for a CMS, and § 3174.10,''

Sheila Mallory,

Acting Chief, Division of Fluid Minerals.

[FR Doc. 2021–22779 Filed 10–19–21; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLHQ430000.L12200000.PM0000; OMB Control No. 1004–0NEW]

Agency Information Collection Activities; Surveys and Focus Groups To Support Outcomes-Focused Management (Recreation Survey and Focus Groups)

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Land Management (BLM) has submitted a new information collection request (ICR) to the Office of Management and Budget (OMB) for review.

DATES: Interested persons are invited to submit comments on or before November 19, 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.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Matt Blocker, Outdoor Recreation Planner, by email at *mblocker@blm.gov,* or by telephone at (801) 539–4011. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the PRA (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1)), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on June 28, 2021 (86 FR 34037). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. 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 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.

Abstract: Information will be collected from visitors of public lands and community members near public lands. Information gathered from visitors and local community residents will be used to inform planning decisions in support of BLM's Planning for Recreation and Visitor Services Handbook H–8320–1. This request is for OMB to approve these new surveys and focus groups for three years.

Title of Collection: Surveys and Focus Groups To Support Outcomes-Focused Management (Recreation Survey and Focus Groups).

OMB Control Number: 1004–0NEW.

Form Numbers: None.

Type of Review: New collection (Request for a new OMB Control Number).

Respondents/Affected Public: Individuals or households.

Total Estimated Number of Annual Respondents: 5,112.

Total Estimated Number of Annual Responses: 7,380.

Estimated Completion Time per Response: Varies from 1 minute to answer an on-site survey to 90 minutes to participate in a focus group.

Total Estimated Number of Annual Burden Hours: 2,093.

Respondent's Obligation: Voluntary.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: $0.

An agency may not conduct or sponsor and, notwithstanding any other provision of law, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Darrin King,

Information Collection Clearance Officer.

[FR Doc. 2021–22816 Filed 10–19–21; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS00000.L51010000.ER0000.LVRWF2007590.20X; N–99407; MO#4500154254]

Notice of Segregation of Public Land for the Rough Hat Nye County Solar Project, Nye County, Nevada

AGENCY: Bureau of Land Management, Department of Interior.

ACTION: Notice of segregation.

SUMMARY: Through this notice the Bureau of Land Management (BLM) is segregating public lands included in the right-of-way application for the Rough Hat Nye County Solar Project from appropriation under the public land laws, including the Mining Law, but not the Mineral Leasing or Material Sales Acts, for a period of 2 years from the date of publication of this notice, subject to valid existing rights. This segregation is to allow for the orderly administration of the public lands to facilitate consideration of development of renewable energy resources. The public lands segregated by this Notice total 7,075.93 acres.

DATES: This segregation for the lands identified in this notice is effective on October 20, 2021.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to the mailing list, send requests to: Beth Ransel, Southern Nevada District Energy & Infrastructure Team, at telephone (702) 515–5284; address 4701 North Torrey Pines Drive, Las Vegas, NV 89130–2301; or email

BLM_NV_SND_EnergyProjects@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Regulations found at 43 CFR 2091.3–1(e) and 2804.25(f) allow the BLM to temporarily segregate public lands within a right-of-way application area for solar energy development from the operation of the public land laws, including the Mining Law, by publication of a **Federal Register** notice. The BLM uses this temporary segregation authority to preserve its ability to approve, approve with modifications, or deny proposed rights-of-way, and to facilitate the orderly administration of the public lands. This temporary segregation is subject to valid existing rights, including existing mining claims located before this segregation notice. Licenses, permits, cooperative agreements, or discretionary land use authorizations of a temporary nature which would not impact lands identified in this notice may be allowed with the approval of an authorized officer of the BLM during the segregation period. The lands segregated under this notice are legally described as follows:

Mount Diablo Meridian, Nevada,

T. 21 S., R. 54 E.,
Sec. 13, N½SW¼ and N½SE¼;
Sec. 14, NE¼SW¼, S½SW¼, N½SE¼, and SW¼SE¼;
Sec. 22, S½NE¼, S½NW¼, and S½;
Sec. 23, W½NE¼, W½NW¼, and W½SE¼;
Sec. 26, W½NE¼ and S½NW¼;
Sec. 27;
Sec. 28, S½SW¼ and S½SE¼;
Sec. 29, S½SW¼ and S½SE¼;
Sec. 32;
Sec. 33, W½ and W½SE¼;
Sec. 34, NE¼, E½SW¼, and SE¼.
T. 21 S., R. 55 E.,
Sec. 18, lots 3 and 4, SE¼SW¼, and SW¼SE¼;
Sec. 19, N½NE¼ and SE¼NE¼;
Sec. 20, SW¼NW¼, N½SW¼, W½SE¼, and SE¼SE¼;
Sec. 27, SW¼SW¼;
Sec. 28, SW¼NE¼, W½NW¼, SE¼NW¼, N½SE¼, and SE¼SE¼;
Sec. 29, NE¼NE¼;
Sec. 34, W½NE¼, SE¼NE¼, N½NW¼, and NE¼SE¼;
Sec. 35, W½SW¼.
T. 22 S., R. 54 E.,
Sec. 3, lots 5 thru 7 and lots 10 thru 12, S½NE¼, SE¼NW¼, E½SW¼, and SE¼;
Sec. 10, NE¼ and E½NW¼;
Sec. 11, N½NE¼ and N½NW¼;
Sec. 12, lot 1, NW¼NE¼, and N½NW¼;
T. 22 S., R. 55 E.,
Sec. 2, lot 4, SW¼NW¼, and W½SW¼;
Sec. 3, SE¼SE¼;
Sec. 7, lot 1, SW¼NE¼, E½NW¼, N½SE¼, and SE¼SE¼;
Sec. 10, N½NE¼, SW¼NE¼, NE¼SW¼, S½SW¼, and NW¼SE¼;
Sec. 15, NW¼NW¼;
Sec. 16, N½NE¼ and N½NW¼;
Sec. 17, N½NE¼ and N½NW¼;
Sec. 18, NE¼NE¼.

The area described contains 7,075.93 acres, according to the official plats of the surveys of the said lands on file with the BLM.

As provided in the regulations, the segregation of lands in this Notice will not exceed 2 years from the date of publication unless extended for an additional 2 years through publication of a new Notice in the **Federal Register**. The segregation period will terminate and the land will automatically reopen to appropriation under the public land laws, including the mining laws, at the earliest of the following dates: Upon issuance of a decision by the authorized officer granting, granting with modifications, or denying the application for a right-of-way; without further administrative action at the end of the segregation provided for in the **Federal Register** notice initiating the segregation; or upon publication of a **Federal Register** notice terminating the segregation.

Upon termination of the segregation of these lands, all lands subject to this segregation would automatically reopen to appropriation under the public land laws, including the mining laws.

Authority: 43 CFR 2091.3–1(e) and 43 CFR 2804.25(f).

Nicholas Pay,

Field Manager—Pahrump Field Office.

[FR Doc. 2021–22786 Filed 10–19–21; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLHQ310000.L13100000. PP0000.21X]

Annual Statutorily Required Increase in Filing Fee for Processing Fiscal Year 2022; Applications for Permit To Drill

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of fee increase.

SUMMARY: The Bureau of Land Management (BLM) hereby updates the filing fee for Applications for Permits to Drill (APD) on Federal oil and gas leases. The updated APD fee amount is $10,900, reflecting the adjustment for inflation as required by statute.

DATES: This updated fee increase takes effect on October 20, 2021.

FOR FURTHER INFORMATION CONTACT: Matthew Warren, National Oil and Gas Program Lead for Division of Fluid Minerals, Bureau of Land Management, Headquarters Office, 301 Dinosaur Drive, Santa Fe, NM 87508; phone 505–216–8832; email *mwarren@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Mr. Warren. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Section 3021(b) of the National Defense Authorization Act of 2015 (Pub. L. 113–291; 30 U.S.C. 191(d)) (the Act) directs the BLM to collect a fee for each new APD submitted to the BLM for fiscal years (FY) 2016 through 2026 and requires the fee amount to be adjusted for inflation. The Act sets the initial fee amount at $9,500 as of October 1, 2015, with updated annual fee amounts to be indexed for United States dollar inflation from that date as measured by the Consumer Price Index. 30 U.S.C. 191(d)(2).

The updated APD fee as adjusted for inflation will be in the amount of $10,900, effective October 20, 2021. This updated fee amount reflects an adjustment to the current fee of $10,360 based on the percentage change in the U.S. Bureau of Labor Statistics' seasonally adjusted Consumer Price Index for all goods and all urban consumers (CPI–U) for August of the previous calendar year to August of the current calendar year, on the business day following its release. The seasonally adjusted CPI–U for August 2021 (273.012) is 5.2 percent higher than the seasonally adjusted CPI–U for August 2020 (259.511). Increasing the 2020 fee of $10,360 by 5.2 percent and rounding the product to the nearest $10 produces a 2021 fee of $10,900.

The source for CPI–U data is the BLS, U.S. Bureau of Labor Statistics, Consumer Price Index for All Urban Consumers: All Items in U.S. City Average [CPIAUCSL], retrieved from FRED, Federal Reserve Bank of St. Louis; *https://fred.stlouisfed.org/series/CPIAUCSL,* accessed on September 14, 2021.

The updated filing fee applies to any new APD submitted on BLM Form 3160–3, including those submitted on leases of Indian minerals, whether submitted individually or as part of a

Master Development Plan. The APD filing fee is non-refundable and is required up front for processing an APD, regardless of whether the BLM subsequently approves the APD. The filing fee is not required for a Notice of Staking. The increase in the filing fee does not change Onshore Oil and Gas Order Number 1 (Onshore Order No. 1) (72 FR 10308 (2007); 82 FR 2906 (2017)) or its implementation.

Because the APD fee is established by statute, the BLM has no discretion to waive it or accept a reduced amount. If an operator submits a new APD without including the full non-refundable filing fee of $10,900, the BLM will not log it in, post, process, or consider it received until the operator pays the full fee. As of October 20, 2021, APDs for which operators submit the previous FY 2021 filing fee of $10,360, will not be considered paid until the BLM receives the full FY 2022 filing fee of $10,900.

In the event that the operator does not submit the full filing fee, the BLM will contact the operator and give the operator 10 business days to submit the required amount. The BLM considers an APD filed and starts the processing clock that is described in Section III.E. of Onshore Order No. 1 only after the operator submits the full filing fee. If the operator fails to pay the full filing fee after the 10-day notice, the BLM will return the APD along with any partial filing fee to the operator. The BLM does not consider an operator's failure to submit the APD fee as a deficiency in an APD under Onshore Order No. 1.

As required by the Act, the APD fee generally applies to all new APDs. In some cases, however, an operator's filing of a Form 3160–3 does not trigger the need to pay the APD fee because it is not a new APD. An operator may need to file a Form 3160–3 for administrative purposes where the operator must use a replacement well due to encountering down-hole problems requiring it to skid the rig a few feet on the same well pad. Since the BLM would have previously completed most of the work to approve the APD in those circumstances, including consultation and environmental work, the filing of an amended Form 3160–3 in this situation would not represent a new APD, and an additional filing fee would not be required.

If the operator moves the well location at the request of the BLM to accomplish agency or resource conservation goals or to accommodate a private surface owner request, and the move results in the operator filing an amended APD, an additional filing fee is not required for the moved well. An example would be a request by the BLM to move a well to reduce a cut and fill or loss of habitat. Additionally, if the BLM requests an adjustment in the drilling location at the on-site inspection or if the operator submits a second Form 3160–3 for the purpose of correcting a clerical error, an additional filing fee is not required. However, if the operator requests the move and the move results in the operator filing a new APD, an additional filing fee is required.

The BLM is not requesting public comment on this fee increase for good cause under 5 U.S.C. 553(b). Since the authorizing statute does not give the BLM discretion to vary the amount of the inflation adjustment for the APD fee to reflect any views or suggestions provided by commenters, providing an opportunity for public comment on this fee increase would serve no purpose.

(Authority: 30 U.S.C. 191(d))

Sheila Mallory,

Acting Chief, Division of Fluid Minerals.

[FR Doc. 2021–22777 Filed 10–19–21; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS00000. L51010000.ER0000.LVRWF2007480.20X; N–99406; MO #4500156363]

Notice of Segregation of Public Land for the Rough Hat Clark County Solar Project, Clark County, Nevada

AGENCY: Bureau of Land Management, Department of Interior.

ACTION: Notice of segregation.

SUMMARY: Through this notice the Bureau of Land Management (BLM) is segregating public lands included in the right-of-way application for the Rough Hat Clark County Solar Project from appropriation under the public land laws, including the Mining Law, but not the Mineral Leasing or Material Sales Acts, for a period of 2 years from the date of publication of this notice, subject to valid existing rights. This segregation is to allow for the orderly administration of the public lands to facilitate consideration of development of renewable energy resources. The public lands segregated by this notice total 3,273.96 acres.

DATES: This segregation for the lands identified in this notice is effective on October 20, 2021.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to the mailing list, send requests to: Beth Ransel, Southern Nevada District Energy & Infrastructure Team, at telephone (702) 515–5284; address 4701 North Torrey Pines Drive, Las Vegas, NV 89130–2301; or email *BLM_NV_SND_EnergyProjects@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Regulations found at 43 CFR 2091.3–1(e) and 2804.25(f) allow the BLM to temporarily segregate public lands within a right-of-way application area for solar energy development from the operation of the public land laws, including the Mining Law, by publication of a **Federal Register** notice. The BLM uses this temporary segregation authority to preserve its ability to approve, approve with modifications, or deny proposed rights-of-way, and to facilitate the orderly administration of the public lands. This temporary segregation is subject to valid existing rights, including existing mining claims located before this segregation notice. Licenses, permits, cooperative agreements, or discretionary land use authorizations of a temporary nature which would not impact lands identified in this notice may be allowed with the approval of an authorized officer of the BLM during the segregation period. The lands segregated under this notice are legally described as follows:

Mount Diablo Meridian, Nevada

T. 21 S., R. 55 E.,
Sec. 18, lots 3 and 4, SE¼SW¼, and SW¼SE¼;
Sec. 19;
Sec. 20, SW¼NW¼, SW¼, W½SE¼, and SE¼SE¼;
Sec. 27, SW¼SW¼;
Sec. 28, SW¼NE¼, NW¼NW¼, S½NW¼, and S½;
Sec. 29;
Sec. 30;
Sec. 34, W½NE¼, SE¼NE¼, N½NW¼, and NE¼SE¼;
Sec. 35, W½SW¼.
T. 22 S., R. 55 E.,
Sec. 2, lot 4 and SW¼NW¼.

The area described contains 3,273.96 acres, according to the official plats of the surveys of the said lands on file with the BLM.

As provided in the regulations, the segregation of lands in this notice will not exceed 2 years from the date of publication unless extended for an additional 2 years through publication of a new notice in the **Federal Register**. The segregation period will terminate

and the land will automatically reopen to appropriation under the public land laws, including the mining laws, at the earliest of the following dates: Upon issuance of a decision by the authorized officer granting, granting with modifications, or denying the application for a right-of-way; without further administrative action at the end of the segregation provided for in the **Federal Register** notice initiating the segregation; or upon publication of a **Federal Register** notice terminating the segregation.

Upon termination of the segregation of these lands, all lands subject to this segregation would automatically reopen to appropriation under the public land laws, including the mining laws.

Authority: 43 CFR 2091.3–1(e) and 43 CFR 2804.25(f).

Shonna Dooman,

Field Manager—Las Vegas Field Office.

[FR Doc. 2021–22781 Filed 10–19–21; 8:45 am]

BILLING CODE 4310–HC–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–298 (Fifth Review)]

Porcelain-on-Steel Cooking Ware From China; Termination of Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission instituted the subject five-year review on July 1, 2021 (86 FR 35127) to determine whether revocation of the antidumping duty order on porcelain-on-steel cooking ware from China would be likely to lead to continuation or recurrence of material injury. On September 29, 2021, the Department of Commerce issued notice that it was revoking the order effective August 11, 2021, because no domestic interested party filed a timely notice of intent to participate. Accordingly, the subject review is terminated.

DATES: August 11, 2021 (effective date of revocation of the order).

FOR FURTHER INFORMATION CONTACT: Lawrence Jones (202–205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained 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*).

Authority: This review is being terminated under authority of title VII of the Tariff Act of 1930 and pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). This notice is published pursuant to § 207.69 of the Commission's rules (19 CFR 207.69).

By order of the Commission.

Issued: October 15, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–22833 Filed 10–19–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1166]

Certain Foodservice Equipment and Components Thereof; Notice of Commission Determination Finding No Violation of Section 337; 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 determined to affirm in part and take no position in part with respect to the final initial determination's (''final ID'') finding that no violation of section 337 has occurred. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. 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: The Commission instituted this investigation on July 3, 2019, based on a complaint filed on behalf of Illinois Tool Works, Inc. of Glenview, Illinois; Vesta Global Limited of Hong Kong; Vesta (Guangzhou) Catering Equipment Co., Ltd. of China; and Admiral Craft Equipment Corp. of Westbury, New York (collectively, ''Complainants''). 84 FR 31911 (Jul. 3, 2019). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation of articles into the United States, or in the sale of such articles by the owner, importer, or consignee of certain foodservice equipment and components thereof by reason of misappropriation of trade secrets and unfair competition through tortious interference with contractual relationships, the threat or effect of which is to destroy or substantially injure a domestic industry. *Id.* at 31911–12. The notice of investigation named as respondents Guangzhou Rebenet Catering Equipment Manufacturing Co., Ltd.; Zhou Hao; Aceplus International Limited (aka Ace Plus International Ltd.); Guangzhou Liangsheng Trading Co., Ltd.; and Zeng Zhaoliang, all of China. *Id.* at 31912. The Office of Unfair Import Investigations (''OUII'') was also named as a party in this investigation. *Id.*

On July 9, 2020, Order No. 52 granted a motion for summary determination of no substantial injury to a domestic industry. The Commission determined to review Order No. 52, and on December 14, 2020, reversed the grant of summary determination.

On June 4, 2021, the Chief Administrative Law Judge (''CALJ'') issued the final ID, which found that Respondents did not violate section 337, primarily based on Complainants' failure to establish a domestic industry. The final ID found that the Commission has *in rem* jurisdiction over the accused products, subject matter jurisdiction, and personal jurisdiction. ID at 99. The final ID also found that Respondents imported and sold the accused products in the United States. *Id.* The final ID further found that Respondents have misappropriated certain of Complainants' trade secrets in the manufacture of certain accused products, but that Complainants have not shown that Respondents tortiously interfered with contractual relationships. *Id.* The final ID additionally found that Complainants have not shown that the importation and sale of accused products has the threat or effect of destroying or substantially injuring a domestic industry.

The RD issued on June 10, 2021. The RD recommended that, if the Commission finds a violation of section 337, the Commission should issue a limited exclusion order having various durations for each of the various categories of accused products. RD at 10. The durations of the recommended exclusion orders range from 1–17 months from issuance. *Id.* at 10–11. The RD further recommended that a cease and desist order would not be necessary. *Id.* at 12. The RD additionally recommended that a bond of 1% of entered value be imposed during the period of Presidential review. The public interest was not delegated to the CALJ.

On June 21, 2021, Complainants, Respondents, and OUII filed petitions for review. On June 29, 2021, the parties filed responses to the petitions.

On August 4, 2021, the Commission determined to review in part the final ID and requested briefing from the parties on the issues under review. 86 FR 44054 (Aug. 11, 2021). In particular, the Commission determined to review the following: (1) The final ID's findings and conclusions as to the existence of a domestic industry and injury to a domestic industry; and (2) the final ID's findings and conclusions regarding the wrongful taking and use of the Bills of Materials Trade Secrets and the Custom Components and Mold Trade Secrets. *Id.* at 44054–55. The Commission also sought briefing from the parties, interested government agencies, and any other interested parties on remedy, public interest, and bonding. *Id.* at 44055.

On August 19, 2021, the parties filed their written submissions on the issues under review and on remedy, public interest, and bonding, and on August 26, 2021, the parties filed their reply submissions.

Having examined the record of this investigation, including the final ID, the petitions for review, the responses thereto, and the written submissions received in response to the Commission's request for briefing, the Commission finds that no violation of section 337 has occurred. More specifically, as explained in the accompanying opinion, the Commission affirms with modifications the final ID's conclusion that Complainants did not satisfy the domestic industry requirement, and takes no position as to the trade secrets issues under review. The Commission therefore finds that the Complainants did not establish that an industry in the United States exists as required by section 337(a)(1)(A)(i) and thus did not establish a substantial injury to a domestic industry. The investigation is hereby terminated.

The Commission vote for this determination took place on October 14, 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: October 14, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–22813 Filed 10–19–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–660 and 731–TA–1543–1544 (Final)]

Utility Scale Wind Towers From India and Malaysia; Scheduling of the Final Phase of Countervailing and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: October 13, 2021.

FOR FURTHER INFORMATION CONTACT: Julie Duffy ((202) 708–2579), 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: Effective March 19, 2021, the Commission established a general schedule for the conduct of the final phase of its investigations on utility scale wind towers (''wind towers'') from India, Malaysia, and Spain (86 FR 20197, April 16, 2021), following preliminary determinations by the U.S. Department of Commerce (''Commerce'') that imports of subject wind towers from India and Malaysia were subsidized by the governments of India and Malaysia (86 FR 15887, March 25, 2021; and 86 FR 15897, March 25, 2021) and imports of subject wind towers from Spain were being sold in the United States at less than fair value (86 FR 17354, April 2, 2021). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on April 16, 2021 (86 FR 20197). Counsel for the Wind Tower Trade Coalition withdrew its previously filed request to appear at the hearing, after no other parties submitted a request to appear, and indicated a willingness to submit written responses to any Commission questions in lieu of an actual hearing. Consequently, since no party to the investigation requested a hearing, the Commission canceled its hearing in connection with these investigations (86 FR 31730, June 15, 2021). Parties to these investigations responded to written questions posed by the Commission in their posthearing briefs.

The Commission subsequently issued its final determination that an industry in the United States was materially injured by reason of imports of wind towers from Malaysia provided for in subheadings 7308.20.00 and 8502.31.00 of the Harmonized Tariff Schedule of the United States (''HTSUS'') that have been found by Commerce to be subsidized by the government of Malaysia (86 FR 41087, July 30, 2021).

The Commission subsequently issued its final determination that an industry in the United States was materially injured by reason of imports of wind towers from Spain provided for in subheadings 7308.20.00 and 8502.31.00 of the HTSUS that have been found by Commerce to be sold in the United States at less than fair value (''LTFV'') (86 FR 44748, August 13, 2021).

Commerce recently has issued a final affirmative countervailing duty determination with respect to wind towers from India (86 FR 56896, October 13, 2021) and final affirmative antidumping duty determinations with respect to wind towers from India and Malaysia (86 FR 56890, October 13, 2021; and 86 FR 56894, October 13, 2021). Accordingly, the Commission currently is issuing a supplemental schedule for its countervailing duty investigation on imports of wind towers from India and antidumping duty investigations on imports of wind towers from India and Malaysia.

This supplemental schedule is as follows: The deadline for filing

supplemental party comments on Commerce's final countervailing and antidumping duty determinations is October 25, 2021. Supplemental party comments may address only Commerce's final countervailing duty determination regarding imports of wind towers from India and antidumping duty determinations regarding imports of wind towers from India and Malaysia. These supplemental final comments may not contain new factual information and may not exceed five (5) pages in length. The supplemental staff report in the final phase of the current investigations will be placed in the nonpublic record on November 8, 2021, and a public version will be issued thereafter.

For further information concerning these investigations see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's 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.

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.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: October 14, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–22804 Filed 10–19–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1211]

Certain Vaporizer Cartridges and Components Thereof; Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on October 14, 2021, the presiding administrative law judge (''ALJ'') issued a Summary Determination on Violation of Section 337. The ALJ also issued a Recommended Determination on remedy and bonding (''RD'') should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public only.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. 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: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States:

> unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. Specifically, the RD recommends a general exclusion order directed to certain vaporizer cartridges and components thereof. Alternatively to the general exclusion order, the RD recommends a limited exclusion order directed to certain vaporizer cartridges and components thereof imported, sold for importation, and/or sold after importation by respondents 101 Smoke Shop, Inc. (''101 Smoke Shop''); Eon Pods LLC (''Eon Pods''); Jem Pods, U.S.A. (''Jem Pods''); Sky Distribution LLC (''Sky Distribution''); Vapers & Papers, LLC (''Vapers & Papers''); Access Vapor LLC d/b/a Cali Pods (''Access Vapor''); eLiquid Stop; Shenzhen Apoc Technology Co., Ltd.; Shenzhen Ocity Times Technology Co., Ltd.; Evergreen Smokeshop; Shenzhen Azure Tech USA LLC f/k/a DS Vaping P.R.C. (''Shenzhen Azure''); DripTip Vapes LLC (''DripTip Vapes''); Modern Age Tobacco; Dongguan Hengtai Biotechnology Co., Ltd. d/b/a Mr. Fog; Shenzhen Yark Technology Co., Ltd.; Guangdong Cellular Workshop Electronic Technology Co., Ltd.; Shenzhen Bauway Technology Ltd.; and Shango Distribution LLC d/b/a Puff E-Cig (''Shango Distribution''). In addition to an exclusion order (general or limited), the RD recommended the issuance of cease and desist orders directed to 101 Smoke Shop, Eon Pods, Jem Pods, Sky Distribution, Vapers & Papers, Access Vapor, eLiquid Stop, Evergreen Smokeshop, Shenzhen Azure, DripTip Vapes, Modern Age Tobacco, and Shango Distribution. Parties to the investigation are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on October 14, 2021. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, 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 recommended

remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended 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 recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on November 5, 2021.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1211'') in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of 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: October 14, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–22815 Filed 10–19–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1167]

Certain Laparoscopic Surgical Staplers, Reload Cartridges, and Components Thereof; Final Determination Finding a Violation of Section 337 and Issuance of Remedial Orders; Suspension of Enforcement of the Remedial Orders Pending Final Resolution of a Final Written Decision by the Patent Trial and Appeal Board; and Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (the ''Commission'') has determined that: (i) The respondents have violated section 337 of the Tariff Act of 1930, as amended, by importing, selling for importation, or selling in the United States after importation certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe complainants' U.S. Patent No. 9,844,379 (''the '379 patent''); (2) the appropriate remedies are a limited exclusion order and cease and desist orders; and (3) enforcement of said remedial orders will be suspended pending final resolution of a Final Written Decision by the Patent Trial and Appeal Board (''PTAB'') that the asserted claims of the '379 patent are unpatentable. This investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Benjamin S. Richards, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–5453. 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: The Commission instituted this investigation on July 5, 2019, based on a complaint filed by Ethicon LLC of Guaynabo, PR; Ethicon Endo-surgery, Inc. of Cincinnati, OH; and Ethicon US, LLC of Cincinnati, OH (collectively, ''Ethicon''). 84 FR 32220 (July 5, 2019); *see also* 84 FR 65174 (Nov. 26, 2019) (amending the caption). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain laparoscopic surgical staplers, reload cartridges, and components thereof by reason of infringement of one or more claims of U.S. Patent Nos. 9,844,379; 9,844,369 (''the '369 patent''); 7,490,749 (''the '749 patent''); 8,479,969 (''the '969 patent''); and 9,113,874 (''the '874 patent''). 84 FR at 32220. The Commission's notice of investigation named the following as respondents: Intuitive Surgical Inc., of Sunnyvale, CA; Intuitive Surgical Operations, Inc., of Sunnyvale, CA; Intuitive Surgical Holdings, LLC, of Sunnyvale, CA; and Intuitive Surgical S. De R.L. De C.V. of Mexicali, Mexico (collectively, ''Intuitive''). *Id.* The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On October 23, 2020, the Chief Administrative Law Judge (''CALJ'') granted Ethicon's motion for leave to amend the complaint, case caption, and notice of investigation to reinstate the original plain English statement of the category of accused products, as well as the original case caption, and to reincorporate Intuitive's laparoscopic surgical staplers and components thereof as articles to be excluded. Order No. 14, *unreviewed by* Comm'n Notice (Nov. 21, 2019). As initially instituted, the investigation covered reload cartridges for those staplers, but not the staplers themselves. *See id.*

On October 29, 2019, the CALJ conducted a *Markman* hearing. Thereafter, on January 7, 2020, the CALJ issued Order No. 15, which construed various terms in the asserted patents.

On March 5, 2020, the CALJ granted Ethicon's motion to terminate claim 1 of the '379 patent and all claims of the '749 patent from the investigation. *See* Order No. 21, *unreviewed by* Comm'n Notice (Mar. 25, 2020).

On April 21, 2020, Ethicon moved for leave to file a second amended complaint to include the Certificate of Correction for the '379 patent. The CALJ granted Ethicon's motion on May 6, 2020, and Ethicon filed its second amended complaint on May 7, 2020. *See* Order No. 36; Doc. ID 709878.

On June 8, 2021, the CALJ issued the subject ID on violation, which found a violation of section 337 based on infringement of the asserted claims of the '369 and '379 patents by Intuitive. The ID found no violation based on the '969 and '874 patents. Also, on June 8, 2021, the CALJ issued his recommended determination on remedy and bonding. The CALJ recommended, upon a finding of violation, that the Commission issue a limited exclusion order, issue cease and desist orders, and impose a bond in the amount of zero percent (0%) of the entered value of any covered products imported during the period of Presidential review.

On June 21, 2021, Ethicon and Intuitive submitted petitions seeking review of the subject ID. Intuitive's petition included a request for suspension of enforcement of any remedial orders directed to the '379 patent based on a Final Written Decision by the PTAB, in which the PTAB found all claims of the '379 patent unpatentable. *See Intuitive Surgical, Inc.* v. *Ethicon LLC,* IPR2020–00050, IPR2020–00051, Patent 9,844,379, Final Written Decision Determining All Challenged Claims Unpatentable (Mar. 26, 2021). On June 29, 2021, Ethicon and Intuitive submitted responses to the other's petitions.

On June 9, 2021, the Commission issued a notice soliciting public comments on the public interest factors, if any, that may be implicated if a remedy were to be issued in this investigation. 85 FR 30735 (May 20, 2020). The Commission received twelve submissions from the public in response to its notice.

On August 16, 2021, issued notice of its determination to review the ID in part with respect to (1) the ID's findings on claim construction, infringement, anticipation, obviousness, and enforceability for the '969 patent; and (2) the ID's findings on claim construction, infringement, and obviousness for the '369 patent. The Commission determined not to review the remainder of the ID, including the ID's determination that a violation of section 337 had occurred with respect to the '379 patent and that no violation occurred with respect to the '874 patent. In connection with its review of the ID, the Commission sought briefing from the parties on several questions germane to the issues on review and on remedy, bonding, and the public interest.

The parties filed their initial response to the Commission's review questions on August 23, 2021, and their respective reply briefs on August 30, 2021.

Having considered the parties' submissions, the ID, and the record in this investigation, the Commission has determined that Intuitive has violated section 337 by importing into the United States, selling for importation, or selling in the United States after importation certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe claims 2 and 3 of the '379 patent. The Commission has further determined to affirm, reverse, and take no position on certain portions of the ID, as explained in the Commission's opinion issued concurrently herewith.

The Commission has determined that the appropriate remedy is: (a) A limited exclusion order prohibiting the importation of certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe claims 2 and 3 of the '379 patent; and (b) cease and desist orders against Intuitive. The Commission has determined that the public interest factors enumerated in section 337(d)(1) and (f)(1) do not preclude issuance of the limited exclusion order or cease and desist orders. The Commission has also determined to set a bond in the amount of zero percent (0%) (*i.e.,* no bond) of the entered value of the excluded products imported during the period of Presidential review (19 U.S.C. 1337(j)).

The Commission has also determined to suspend enforcement of its remedial orders, including the bond provision, pending final resolution of a Final Written Decision issued by the PTAB on March 26, 2021, finding all claims of the '379 patent to be unpatentable. *See* 35 U.S.C. 318(b); *Intuitive Surgical, Inc.* v. *Ethicon LLC,* IPR2020–00050, IPR2020–00051, Patent 9,844,379, Final Written Decision Determining All Challenged Claims Unpatentable (Mar. 26, 2021).

The Commission's orders and opinion were delivered to the President and United States Trade Representative on the day of their issuance.

The Commission vote for this determination took place on October 14, 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 210).

By order of the Commission.

Issued: October 14, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–22814 Filed 10–19–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–531–532 and 731–TA–1270–1273 (Review)]

Polyethylene Terephthalate (PET) Resin From Canada, China, India, and Oman; Scheduling of Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the countervailing duty orders on polyethylene terephthalate (''PET'') resin from China and India and the antidumping duty orders on PET resin from Canada, China, India, and Oman would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: October 14, 2021.

FOR FURTHER INFORMATION CONTACT: Keysha Martinez (202–205–2136), 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 reviews may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On July 7, 2021, the Commission determined that responses to its notice of institution of the subject

five-year reviews were such that full reviews should proceed (86 FR 37343, July 15, 2021); accordingly, full reviews are being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's website.

Participation in the reviews and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

For further information concerning the conduct of these reviews 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, D, E, and F (19 CFR part 207).

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.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the reviews. A party granted access to BPI following publication of the Commission's notice of institution of the reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the reviews will be placed in the nonpublic record on January 10, 2022, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.— The Commission will hold a hearing in connection with the final phase of this investigation beginning at 9:30 a.m. on January 27, 2022. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.* Interested parties should check the Commission's website periodically for updates. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before January 21, 2022. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on January 24, 2022. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is January 19, 2022. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is February 7, 2022. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before February 7, 2022. On March 4, 2022, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before March 8, 2022, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 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.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (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.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: October 14, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–22802 Filed 10–19–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Resource Conservation and Recovery Act and Other Statutes

On October 13, 2021, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Eastern District of Texas in the lawsuit entitled *United States and State of Texas* v. *E.I. du Pont de Nemours and Company and*

Performance Materials NA, Inc., Case No. 1:21–cv–00516, for violations of federal and state environmental laws during their respective periods of ownership and operation of an ethylene production facility located in Orange, Texas.

The proposed Consent Decree resolves the claims of the United States and the State of Texas under (1) the Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.,* implementing regulations and the authorized program under the Texas Solid Waste Disposal Act (Texas Health and Safety Code ch. 361), (2) the Clean Air Act, 42 U.S.C. 7401 *et seq.,* implementing regulations, and Texas Clean Air Act (Tex. Health and Safety Code ch. 382), and (3) the Clean Water Act, 33 U.S.C. 1251, *et seq.,* implementing regulations, and the Texas Water Code ch. 26 and the general enforcement authority of Texas Water Code ch. 7. The Consent Decree provides for payment of a civil penalty of $3,100,000 ($1,675,000 to the United States and $1,425,000 to the State of Texas), payment of attorneys' fees to the State of Texas, and performance of injunctive relief to resolve the violations alleged in the Complaint.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to entitled *United States and State of Texas* v. *E.I. du Pont de Nemours and Company and Performance Materials NA, Inc.*. Case No. 1:21–cv–00516, D.J. Ref. No. 90–7–1–10173. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $15.50 (25 cents per page reproduction cost) for the Consent Decree or $24.75 (25 cents per page reproduction cost) for the Consent Decree and Appendices, payable to the United States Treasury.

Karen Dworkin,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–22762 Filed 10–19–21; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act and Oil Pollution Act

On October 13, 2021, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Northern District of Illinois in the lawsuit entitled *United States and Illinois* v. *Buckeye Pipe Line Company, L.P. and West Shore Pipe Line Company,* Civil Action No. 21–cv–5424.

The United States filed a Complaint for civil penalties and injunctive relief alleging violations of Sections 311(b) and 404(s) of the Clean Water Act (CWA) arising out of the discharge of approximately 1,857 barrels of crude oil from a pipeline near Lockport, Will County, Illinois. The State of Illinois joined the United States claim under Section 1002 of the Oil Pollution Act for injuries to natural resources. The United States' complaint names as defendants Buckeye Pipe Line Company, L.P., the operator of the pipeline, and West Shore Pipe Line Company, the owner of the pipeline. Both defendants signed the proposed Consent Decree to resolve these claims, agreeing to pay a total of $1,500,000 in civil penalties and $7,200,000 in natural resource damages and wetland mitigation.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and Illinois* v. *Buckeye Pipe Line Co., L.P., et al.,* D.J. Ref. Nos. 90–5–1–1–11370 and 90–5–1–1–20834. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	pubcomment-ees.enrd@usdoj.gov.
By mail	Assistant Attorney General, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $14.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Patricia McKenna,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–22822 Filed 10–19–21; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; United States-Mexico-Canada Agreement (USMCA) Web-Based Hotline

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Bureau of International Labor Affairs (ILAB)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before November 19, 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.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Section 711 of the United States-Mexico-Canada Agreement (USMCA) Implementation Act prescribes the establishment of an Interagency Labor Committee for Monitoring and Enforcement (ILC) and Section 717 charges the ILC with establishing a ''web-based hotline'' monitored by the Department of Labor. This USMCA web-based hotline serves as an electronic portal to collect and receive confidential information regarding labor issues among USMCA countries directly from interested parties, including Mexican workers. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on September 21, 2020 (85 FR 59330).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ILAB.

Title of Collection: United States-Mexico-Canada Agreement (USMCA) Web-based Hotline.

OMB Control Number: 1255–0NEW.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 2,300.

Total Estimated Number of Responses: 2,392.

Total Estimated Annual Time Burden: 573 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: October 14, 2021.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2021–22820 Filed 10–19–21; 8:45 am]

BILLING CODE 4510–28–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0125]

On-Site Consultation Agreements; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements contained in the regulations addressing On-Site Consultation Agreements.

DATES: Comments must be submitted (postmarked, sent, or received) by December 20, 2021.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov.* Documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and the OSHA docket number for this **Federal Register** notice (OSHA–2011–0125). OSHA will place comments and requests to speak, including personal information, in the public docket, which may be available online. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security numbers and birthdates. For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Patrick Showalter, Director, Office of Small Business Assistance, Directorate of Cooperative and State Programs, OSHA, U.S. Department of Labor, telephone (202) 693–2220.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance process to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires OSHA to obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

Section 7(c)(1) of the OSH Act authorizes the Secretary of Labor (Secretary) to, ''with the consent of any State or political subdivision thereof, accept and use the services, facilities, and personnel of any agency of such

State or subdivision with reimbursement.'' Section 21(c) of the OSH Act authorizes the Secretary to ''consult with and advise employers and employees . . . as to effective means of preventing occupational illnesses and injuries.''

Additionally, Section 21(d) of the OSH Act instructs the Secretary to ''establish and support cooperative agreements with the States under which employers subject to the Act may consult with State personnel with respect to the application of occupational safety and health requirements under the Act or under State plans approved under section 18 of the Act.'' This gives the Secretary authority to enter into agreements with the States to provide On-Site Consultation services, and establish rules under which employers may qualify for an inspection exemption. To satisfy the intent of these and other sections of the OSH Act, OSHA codified the terms that govern cooperative agreements between OSHA and State governments whereby State agencies provide On-Site Consultation services to private employers to assist them in complying with the requirements of the OSH Act. The terms were codified as the Consultation Agreement regulations (29 CFR part 1908).

The On-Site Consultation Agreement regulations specify services to be provided, and practices and procedures to be followed by the State On-Site Consultation Agreement Programs. Information collection requirements set forth in the On-Site Consultation Agreement regulations are in two categories: State Responsibilities and Employer Responsibilities. Eight regulatory provisions require information collection activities by the State. The Federal government provides 90 percent of the funds for On-Site Consultation services delivered by the States, which result in the information collection. Four requirements apply to employers and specify conditions for receiving the free consultation services.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply—for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting an extension of the current approval of the collection of information requirements for the regulation. The agency is requesting an adjustment increase of 8,745 burden hours (from 214,750 to 223,495 hours). This increase is primarily due to adding Puerto Rico Consultation to the OSHA 21(d) Program. Prior to 2018, Puerto Rico Consultation had operated under OSHA State Plans, under the governance of section 23(g) of the OSHA Act.

In addition, the agency requests OMB approval to update the Safety and Health Program Assessment Worksheet, OSHA Form 33, to include minor edits.

Type of Review: Extension of a currently approved collection.

Title: On-Site Consultation Agreements (29 CFR part 1908).

OMB Control Number: 1218–0110.

Affected Public: Business or other for-profits.

Number of Respondents: 22,896 (53 State Consultation Programs and 22,843 Employers).

Frequency: Initial, annual, quarterly, periodic.

Average Time per Response: Varies.

Estimated Number of Responses: 94,838.

Estimated Total Burden Hours: 223,495.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. Please note: While OSHA's Docket Office is continuing to accept and process submissions by hand, express mail, messenger, and courier service. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA–2011–0125) for the ICR. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so that the agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627)).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available through the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Acting Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on October 13, 2021.

James S. Frederick,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2021–22819 Filed 10–19–21; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2022–005]

Freedom of Information Act (FOIA) Advisory Committee; Solicitation for Committee Member Nominations

AGENCY: Office of Government Information Services (OGIS), National

Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: The National Archives and Records Administration (NARA) is soliciting applications to fill a vacancy on the Freedom of Information Act (FOIA) Federal Advisory Committee (Committee). We are seeking a representative from a Federal agency who has significant expertise in FOIA. The new member will serve the remainder of the term through June 30, 2022.

DATES: We must receive nominations for Committee membership no later than 5:00 p.m. EDT on Wednesday, October 27, 2021.

ADDRESSES: Email nominations to OGIS at *foia-advisory-committee@nara.gov.* We cannot accept submissions by mail or delivery during this time period because the building is closed due to COVID–19 restrictions. If you are unable to submit by email, please contact Kirstin Mitchell, Designated Federal Officer, at the contact information below.

FOR FURTHER INFORMATION CONTACT: Kirsten Mitchell by phone at 202–741–5775 or by email at *foia-advisory-committee@nara.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The National Archives and Records Administration (NARA) established the Freedom of Information Act (FOIA) Advisory Committee in accordance with the United States Second Open Government National Action Plan, released on December 5, 2013, and operates under the directive in FOIA, 5 U.S.C. 552(h)(2)(C), that the Office of Government Information Services (OGIS) within NARA ''identify procedures and methods for improving compliance'' with FOIA. The Committee is governed by the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

II. Charter and Membership Appointment Terms

NARA initially chartered the Committee on May 20, 2014. The Archivist of the United States renewed the Committee's charter for a fourth term on May 7, 2020, and in July 2020 appointed 20 members to serve for two years, concurrent with the Committee charter. A Government representative member has resigned from the Committee, creating a vacancy.

III. Committee Membership

The 2020–2022 FOIA Advisory Committee consists of no more than 20 individuals who include a range of Government and non-Government representatives. Members are selected in accordance with the charter.

Nominations for the vacant seat should be FOIA professionals from Cabinet-level departments or non-Cabinet agencies. For more information about the Committee's charter and membership, see *https://www.archives.gov/ogis/foia-advisory-committee/2020-2022-term.*

IV. Committee Members' Responsibilities

All Committee members are expected to attend a minimum of four virtual or in-person public meetings remaining in the two-year Committee term that ends June 30, 2022. All Committee members are expected to volunteer for one or more of four working subcommittees that meet at various times during the two-year term. The remaining meetings of the 2020–2022 Committee term are scheduled for Thursday, December 9, 2021; Thursday, May 5, 2002; and Thursday, June 9, 2022. The December meeting will be conducted virtually.

V. Nomination Information

All nominations for Committee membership must include the following information:

1. *If you are self-nominating:* Your name, title, and relevant contact information (including telephone and email address);

2. *If you are nominating another individual:* The nominee's name, title, and relevant contact information;

3. *For both self-nominations and nominations by other individuals:* (a) A short paragraph or biography about the nominee (fewer than 250 words), summarizing their resumé or otherwise highlighting the contributions the nominee would bring to the Committee; and (b) the nominee's resumé or curriculum vitae.

The Archivist of the United States will review the nominations and make final appointments prior to Committee meeting in December. OGIS will notify in writing the nominee the Archivist selects.

Tasha M. Ford,

Committee Management Officer.

[FR Doc. 2021–22857 Filed 10–19–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–21–0015; NARA–2022–004]

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 responses on the schedules listed in this notice by December 6, 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 the Air Force, Agency-wide, Personnel (36 Series)-Enlistment and Reenlistment Records (T36–14) (DAA–AFU–2021–0003).

2. Securities and Exchange Commission, Agency-wide, Rulemaking Records (DAA–0266–2020–0002).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2021–22573 Filed 10–19–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meeting of Humanities Panel

AGENCY: National Endowment for the Humanities; National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: The National Endowment for the Humanities (NEH) will hold twenty-six meetings, by videoconference, of the Humanities Panel, a federal advisory committee, during November 2021. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965.

DATES: See **SUPPLEMENTARY INFORMATION** for meeting dates. The meetings will open at 8:30 a.m. and will adjourn by 5:00 p.m. on the dates specified below.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, Room 4060, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given of the following meetings:

1. *Date:* November 2, 2021

This video meeting will discuss applications on the topic of U.S. History, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

2. *Date:* November 2, 2021

This video meeting will discuss applications on the topic of International Topics, for Media Projects: Production Grants, submitted to the Division of Public Programs.

3. *Date:* November 3, 2021

This video meeting will discuss applications for Kluge Fellowships, submitted to the Division of Research Programs.

4. *Date:* November 4, 2021

This video meeting will discuss applications on the topic of U.S. History, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

5. *Date:* November 4, 2021

This video meeting will discuss applications on the topics of Arts and Literature, for Media Projects: Production Grants, submitted to the Division of Public Programs.

6. *Date:* November 4, 2021
This video meeting will discuss applications for Humanities Connections Planning Grants, submitted to the Division of Education Programs.
7. *Date:* November 4, 2021
This video meeting will discuss applications for Kluge Fellowships, submitted to the Division of Research Programs.
8. *Date:* November 5, 2021
This video meeting will discuss applications on the topics of African American History and Culture, for the Public Humanities Projects: Exhibitions (Implementation) grant program, submitted to the Division of Public Programs.
9. *Date:* November 8, 2021
This video meeting will discuss applications for Humanities Connections Planning Grants, submitted to the Division of Education Programs.
10. *Date:* November 9, 2021
This video meeting will discuss applications for Humanities Connections Planning Grants, submitted to the Division of Education Programs.
11. *Date:* November 9, 2021
This video meeting will discuss applications for Humanities Connections Implementation Grants, submitted to the Division of Education Programs.
12. *Date:* November 9, 2021
This video meeting will discuss applications on the topic of U.S. History, for Media Projects: Production Grants, submitted to the Division of Public Programs.
13. *Date:* November 9, 2021
This video meeting will discuss applications on the topic of U.S. History, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.
14. *Date:* November 10, 2021
This video meeting will discuss applications on the topic of U.S. History, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.
15. *Date:* November 10, 2021
This video meeting will discuss applications for the Short Documentaries grant program, submitted to the Division of Public Programs.
16. *Date:* November 10, 2021
This video meeting will discuss applications for Humanities Connections Implementation Grants, submitted to the Division of Education Programs.
17. *Date:* November 10, 2021
This video meeting will discuss applications for Humanities Connections Planning Grants, submitted to the Division of Education Programs.
18. *Date:* November 10, 2021
This video meeting will discuss applications on the topic of Ethnography, for the Archaeological and Ethnographic Field Research grant program, submitted to the Division of Research Programs.
19. *Date:* November 12, 2021
This video meeting will discuss applications on the topic of New World Archaeology, for the Archaeological and Ethnographic Field Research grant program, submitted to the Division of Research Programs.
20. *Date:* November 12, 2021
This video meeting will discuss applications on the topic of Art History, for the Public Humanities Projects: Exhibitions (Implementation) grant program, submitted to the Division of Public Programs.
21. *Date:* November 15, 2021
This video meeting will discuss applications on the topic of Old-World Archaeology, for the Archaeological and Ethnographic Field Research grant program, submitted to the Division of Research Programs.
22. *Date:* November 15, 2021
This video meeting will discuss applications for Humanities Connections Implementation Grants, submitted to the Division of Education Programs.
23. *Date:* November 16, 2021
This video meeting will discuss applications for Humanities Connections Planning Grants, submitted to the Division of Education Programs.
24. *Date:* November 16, 2021
This video meeting will discuss applications on the topic of American Studies, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.
25. *Date:* November 23, 2021
This video meeting will discuss applications on the topic of World Studies, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.
26. *Date:* November 30, 2021
This video meeting will discuss applications on the topic of Literary Studies, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: October 14, 2021.

Samuel Roth,

Attorney-Advisor, National Endowment for the Humanities.

[FR Doc. 2021–22758 Filed 10–19–21; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL LABOR RELATIONS BOARD

Notice of Appointments of Individuals To Serve as Members of Performance Review Boards

AGENCY: National Labor Relations Board.

ACTION: Notice; appointment to serve as members of performance review boards.

SUMMARY: The National Labor Relations Board is issuing this notice that the individuals whose names and position titles appear below have been appointed to serve as members of performance review boards in the National Labor Relations Board for the rating year beginning October 1, 2020 and ending September 30, 2021.

FOR FURTHER INFORMATION CONTACT: Roxanne L. Rothschild, Executive Secretary, National Labor Relations Board, 1015 Half Street SE, Washington, DC 20570, (202) 273–1940 (this is not a toll-free number), 1–866–315–6572 (TTY/TDD).

SUPPLEMENTARY INFORMATION:

Name and Title

Andrew Krafts—Executive Assistant to the Chairman (Chief of Staff), the Board
Peter Sung Ohr—Deputy General Counsel, Office of the General Counsel
Lara Zick—Deputy Chief Counsel to Member Prouty
Grant Kraus—Deputy Chief Counsel to Member Ring
Mark Arbesfeld—Director, Office of Appeals
Terence Schoone-Jongen—(Alternate)—Director of the Office of Representation Appeals
Nancy Platt—(Alternate)—Associate General Counsel, Division of Legal Counsel

Authority: 5 U.S.C. 4314(c)(4).

Dated: October 15, 2021.

By Direction of the Board.

Roxanne L. Rothschild,

Executive Secretary.

[FR Doc. 2021–22823 Filed 10–19–21; 8:45 am]

BILLING CODE 7545–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by November 19, 2021. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314 or *ACApermits@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, at the above address, 703–292–8030.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 671), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2022–017

1. *Applicant:* Dr. Heather Lynch, Stony Brook University IACS 163 Stony Brook, NY 11794

Activity for Which Permit is Requested: Take, Harmful Interference. The applicant seeks an Antarctic Conservation Act permit for activities associated with long-term population studies of Antarctic penguin species. The applicant proposes using unmanned aerial systems (UAVs) and manual surveying techniques to improve understanding of penguin distribution and abundance in the Weddell Sea region. Flights will be conducted by trained pilots in fair-weather conditions and in the presence of observers. All flights over wildlife concentrations will be conducted at an altitude of no less than 40 meters, to limit possible disturbance to wild populations. This permit seeks to cover any harmful interference with wild populations that may result from UAV use as well as any take that may occur as a result of research activities.

Location: Danger Islands, Weddell Sea, Antarctica.

Dates of Permitted Activities: January 1, 2022–April 1, 2022.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–22855 Filed 10–19–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by November 19, 2021. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314 or *ACApermits@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, at the above address, 703–292–8030.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 670), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2022–018

1. *Applicant:* Dr. Heather Lynch, Stony Brook University IACS 163 Stony Brook, NY 11794

Activity for Which Permit Is Requested: Waste Management. The applicant seeks an Antarctic Conservation Act waste management permit for activities associated with long-term penguin research in the Weddell Sea. The applicant proposes using battery-powered, quadrotor unmanned aerial systems (UAVs) to assist in the collection of data for a multi-scale population census of penguin colonies in the Weddell Sea. Mitigation measures will be put in place to prevent loss of aircraft. These measures include UAVs being flown by trained pilots in fair-weather conditions and having stationed observers maintain visual contact with the aircraft at all times. The applicant proposes various recovery methods in the unlikely event that an aircraft is lost over land or sea. These measures will limit any potential impacts on the Antarctic environment. The applicant seeks a waste permit to cover any accidental release that may result from UAV use.

Location: Danger Islands, Weddell Sea, Antarctica.

Dates of Permitted Activities: January 1, 2022–April 1, 2022.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–22854 Filed 10–19–21; 8:45 am]

BILLING CODE 7555–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93332; File Nos. SR–NYSE–2021–15, SR–NYSEAMER–2021–13, SR–NYSEArca–2021–15, SR–NYSENAT–2021–05, SR–NYSECHX–2021–04)]

Self-Regulatory Organizations; New York Stock Exchange LLC; NYSE American LLC; NYSE Arca, Inc.; NYSE National, Inc.; NYSE Chicago, Inc.; Notice of Withdrawal of Proposed Rule Changes To Amend Each of the Exchange's Fee Schedules Related to Co-Location

October 14, 2021.

On March 10, 2021, New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''),

NYSE Arca, Inc. (''NYSE Arca''), NYSE National, Inc. (''NYSE National''), and NYSE Chicago, Inc. (''NYSE Chicago'') (each an ''Exchange,'' collectively, the ''Exchanges'') each 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 amend the Exchanges' fee schedules related to co-location to provide Users with access to the systems and connectivity to the data feeds of several third parties and establish associated fees. Each proposed rule change was immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.[3]

The proposed rule changes were published for comment in the **Federal Register** on March 29, 2021.[4] On May 7, 2021, the Commission, pursuant to Section 19(b)(3)(C) of the Act[5] temporarily suspended File Nos. SR–NYSE–2021–15, SR–NYSEAMER–2021–13, SR–NYSEArca–2021–15, SR–NYSENAT–2021–05, and SR–NYSECHX–2021–04; and (2) instituted proceedings to determine whether to approve or disapprove File Nos. SR–NYSE–2021–15, SR–NYSEAMER–2021–13, SR–NYSEArca–2021–15, SR–NYSENAT–2021–05, and SR–NYSECHX–2021–04.[6] The Commission received two comment letters on the proposal from the Exchanges.[7] On September 23, 2021, pursuant to Section 19(b)(2) of the Act,[8] the Commission designated a longer period for Commission action on the proceedings to determine whether to approve or disapprove the proposed rule changes.[9] On October 12, 2021, each Exchange withdrew its proposed rule change (SR–NYSE–2021–15, SR–NYSEAMER–2021–13, SR–NYSEArca–2021–15, SR–NYSENAT–2021–05, SR–NYSECHX–2021–04).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22799 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] *See* Securities Exchange Act Release Nos. 91386 (March 23, 2021), 86 FR 16410 (March 29, 2021); 91387 (March 23, 2021), 86 FR 16417 (March 29, 2021); 91388 (March 23, 2021), 86 FR 16433 (March 29, 2021); 91389 (March 23, 2021), 86 FR 16403 (March 29, 2021); 91390 (March 23, 2021), 86 FR 16424 (March 29, 2021).

[5] 15 U.S.C. 78s(b)(3)(C).

[6] *See* Securities Exchange Act Release No. 91790 (May 7, 2021), 86 FR 26242 (May 13, 2021).

[7] The comment letters received by the Commission on the proposed rule changes are available on the Commission's website at: *https://www.sec.gov/comments/sr-nyse-2021-15/srnyse202115.htm.* NYSE filed comment letters on behalf of all of the Exchanges.

[8] 15 U.S.C. 78s(b)(2).

[9] *See* Securities Exchange Act Release No. 93107, 86 FR 53995 (September 29, 2021).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93324; File No. 4–700]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d–2; Notice of Filing and Order Approving and Declaring Effective an Amended Plan for the Allocation of Regulatory Responsibilities Between the Financial Industry Regulatory Authority, Inc. and Investors' Exchange LLC

October 14, 2021.

Notice is hereby given that the Securities and Exchange Commission (''Commission'') has issued an Order, pursuant to Section 17(d) of the Securities Exchange Act of 1934 (''Act''),[1] approving and declaring effective an amendment to the plan for allocating regulatory responsibility (''Plan'') filed on September 13, 2021, pursuant to Rule 17d–2 of the Act,[2] by the Financial Industry Regulatory Authority, Inc. (''FINRA'') and Investors' Exchange LLC (''IEX'') (collectively, ''Participating Organizations'' or ''parties''). This agreement amends and restates the agreement entered into between FINRA and IEX on June 20, 2016, entitled ''Agreement between Financial Industry Regulatory Authority, Inc. and Investors' Exchange LLC pursuant to Rule 17d–2 under the Securities Exchange Act of 1934,'' and any subsequent amendments thereafter.

I. Introduction

Section 19(g)(1) of the Act,[3] among other things, requires every self-regulatory organization (''SRO'') registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO's own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d)[4] or Section 19(g)(2)[5] of the Act. Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO (''common members''). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act[6] was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.[7] With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17d–2 under the Act.[8] Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority (''DEA'') to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.[9] When an SRO has been named as a common member's DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO's obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d–2 under the Act.[10] Rule 17d–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect

[1] 15 U.S.C. 78q(d).

[2] 17 CFR 240.17d–2.

[3] 15 U.S.C. 78s(g)(1).

[4] 15 U.S.C. 78q(d).

[5] 15 U.S.C. 78s(g)(2).

[6] 15 U.S.C. 78q(d)(1).

[7] *See* Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

[8] 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

[9] *See* Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

[10] *See* Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

to their common members. Under paragraph (c) of Rule 17d–2, the Commission may declare such a plan effective if, after providing for appropriate notice and opportunity for comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors, to foster cooperation and coordination among the SROs, to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system, and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. The Plan

On July 28, 2016, the Commission declared effective the Plan entered into between FINRA and IEX for allocating regulatory responsibility pursuant to Rule 17d–2.[11] The Plan is intended to reduce regulatory duplication for firms that are common members of FINRA and IEX by allocating regulatory responsibility with respect to certain applicable laws, rules, and regulations that are common among them. Included in the Plan is an exhibit that lists every IEX rule for which FINRA bears responsibility under the Plan for overseeing and enforcing with respect to IEX members that are also members of FINRA and the associated persons therewith (''Certification'').

III. Proposed Amendment to the Plan

On September 13, 2021, the parties submitted a proposed amendment to the Plan (''Amended Plan''). The primary purpose of the Amended Plan is to clarify what is considered a Common Rule under the Plan, add Securities Exchange Act Rules 604, 610(d), and 611 to the Certification, eliminate the requirement that IEX provide to FINRA a current list of members each quarter, and eliminate the requirement that IEX and FINRA notify Dual Members of the Agreement after the Effective Date by a uniform joint notice. The text of the proposed Amended Plan is as follows (additions are italicized; deletions are [bracketed]):

* * * * *

AGREEMENT BETWEEN FINANCIAL INDUSTRY REGULATORY AUTHORITY, INC. AND INVESTORS' EXCHANGE LLC PURSUANT TO RULE 17d–2 UNDER THE SECURITIES EXCHANGE ACT OF 1934

This Agreement, by and between the Financial Industry Regulatory Authority, Inc. (''FINRA'') and Investors' Exchange LLC (''IEX''), is made this [20th]*9th* day of [June 20, 2016] *September, 2021* (the ''Agreement''), pursuant to Section 17(d) of the Securities Exchange Act of 1934 (the ''Exchange Act'') and Rule 17d–2 thereunder, which permits agreements between self-regulatory organizations to allocate regulatory responsibility to eliminate regulatory duplication. FINRA and IEX may be referred to individually as a ''party'' and together as the ''parties.''

This Agreement amends and restates the agreement entered into between FINRA and IEX on June 20, 2016, entitled ''Agreement between Financial Industry Regulatory Authority, Inc. and Investors' Exchange LLC pursuant to Rule 17d–2 under the Securities Exchange Act of 1934,'' and any subsequent amendments thereafter.

WHEREAS, FINRA and IEX desire to reduce duplication in the examination and surveillance of their Dual Members (as defined herein) and in the filing and processing of certain registration and membership records; and

WHEREAS, FINRA and IEX desire to execute an agreement covering such subjects pursuant to the provisions of Rule 17d–2 under the Exchange Act and to file such agreement with the Securities and Exchange Commission (the ''SEC'' or ''Commission'') for its approval.

NOW, THEREFORE, in consideration of the mutual covenants contained hereinafter, FINRA and IEX hereby agree as follows:

1. Definitions. Unless otherwise defined in this Agreement or the context otherwise requires, the terms used in this Agreement shall have the same meaning as they have under the Exchange Act and the rules and regulations thereunder. As used in this Agreement, the following terms shall have the following meanings:

(a) ''*IEX Rules*'' or ''*FINRA Rules*'' shall mean: (i) The rules of IEX, or (ii) the rules of FINRA, respectively, as the rules of an exchange or association are defined in Exchange Act Section 3(a)(27).

(b) ''*Common Rules*'' shall mean IEX Rules that are substantially similar to the applicable FINRA Rules and certain provisions of the Exchange Act and SEC rules set forth on *Exhibit 1* in that examination or surveillance for compliance with such provisions and rules would not require FINRA to develop one or more new examination or surveillance standards, modules, procedures, or criteria in order to analyze the application of the provision or rule, or a Dual Member's activity, conduct, or output in relation to such provision or rule; provided, however, Common Rules shall not include the application of the SEC, IEX or FINRA rules as they pertain to violations of insider trading activities, which is covered by a separate 17d–2 Agreement by and among [BATS Exchange, Inc., BATS Y–Exchange, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, the NASDAQ Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange LLC, NYSE Amex LLC, and NYSE Arca Inc., effective December 16, 2011], *Cboe BZX Exchange, Inc., Cboe BYX Exchange, Inc., NYSE Chicago, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., MEMX, LLC, MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq PHLX LLC, The Nasdaq Stock Market LLC, NYSE National, Inc., New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., Investors Exchange LLC and Long-Term Stock Exchange, Inc.* approved by the Commission on *September 23, 2020* as may be amended from time to time. *Common Rules shall not include any provisions regarding: (i) Notice, reporting or any other filings made directly to or from IEX; (ii) incorporation by reference of other IEX Rules that are not Common Rules; (iii) exercise of discretion in a manner that differs from FINRA's exercise of discretion including, but not limited to exercise of exemptive authority by IEX; (iv) prior written approval of IEX; and (v) payment of fees or fines to IEX.*

(c) ''*Dual Members*'' shall mean those IEX members that are also members of FINRA and the associated persons therewith.

(d) ''*Effective Date*'' shall be the date this Agreement is approved by the Commission.

(e) ''*Enforcement Responsibilities*'' shall mean the conduct of appropriate proceedings, in accordance with FINRA's Code of Procedure (the Rule 9000 Series) and other applicable FINRA procedural rules, to determine whether violations of Common Rules have occurred, and if such violations are deemed to have occurred, the imposition of appropriate sanctions as specified under FINRA's Code of Procedure and sanctions guidelines.

(f) ''*Regulatory Responsibilities*'' shall mean the examination responsibilities, surveillance responsibilities and Enforcement Responsibilities relating to compliance by the Dual Members with the Common Rules and the provisions of the Exchange Act and the rules and regulations thereunder, and other applicable laws, rules and regulations, each as set forth on *Exhibit 1* attached hereto.

2. Regulatory and Enforcement Responsibilities. FINRA shall assume Regulatory Responsibilities and Enforcement Responsibilities for Dual Members. Attached as *Exhibit 1* to this Agreement and made part hereof, IEX furnished FINRA with a current list of Common Rules and certified to FINRA that such rules that are IEX Rules are substantially similar to the corresponding FINRA Rules (the ''Certification''). FINRA hereby agrees that the rules listed in the Certification are Common Rules as defined in this Agreement. Each year following the Effective Date of this Agreement, or more frequently if required by changes in either the rules of IEX or FINRA, IEX shall submit an updated list of Common Rules to FINRA for review which shall add IEX Rules not included in the current list of Common Rules

[11] *See* Securities Exchange Act Release No. 54136 (July 12, 2006), 81 FR 51256 (August 3, 2016).

that qualify as Common Rules as defined in this Agreement; delete IEX Rules included in the current list of Common Rules that no longer qualify as Common Rules as defined in this Agreement; and confirm that the remaining rules on the current list of Common Rules continue to be IEX Rules that qualify as Common Rules as defined in this Agreement. Within 30 days of receipt of such updated list, FINRA shall confirm in writing whether the rules listed in any updated list are Common Rules as defined in this Agreement. Notwithstanding anything herein to the contrary, it is explicitly understood that the term ''Regulatory Responsibilities'' does not include, and IEX shall retain full responsibility for (unless otherwise addressed by separate agreement or rule) (collectively, the ''Retained Responsibilities'') the following:

(a) Surveillance, examination, investigation and enforcement with respect to trading activities or practices involving IEX's own marketplace for rules that are not Common Rules;

(b) registration pursuant to its applicable rules of associated persons (*i.e.,* registration rules that are not Common Rules);

(c) discharge of its duties and obligations as a Designated Examining Authority pursuant to Rule 17d–1 under the Exchange Act; and

(d) any IEX Rules that are not Common Rules, except for IEX Rules for IEX Services LLC as provided in paragraph [6]*5.*

[3. Dual Members. Prior to the Effective Date, IEX shall furnish FINRA with a current list of Dual Members, which shall be updated no less frequently than once each quarter.]

[4]*3.* No Charge. There shall be no charge to IEX by FINRA for performing the Regulatory Responsibilities and Enforcement Responsibilities under this Agreement except as otherwise agreed by the parties, either herein or in a separate agreement.

[5]*4.* Applicability of Certain Laws, Rules, Regulations or Orders. Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the Commission. To the extent such statute, rule or order is inconsistent with this Agreement, the statute, rule or order shall supersede the provision(s) hereof to the extent necessary for them to be properly effectuated and the provision(s) hereof in that respect shall be null and void.

[6]*5.* Notification of Violations.

(a) In the event that FINRA becomes aware of apparent violations of any IEX Rules, which are not listed as Common Rules, discovered pursuant to the performance of the Regulatory Responsibilities assumed hereunder, FINRA shall notify IEX of those apparent violations for such response as IEX deems appropriate.

(b) In the event that IEX becomes aware of apparent violations of any Common Rules, discovered pursuant to the performance of the Retained Responsibilities, IEX shall notify FINRA of those apparent violations and such matters shall be handled by FINRA as provided in this Agreement. With respect to apparent violations of IEX Services LLC FINRA shall not make referrals to IEX pursuant to this paragraph [6]5. Such apparent violations shall be processed by, and enforcement proceedings in respect thereto will be conducted by, FINRA as provided in this Agreement.

(c) Apparent violations of Common Rules shall be processed by, and enforcement proceedings in respect thereto shall be conducted by FINRA as provided hereinbefore; provided, however, that in the event a Dual Member is the subject of an investigation relating to a transaction on IEX, IEX may in its discretion assume concurrent jurisdiction and responsibility.

(d) Each party agrees to make available promptly all files, records and witnesses necessary to assist the other in its investigation or proceedings.

[7]6. Continued Assistance.

(a) FINRA shall make available to IEX all information obtained by FINRA in the performance by it of the Regulatory Responsibilities hereunder with respect to the Dual Members subject to this Agreement. In particular, and not in limitation of the foregoing, FINRA shall furnish IEX any information it obtains about Dual Members which reflects adversely on their financial condition. IEX shall make available to FINRA any information coming to its attention that reflects adversely on the financial condition of Dual Members or indicates possible violations of applicable laws, rules or regulations by such firms.

(b) The parties agree that documents or information shared shall be held in confidence, and used only for the purposes of carrying out their respective regulatory obligations. Neither party shall assert regulatory or other privileges as against the other with respect to documents or information that is required to be shared pursuant to this Agreement.

(c) The sharing of documents or information between the parties pursuant to this Agreement shall not be deemed a waiver as against third parties of regulatory or other privileges relating to the discovery of documents or information.

[8]7. Statutory Disqualifications. When FINRA becomes aware of a statutory disqualification as defined in the Exchange Act with respect to a Dual Member, FINRA shall determine pursuant to Sections 15A(g) and/or Section 6(c) of the Exchange Act the acceptability or continued applicability of the person to whom such disqualification applies and keep IEX advised of its actions in this regard for such subsequent proceedings as IEX may initiate.

[9]8. Customer Complaints. IEX shall forward to FINRA copies of all customer complaints involving Dual Members received by IEX relating to FINRA's Regulatory Responsibilities under this Agreement. It shall be FINRA's responsibility to review and take appropriate action in respect to such complaints.

[10]9. Advertising. FINRA shall assume responsibility to review the advertising of Dual Members subject to the Agreement, provided that such material is filed with FINRA in accordance with FINRA's filing procedures and is accompanied with any applicable filing fees set forth in FINRA Rules.

[11]10. No Restrictions on Regulatory Action. Nothing contained in this Agreement shall restrict or in any way encumber the right of either party to conduct its own independent or concurrent investigation, examination or enforcement proceeding of or against Dual Members, as either party, in its sole discretion, shall deem appropriate or necessary.

[12]11. Termination. This Agreement may be terminated by IEX or FINRA at any time upon the approval of the Commission after one (1) year's written notice to the other party.

[13]12. Arbitration. In the event of a dispute between the parties as to the operation of this Agreement, IEX and FINRA hereby agree that any such dispute shall be settled by arbitration in Washington, DC in accordance with the rules of the American Arbitration Association then in effect, or such other procedures as the parties may mutually agree upon. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction. Each party acknowledges that the timely and complete performance of its obligations pursuant to this Agreement is critical to the business and operations of the other party. In the event of a dispute between the parties, the parties shall continue to perform their respective obligations under this Agreement in good faith during the resolution of such dispute unless and until this Agreement is terminated in accordance with its provisions. Nothing in this Section [13]12 shall interfere with a party's right to terminate this Agreement as set forth herein.

[14. Notification of Members. IEX and FINRA shall notify Dual Members of this Agreement after the Effective Date by means of a uniform joint notice.]

[15]13. Amendment. This Agreement may be amended in writing duly approved by each party. All such amendments must be filed with and approved by the Commission before they become effective.

[16]14. Limitation of Liability. Neither FINRA nor IEX nor any of their respective directors, governors, officers or employees shall be liable to the other party to this Agreement for any liability, loss or damage resulting from or claimed to have resulted from any delays, inaccuracies, errors or omissions with respect to the provision of Regulatory Responsibilities as provided hereby or for the failure to provide any such responsibility, except with respect to such liability, loss or damages as shall have been suffered by one or the other of FINRA or IEX and caused by the willful misconduct of the other party or their respective directors, governors, officers or employees. No warranties, express or implied, are made by FINRA or IEX with respect to any of the responsibilities to be performed by each of them hereunder.

[17]15. Relief from Responsibility. Pursuant to Sections 17(d)(1)(A) and 19(g) of the Exchange Act and Rule 17d–2 thereunder, FINRA and IEX join in requesting the Commission, upon its approval of this Agreement or any part thereof, to relieve IEX of any and all responsibilities with respect to matters allocated to FINRA pursuant to this Agreement; provided, however, that this Agreement shall not be effective until the Effective Date.

[18]16. Severability. Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

[19]17. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and such counterparts together shall constitute one and the same instrument.

Note: The entire existing table of rules should be deleted and replaced with the table below and for the remainder of the exhibit new text is italicized and deleted text is in brackets.

EXHIBIT 1

IEX CERTIFICATION OF COMMON RULES

IEX hereby certifies that the requirements contained in the rules listed below for IEX are identical to, or substantially similar to, the comparable FINRA [(NASD)] Rules, Exchange Act provision or SEC rule identified (''Common Rules'').

 # Common Rules shall not include provisions regarding (i) notice, reporting or any other filings made directly to or from IEX, (ii) incorporations by reference of other IEX Rules that are not Common Rules (iii) exercise of discretion in a manner that differs from FINRA's exercise of discretion including, but not limited to exercise of exemptive authority, by IEX, (iv) prior written approval of IEX, and (v) payment of fees or fines to IEX.

IEX rule	FINRA rule, exchange act provision, SEC rule
Rule 2.140 Prohibited Conditions Relating to Expungement of Customer Dispute.	FINRA Rule 2081 Prohibited Conditions Relating to Expungement of Customer Dispute.
Rule 2.160(o) Lapse of Registration and Expiration of SIE	FINRA Rule 1210.08—Registration Requirements—Lapse of Registration and Expiration of SIE.
Rule 2.160(p) Restrictions on Membership—Continuing Education Requirements #.	FINRA Rule 1240(a)(1)–(4), (6)–(7) and (b) Continuing Education Requirements.
Rule 2.160(q) and (r) Registration Requirements and Restrictions on Membership, and Rule 2.170(b) and (g) Application Procedures for Membership or to become an Associated Person of a Member #.	FINRA By-Laws of the Corporation Article IV, Sec 1(c) Application for Membership, Article V, Sections 2 and 3 Application for Registration and Notification by Member to the Corporation and Associated Person of Termination; Amendments to Notification, FINRA Rule 1010(c) and (e) Electronic Filing Requirements for Uniform Forms and FINRA Rule 4517 Members Filing and Contact Information Requirements.
Rule 2.240 Fidelity Bonds #	FINRA Rule 4360 Fidelity Bonds.
Rule 3.110 Business Conduct of Members ^	FINRA Rule 2010 Standards of Commercial Honor and Principles of Trade. ^
Rule 3.120 Violations Prohibited[1] ^ #	FINRA Rule 2010 Standards of Commercial Honor and Principles of Trade ^ and FINRA Rule 3110 Supervision.
Rule 3.130 Use of Fraudulent Devices ^	FINRA Rule 2020 Use of Manipulative, Deceptive or Other Fraudulent Devices. ^
Rule 3.150 Know Your Customer	FINRA Rule 2090 Know Your Customer.
Rule 3.160 Fair Dealing with Customers	FINRA Rule 2020 Use of Manipulative, Deceptive or Other Fraudulent Devices. ^
Rule 3.170 Suitability	FINRA Rule 2111 Suitability.
Rule 3.180(a) The Prompt Receipt and Delivery of Securities	FINRA Rule 11860 COD Orders.
Rule 3.180(b) The Prompt Receipt and Delivery of Securities	SEA Regulation SHO.
Rule 3.190 Charges for Services Performed	FINRA Rule 2122 Charges for Services Performed.
Rule 3.200 Use of Information Obtained in a Fiduciary Capacity	FINRA Rule 2060 Use of Information Obtained in Fiduciary Capacity.
Rule 3.210 Publication of Transactions and Quotations	FINRA Rule 5210 Publication of Transactions and Quotations.
Rule 3.220 Offers at Stated Prices	FINRA Rule 5220 Offers at Stated Prices.
Rule 3.230 Payments Involving Publications that Influence the Market Price of a Security.	FINRA Rule 5230 Payments Involving Publications that Influence the Market Price of a Security.
Rule 3.240 Customer Confirmations	FINRA Rule 2232(a) Customer Confirmations and SEA Rule 10b–10 Confirmation of Transactions.
Rule 3.250 Disclosure of Control Relationship with Issuer	FINRA Rule 2262 Disclosure of Control Relationship with Issuer.
Rule 3.260 Discretionary Accounts	FINRA Rule 3260 Discretionary Accounts.
Rule 3.270 Improper Use of Customers' Securities or Funds; Prohibition Against Guarantees and Sharing in Accounts.	FINRA Rule 2150(a)–(c) and SM .03 Improper Use of Customers' Securities or Funds; Prohibition Against Guarantees and Sharing in Accounts.
Rule 3.280 Communications with the Public	FINRA Rule 2210 Communications with the Public.
	FINRA Rule 2265 Extended Hours Trading Risk Disclosure.
Rule 3.291 Influencing or Rewarding Employees of Others; Gratuities	FINRA Rule 3220 Influencing or Rewarding Employees of Others.
Rule 3.292 Telemarketing	FINRA Rule 3230 Telemarketing.
Rule 3.293 Short-Interest Reporting	FINRA Rule 4560 Short-Interest Reporting.
Rule 4.511 General Requirements	FINRA Rule 4511 General Requirements.
Rule 4.512 Customer Account Information	FINRA Rule 4512 Customer Account Information.
Rule 4.513 Record of Written Customer Complaints	FINRA Rule 4513 Record of Written Customer Complaints.
Rule 4.550 Disclosure of Financial Condition	FINRA Rule 2261 Disclosure of Financial Condition.
Rule 5.110 Supervision #	FINRA Rule 3110 Supervision.
Rule 5.120 Supervisory Control System #	FINRA Rule 3120 Supervisory Control System.
Rule 5.130 Annual Certification of Compliance and Supervisory Processes #.	FINRA Rule 3130 Annual Certification of Compliance and Supervisory Processes.
Rule 5.160 Anti-Money Laundering Compliance Program #	FINRA Rule 3310 Anti-Money Laundering Compliance Program.
Rule 5.170 Transactions for or by Associated Persons	FINRA Rule 3210 Accounts At Other Broker-Dealers and Financial Institutions.
Rule 6.120 Failure to Deliver and Failure to Receive	Regulation SHO Rules 200 and 203.
Rule 6.130(a), (b), (d)–(i) Forwarding of Proxy and Other Issuer-Related Materials; Proxy Voting.	FINRA Rule 2251 Processing and Forwarding of Proxy and Other Issuer-Related Materials.
Rule 10.110(a) Market Manipulation	FINRA Rule 6140 Other Trading Practices.

IEX rule	FINRA rule, exchange act provision, SEC rule
Rule 10.110(b) Market Manipulation	FINRA Rule 5210 Publication of Transactions and Quotations, FINRA Rule 2020 Use of Manipulative, Deceptive or Other Fraudulent Devices, FINRA Rule 2010 Standards of Commercial Honor and Principles of Trade, and FINRA Rule 6140(a) Other Trading Practices.
Rule 10.120 Fictitious Transactions	FINRA Rule 6140 Other Trading Practices and FINRA Rule 5210 Supplementary Material .02 Self-Trades.
Rule 10.130 Excessive Sales By A Member	FINRA Rule 6140(c) Other Trading Practices.
Rule 10.140 Manipulative Transactions	FINRA Rule 6140 Other Trading Practices.
Rule 10.150 Dissemination of False Information	FINRA Rule 6140(e) Other Trading Practices.
Rule 10.160 Prohibition Against Trading Ahead of Customer Orders # **	FINRA Rule 5320 Prohibition Against Trading Ahead of Customer Orders. **
Rule 10.180 Influencing the Consolidated Tape	FINRA Rule 6140(a) Other Trading Practices and FINRA Rule 5210 Publication of Transactions and Quotations.
Rule 10.190 Trade Shredding	FINRA Rule 5290 Order Entry and Execution Practices.
Rule 10.220 Best Execution and Interpositioning **	FINRA Rule 5310 Best Execution and Interpositioning. **
Rule 10.240 Trading Ahead of Research Reports **	FINRA Rule 5280 Trading Ahead of Research Reports. **
Rule 10.260 Front Running of Block Transactions **	FINRA Rule 5270 Front Running of Block Transactions. **
Rule 11.151(e) Market Maker Obligations.	FINRA Rule 6240(a)–(c), (d)(1) and (2) Prohibition from Locking or Crossing Quotations in NMS Stocks
Rule 11.280(e)(3) & (4) Trading Halts Due to Extraordinary Market Volatility.	FINRA Rule 6190(a)&(b) Compliance with Regulation NMS Plan to Address Extraordinary Market Volatility.
Rule 11.310 Locking or Crossing Quotations in NMS Stocks **	FINRA Rule 6240(a),–(c), (d)(1) and (2) Prohibition from Locking or Crossing Quotations in NMS Stocks. **
Rule 11.420(c) Order Audit Trail System Requirements	FINRA Rule 4590 Synchronization of Member Business Clocks.
Rule 11.420(d)—Order Audit Trail System Requirements—Recording of Order Information.	FINRA Rule 7440—Recording of Order Information.
Rule 11.420(e)—Order Audit Trail System Requirements—Order Data Transmission Requirements.	FINRA Rule 7450—Order Data Transmission.
Rule 12.110(c) Arbitration	FINRA Rule 2268 Requirements When Using Predispute Arbitration Agreements for Customer Accounts.

[1] FINRA shall only have Regulatory Responsibilities for Rule 3.120(a) regarding conduct in violation of the Act, or the rules or regulations thereunder.

In addition, the following provisions shall be part of this 17d–2 Agreement:

Securities Exchange Act of 1934 ("SEA"):

Section 15(g)

SEA Rules:

- SEA Rule 200 of Regulation SHO—Definition of Short Sales and Marking Requirements**
- SEA Rule 201 of Regulation SHO—Circuit Breaker**
- SEA Rule 203 of Regulation SHO—Borrowing and Delivery Requirements**
- SEA Rule 204 of Regulation SHO—Close-Out Requirement**
- SEA Rule 101 of Regulation M—Activities by Distribution Participants**
- SEA Rule 102 of Regulation M—Activities by Issuers and Selling Security Holders During a Distribution**
- SEA Rule 103 of Regulation M—Nasdaq Passive Market Making**
- SEA Rule 104 of Regulation M—Stabilizing and Other Activities in Connection with an Offering**
- SEA Rule 105 of Regulation M—Short Selling in Connection With a Public Offering**
- *SEA Rule 604 of Regulation NMS—Display of Customer Limit Orders***
- *SEA Rule 610(d) of Regulation NMS—Locking or Crossing Quotations***
- *SEA Rule 611 of Regulation NMS—Order Protection Rule***
- SEA Rule 10b–5 Employment of Manipulative and Deceptive Devices ^
- SEA Rule 17a–3/17a–4—Records to Be Made by Certain Exchange Members, Brokers, and Dealers/Records to Be Preserved by Certain Exchange Members, Brokers, and Dealers ^

[# FINRA shall not have Regulatory Responsibilities regarding notification or reporting to IEX.]

^ FINRA shall not have any Regulatory Responsibilities for these rules as they pertain to violations of insider trading activities, which is covered by a separate 17d–2 Agreement by and among [BATS Exchange, Inc., BATS–Y Exchange, Inc., Chicago Board Options Exchange, Incorporated, Chicago Stock Exchange, Inc., EDGA Exchange Inc., EDGX Exchange Inc., Financial Industry Regulatory Authority, Inc., NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, The NASDAQ Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange, LLC, NYSE Amex LLC, and NYSE Arca Inc. effective December 16, 2011] *Cboe BZX Exchange, Inc., Cboe BYX Exchange, Inc., NYSE Chicago, Inc., Cboe EDGA Exchange Inc., Cboe EDGX Exchange Inc., Financial Industry Regulatory Authority, Inc., MEMX, LLC, MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq PHLX LLC, The Nasdaq Stock Market LLC, NYSE National, Inc., New York Stock Exchange, LLC, NYSE American LLC, NYSE Arca Inc., and Investors' Exchange LLC and the Long-Term Stock Exchange, Inc. as approved by the SEC on September 23, 2020,* as may be amended from time to time.

** FINRA shall perform the surveillance responsibilities for the double star rules. These rules may be cited by FINRA in both the context of this Agreement and the Regulatory Services Agreement.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. 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 4–700 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 4–700. 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 plan that are filed with the Commission, and all written communications relating to the proposed plan 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 plan also will be available for inspection and copying at the principal offices of FINRA and IEX. 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 4–700 and should be submitted on or before November 10, 2021.

V. Discussion

The Commission finds that the proposed Amended Plan is consistent with the factors set forth in Section 17(d) of the Act [12] and Rule 17d–2(c) thereunder [13] in that the proposed Amended Plan is necessary or appropriate in the public interest and for the protection of investors, fosters cooperation and coordination among SROs, and removes impediments to and fosters the development of the national market system. In particular, the Commission believes that the proposed Amended Plan should reduce unnecessary regulatory duplication by allocating to FINRA certain examination and enforcement responsibilities for Dual Members that would otherwise be performed by FINRA and IEX. Accordingly, the proposed Amended Plan promotes efficiency by reducing costs to Dual Members. Furthermore, because IEX and FINRA will coordinate their regulatory functions in accordance with the Amended Plan, the Amended Plan should promote investor protection.

The Commission notes that, under the Amended Plan, IEX and FINRA have allocated regulatory responsibility for those IEX rules, set forth in the Certification, that are substantially similar to the applicable FINRA rules in that examination for compliance with such provisions and rules would not require FINRA to develop one or more new examination standards, modules, procedures, or criteria in order to analyze the application of the rule, or a Dual Member's activity, conduct, or output in relation to such rule. In addition, under the Amended Plan, FINRA would assume regulatory responsibility for certain provisions of the federal securities laws and the rules and regulations thereunder that are set forth in the Certification. The Common Rules covered by the Amended Plan are specifically listed in the Certification, as may be amended by the Parties from time to time.

According to the Amended Plan, IEX will review the Certification at least annually, or more frequently if required by changes in either the rules of IEX or FINRA, and, if necessary, submit to FINRA an updated list of Common Rules to add IEX rules not included on the then-current list of Common Rules that are substantially similar to FINRA rules; delete IEX rules included in the then-current list of Common Rules that no longer qualify as common rules; and confirm that the remaining rules on the list of Common Rules continue to be IEX rules that qualify as common rules.[14] FINRA will then confirm in writing whether the rules listed in any updated list are Common Rules as defined in the Amended Plan. The Commission believes that these provisions are designed to provide for continuing communication between the Parties to ensure the continued accuracy of the scope of the proposed allocation of regulatory responsibility.

The Commission is hereby declaring effective an Amended Plan that, among other things, allocates regulatory responsibility to FINRA for the oversight and enforcement of all IEX rules that are substantially similar to the rules of FINRA for Dual Members of IEX and FINRA. Therefore, modifications to the Certification need not be filed with the Commission as an amendment to the Amended Plan, provided that the Parties are only adding to, deleting from, or confirming changes to IEX rules in the Certification in conformance with the definition of Common Rules provided in the Amended Plan. However, should the Parties decide to add an IEX rule to the Certification that is not substantially similar to a FINRA rule; delete an IEX rule from the Certification that is substantially similar to a FINRA rule; or leave on the Certification an IEX rule that is no longer substantially similar to a FINRA rule, then such a change would constitute an amendment to the Amended Plan, which must be filed with the Commission pursuant to Rule 17d–2 under the Act.[15]

Under paragraph (c) of Rule 17d–2, the Commission may, after appropriate notice and comment, declare a plan, or any part of a plan, effective. In this instance, the Commission believes that appropriate notice and comment can take place after the proposed amendment is effective. The primary purpose of the Amended Plan to clarify what is considered a Common Rule under the Plan, add Securities Exchange Act Rules 604, 610(d), and 611 to the Certification, eliminate the requirement that IEX provide FINRA a current list of members each quarter, and eliminate the requirements that IEX and FINRA notify Dual Members of the Agreement after the Effective Date by a uniform joint notice. The Commission notes that the prior version of this plan immediately prior to this proposed amendment was published for comment and the Commission did not receive any comments thereon.[16] Furthermore, the Commission does not believe that the amendment to the plan raises any new regulatory issues that the Commission has not previously considered. The Commission notes that FINRA has access to real-time information regarding Exchange membership via its Central Registration Depository.

VI. Conclusion

This order gives effect to the Amended Plan filed with the Commission in File No. 4–700. The Parties shall notify all members affected by the Amended Plan of their rights and obligations under the Amended Plan.

It is therefore ordered, pursuant to Section 17(d) of the Act, that the Amended Plan in File No. 4–700, between the FINRA and IEX, filed pursuant to Rule 17d–2 under the Act, hereby is approved and declared effective.

It is further ordered that IEX is relieved of those responsibilities allocated to FINRA under the Amended Plan in File No. 4–700.

[12] 15 U.S.C. 78q(d).

[13] 17 CFR 240.17d–2(c).

[14] *See* paragraph 2 of the Amended Plan.

[15] The addition to or deletion from the Certification of any federal securities laws, rules, and regulations for which FINRA would bear responsibility under the Amended Plan for examining, and enforcing compliance by, Dual Members, also would constitute an amendment to the Amended Plan.

[16] *See supra* note 11 (citing to Securities Exchange Act Release No. 78434).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22810 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93333; File Nos. SR–NYSE–2021–25, SR–NYSEAMER–2021–21, SR–NYSEArca–2021–24, SR–NYSECHX–2021–07, SR–NYSENAT–2021–09]

Self-Regulatory Organizations; New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc.; Notice of Withdrawal of Proposed Rule Changes To Amend the Fee Schedule To Add Meet-Me-Room Connectivity Services Available at the Mahwah Data Center

October 14, 2021.

On April 9, 2021, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (collectively, the ''Exchanges'') each 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 amend the schedule of connectivity services available at the Mahwah data center to add services available to customers in the meet me rooms in the Mahwah data center and procedures for the allocation of cabinets and power to such customers.

The proposed rule changes were published for comment in the **Federal Register** on April 22, 2021.[3] On June 2, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule changes, disapprove the proposed rule changes, or institute proceedings to determine whether to disapprove the proposed rule changes.[5] On July 9, 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 changes.[7] On September 28, 2021, pursuant to Section 19(b)(2) of the Act,[8] the Commission designated a longer period for Commission action on the proceedings to determine whether to approve or disapprove the proposed rule changes.[9] The Commission has received one comment letter on the proposed rule changes.[10] On October 12, 2021, the Exchanges withdrew the proposed rule changes (SR–NYSE–2021–25, SR–NYSEAMER–2021–21, SR–NYSEArca–2021–24, SR–NYSECHX–2021–07, SR–NYSENAT–2021–09).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22800 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93328; File No. SR–BX–2021–046]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Related to Clearly Erroneous Transactions Until April 20, 2022

October 14, 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 October 8, 2021, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the 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 proposes to extend the current pilot program related to BX Equity 11, Rule 11890 (Clearly Erroneous Transactions) to the close of business on April 20, 2022.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* 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 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 purpose of the proposed rule change is to extend the current pilot program related to Equity 11, Rule 11890, Clearly Erroneous Transactions, to the close of business on April 20, 2022. The pilot program is currently due to expire on October 20, 2021.

On September 10, 2010, the Commission approved, on a pilot basis, changes to Equity 11, Rule 11890 that, among other things: (i) Provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[3] In 2013, the Exchange adopted a provision designed to address the operation of the Plan.[4] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) A series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions

[17] 17 CFR 200.30–3(a)(34).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release Nos. 91598 (April 16, 2021), 86 FR 21373 (April 22, 2021) (SR–NYSE–2021–25); 91599 (April 16, 2021), 86 FR 21365 (April 22, 2021) (SR–NYSEAMER–2021–21); 91600 (April 16, 2021), 86 FR 21384 (April 22, 2021) (SR–NYSEArca–2021–24); 91601 (April 16, 2021), 86 FR 21410 (April 22, 2021) (SR–NYSECHX–2021–07); and 91602 (April 16, 2021), 86 FR 21393 (April 22, 2021) (SR–NYSENAT–2021–09).

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92089 (June 2, 2021), 86 FR 30510 (June 8, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 92368 (July 9, 2021), 86 FR 37356 (July 15, 2021).

[8] 15 U.S.C. 78s(b)(2).

[9] *See* Securities Exchange Act Release No. 93160 (September 28, 2021), 86 FR 54770 (October 4, 2021).

[10] The comment letter received on the proposed rule changes is available at: *https://www.sec.gov/comments/sr-nyse-2021-25/srnyse202125.htm.*

[11] 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. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–BX–2010–040).

[4] *See* Securities Exchange Act Release No. 68818 (February 1, 2013), 78 FR 9100 (February 7, 2013) (SR–BX–2013–010).

were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[5]

These changes were originally scheduled to operate for a pilot period to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or ''LULD Plan'').[6] In April 2019, the Commission approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[7] In light of that change, the Exchange amended Equity 11, Rule 11890 to untie the pilot program's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019.[8] Subsequently, the Exchange amended Rule 11890 to extend the pilot's effectiveness to the close of business on October 20, 2021.[9]

The Exchange now proposes to amend Equity 11, Rule 11890 to extend the pilot's effectiveness for a further six months until the close of business on April 20, 2022. If the pilot period is not either extended, replaced or approved as permanent, the prior versions of paragraphs (a)(2)(C), (c)(1), (b)(i), and (b)(ii) shall be in effect, and the provisions of paragraphs (g) through (i) shall be null and void.[10] In such an event, the remaining sections of Rule 11890 would continue to apply to all transactions executed on the Exchange. The Exchange understands that the other national securities exchanges and Financial Industry Regulatory Authority (''FINRA'') will also file similar proposals to extend their respective clearly erroneous execution pilot programs, the substance of which are identical to Rule 11890.

The Exchange does not propose any additional changes to Equity 11, Rule 11890. Extending the effectiveness of Rule 11890 for an additional six months will provide the Exchange and other self-regulatory organizations additional time to consider whether further amendments to the clearly erroneous execution rules are appropriate.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[11] in general, and Section 6(b)(5) of the Act,[12] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning review of transactions as clearly erroneous. The Exchange believes that extending the clearly erroneous execution pilot under Equity 11, Rule 11890 for an additional six months would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Based on the foregoing, the Exchange believes the amended clearly erroneous executions rule should continue to be in effect on a pilot basis while the Exchange and other self-regulatory organizations consider whether further amendments to these rules are appropriate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal would ensure the continued, uninterrupted operation of harmonized clearly erroneous execution rules across the U.S. equities markets while the Exchange and other self-regulatory organizations consider whether further amendments to these rules are appropriate. The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals to extend their respective clearly erroneous execution pilot programs. 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 either solicited or received.

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)(iii) of the Act [13] and subparagraph (f)(6) of Rule 19b–4 thereunder.[14]

A proposed rule change filed under Rule 19b–4(f)(6) [15] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative

[5] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–BX–2014–021).

[6] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[7] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (approving Eighteenth Amendment to LULD Plan).

[8] *See* Securities Exchange Act Release No. 85613 (April 11, 2019), 84 FR 16077 (April 17, 2019) (SR–BX–2019–009).

[9] *See* Securities Exchange Act Release No. 91575 (April 15, 2021), 86 FR 20779 (April 21, 2021) (SR–BX–2021–016).

[10] *See* notes 3–5, *supra*. The prior versions of paragraphs (a)(2)(C), (c)(1), (b)(i), and (b)(ii) generally provided greater discretion to the Exchange with respect to breaking erroneous trades.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization 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.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current clearly erroneous execution pilot program to continue uninterrupted, without any changes, while the Exchange and the other national securities exchanges consider a permanent proposal for clearly erroneous execution reviews. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[17]

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–BX–2021–046 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–BX–2021–046. 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–BX–2021–046 and should be submitted on or before November 10, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22795 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93316; File No. SR–CboeBZX–2021–014]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Withdrawal of a Proposed Rule Change To Allow Invesco Focused Discovery Growth ETF and Invesco Select Growth ETF To Strike and Publish Multiple Intraday Net Asset Values

October 14, 2021.

On January 22, 2021, Cboe BZX Exchange, Inc. (the ''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 allow Invesco Focused Discovery Growth ETF and Invesco Select Growth ETF to strike and publish multiple intraday net asset values.

The proposed rule change was published for comment in the **Federal Register** on February 10, 2021.[3] On March 24, 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 May 11, 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] On August 6, 2021, the Commission designated a longer period within which to issue an order approving or disapproving the proposed rule change.[8] The Commission received no comment letters on the proposed rule change. On August 12, 2021, the Exchange withdrew the proposed rule change (SR–CboeBZX–2021–014).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22808 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91064 (February 4, 2021), 86 FR 8935.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 91398, 86 FR 16650 (March 30, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 91845, 86 FR 26767 (May 17, 2021).

[8] *See* Securities Exchange Act Release No. 92564, 86 FR 44459 (August 12, 2021).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93326; File No. SR–CBOE–2021–059]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend Rule 5.54 and Rule 5.55 in Connection With a Designated Primary Market-Maker's and a Lead Market-Maker's Obligation To Submit Opening Quotes for the Regular Trading Hours Session in Index Options

October 14, 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 October 8, 2021, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the

proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] 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

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend Rule 5.54 and Rule 5.55 in connection with a Designated Primary Market-Maker's (''DPM'') and a Lead Market-Maker's (''LMM'') obligation to submit opening quotes for the Regular Trading Hours session in index options, and to make a clarifying, nonsubstantive change. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, 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 Rule 5.54 and Rule 5.55 in connection with a DPM's and an LMM's obligation, respectively, to submit opening quotes for the Regular Trading Hours trading session in index options.

Current Rule 5.54(a)(6) requires each DPM to enter opening quotes for the Regular Trading Hours trading [5] session within one minute of the initiation of an opening rotation in any series that is not open due to the lack of a quote pursuant to Rule 5.31. Likewise, current Rule 5.55(a)(2) requires each LMM to enter opening quotes for the Regular Trading Hours trading session within one minute of the initiation of an opening rotation in any series that is not open due to the lack of a quote pursuant to Rule 5.31. Pursuant to Rule 5.31(e)(1), the System initiates an opening rotation for an option series following the occurrence of an opening rotation trigger pursuant to Rule 5.31(d). Specifically, Rule 5.31(d)(1)(B) governs the opening rotation trigger for index options and provides that the System initiates the opening rotation for index options after a time period (which the Exchange determines for all classes) following the System's observation after 9:30 a.m.[6] of the first disseminated index value for the index underlying an index option.[7] The Exchange has observed that index reporting authorities generally disseminate the first index value beginning at 9:30 a.m., regardless of whether all of the underlying index components have opened. The System then initiates the opening rotation in an index option one second [8] after the first index value publication and then determines if a series is eligible to open pursuant to Rule 5.31(e)(1). If there is no Composite Market (which is comprised of the better of Market-Maker bulk messages on the Exchange or any away market quotes),[9] a series is ineligible to open until certain conditions are met.[10] Because the System is unable to open a series due to a lack of a quote, the DPM or LMM in that index class is then obligated to enter opening quotes within the same minute of the initiation of the opening rotation pursuant to Rule 5.54(a)(6) or Rule 5.55(a)(2), respectively.

As stated, index reporting authorities generally disseminate the first index value at 9:30 a.m., which is usually before all of the underlying index components are opened. While underlying index components usually begin opening at 9:30 a.m., for some indexes, a substantial portion of the underlying components may not regularly open within the 9:30 a.m. minute—that is, within one minute of the first disseminated index value (*i.e.,* the initiation of an opening rotation), in which a DPM or LMM must provide opening quotes for a series not open due to the lack of quote. The Exchange understands that DPMs and LMMs often use the pricing of the related index futures products, which are already trading at 9:30 a.m., rather than the index spot value to price the index options. However, some indexes do not have a related futures product, and DPMs in these index options must rely on the index spot value to price the options. DPMs and LMMs in such index options have expressed to the Exchange that, for purposes of their quoting risk profiles, they do not wish to begin quoting before a substantial number of the underlying index components have opened (which may not necessarily be within the 9:30 a.m. minute).[11] Without the opening prices for a substantial number of the underlying index components available, DPMs and LMMs that may use the index spot value to the options (particularly those without a related index futures) may not be able to provide quotes that reflect then-current market conditions for the series in those options in the same manner as they would be able to for an index series in which all or a substantial number of the underlying index components have opened. Therefore, the Exchange proposes to amend the DPM and LMM opening quote requirement to provide the Exchange with the flexibility to specify the period of time from the initiation of the opening rotation in certain index options before a DPM or LMM is required to provide opening quotes.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The proposed rule change makes a nonsubstantive change by updating ''Regular Trading session'' to ''Regular Trading Hours trading session'', which is more in line with the defined term and the corresponding language that governs the opening quote requirement for LMMs. *See* Rule 1.1, definition of Regular Trading Hours and RTH; *and* Rule 5.55(a)(3).

[6] Unless otherwise specified, all times in the Rules are Eastern Time. *See* Rule 1.6.

[7] For VIX Index options, the System initiates the opening rotation at 9:30 a.m. *See* Rule 5.31(d)(1)(C).

[8] The current delay period following the first disseminated index value, as determined by the Exchange, is one second.

[9] *See* Rule 5.31(a), which provides that the term ''Composite Market'' means the market for a series comprised of (1) the higher of the then current best appointed Market-Maker bulk message bid on the Exchange and the away best bid (''ABB'') (if there is an ABB) and (2) the lower of the then-current best appointed Market-Maker bulk message offer on the Exchange and the away best offer (''ABO'') (if there is an ABO).

[10] Specifically, until one of the conditions in Rule 5.31(e)(1)(A) or (B) for the series is satisfied, until the series opens pursuant to a forced opening as set forth in Rule 5.31(e)(4), or the Exchange opens the series pursuant to Rule 5.31(h).

[11] The Exchange notes it is possible that some DPMs and LMMs may also rely on spot values as input in their option pricing models for index options for which a related index futures product is available. However, the Exchange understands from DPMs and LMMs that the spot values are generally not the primary source of information used for pricing for such index options.

Specifically, the proposed rule change updates Rule 5.54(a)(6) and Rule 5.55(a)(2) to require each DPM and LMM, respectively, to enter opening quotes for the Regular Trading Hours trading session in any series that is not open due to the lack of a quote pursuant to Rule 5.31 within (i) a specified time period (determined by the Exchange on a class-by-class basis) for index options, and (ii) one minute for equity options, of the initiation of an opening rotation. The proposed rule change is designed to allow the Exchange to specify a period of time following the initiation of the opening rotation in index options long enough to allow a substantial portion of the underlying index components to open before a DPM or LMM is required to submit opening quotes in series that are ineligible to open given a lack of quote. The Exchange this will enable DPMs and LMMs to price those index options in a manner that may more closely reflect then-current market conditions at the open and provide a tighter market upon which a series may open.

As indicated above, different option classes may have different characteristics and trading models, and the proposed flexibility will permit the Exchange to apply different timing parameters in connection with a DPM's or LMM's opening quote obligation to address those differences, in much the same way the Exchange Rules already permit the Exchange to apply different parameters in many places. The Exchange notes that the Exchange Rules provide the Exchange with similar flexibility regarding timing in connection with the opening of trading on the Exchange,[12] as well as similar flexibility to apply different settings or designations on a class-by-class basis, including in connection with Market-Maker obligations.[13]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[14] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[15] requirements that the rules of an exchange be 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 mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[16] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and protect investors, because it is designed to allow the Exchange to specify a period of time following the initiation of the opening rotation in index options long enough to allow a substantial portion of the underlying index components to open before a DPM or LMM is required to submit opening quotes in series that are ineligible to open given a lack of quote. The Exchange believes it will protect investors to not require DPMs and LMMs to submit quotes when index spot values may not be fully representative of the market due to the lack of a substantial portion of the components being open. As noted above, while DPMs and LMMs generally rely on futures pricing if there is a related index future trading, DPMs and LMMs will generally rely on index spot values when there is not such futures product. The Exchange believes it is reasonable and appropriate to not require DPMs and LMMs to quote in such an index option prior to the time when a substantial portion of the underlying index components have opened, particularly when DPMs' and LMMs' quoting risk profiles rely on index spot values, which may not regularly occur for some indexes within the 9:30 a.m. minute after the first index value is disseminated. By allowing the Exchange to specify a period of time following the initiation of an opening rotation in index options long enough to allow a substantial portion of the underlying index components to open before a DPM's or an LMM's opening quote obligation is triggered, the proposed rule change will enable DPMs and LMMs to provide pricing in those index options that may better reflect then-current market conditions at the open and a tighter market upon which the series may open, to the benefit of all investors. In addition to this, and as described above, the Exchange notes that, because different option classes may have different characteristics and trading models, the Exchange Rules currently permit the Exchange to apply different parameters in many places to address such differences; including in connection with the opening of trading on the Exchange[17] and in connection with Market-Maker obligations.

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 does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because allowing different time periods during which DPMs and LMMs may have an opening quote obligation will reflect differing characteristics of index options listed on the Exchange. For some indexes, a substantial portion of the underlying components may not regularly open within a minute (*i.e.,* 9:30 a.m.) of the first disseminated index value. As noted above, while some DPMs and LMMs quote options based on pricing of related index futures, DPMs and LMMs in options that do not have related index futures quote primarily based on these index values. If a DPM or LMM is required to submit opening quotes in such an index option prior to a substantial portion of the underlying components being open, the DPM's or LMM's quotes may not reflect then-current market conditions. The proposed rule change will allow for enough time to pass in order for a substantial portion of the underlying index components for certain indexes to open, particularly those in which the Exchange understands DPMs and LMMs may rely on the index spot values (*e.g.,* because the index does not have a related futures product). Therefore, the Exchange believes the proposed rule change will impose the opening quoting requirement on DPMs and LMMs at a time when they can quote using

[12] *See* Rule 5.31(d)(1)(B), which provides that, for index options, the System initiates the opening rotation after a time period (which the Exchange determines for all classes) following the System's observation after 9:30 a.m. of the first disseminated index value for the index underlying an index option (except for VIX Index options).

[13] *See* Rule 5.52(b), which allows the Exchange to determine the minimum size required for a Market-Maker's quotes on a class-by-class basis; and Rule 3.53, which permits the Exchange to authorize a DPM to function remotely away from the Exchange's trading floor on a class-by-class basis.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] *Id.*

[17] *See supra* note 8.

information that more fully incorporates then-current market conditions, enabling DPMs and LMMs to more accurately price such options and provide for a tighter spread upon the opening of the series. An Exchange-determined period of time before a DPM's and LMM's opening quote obligations are triggered in an index option class will apply uniformly to any DPM and/or LMM that may be appointed in that class.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because it relates solely to a quoting obligation applicable to DPMs and LMMs on the Exchange. The Exchange notes that other options exchanges that may have similar opening quote requirements for their market makers may, in their discretion, adopt similar flexibility regarding the timing of the opening quote requirements in connection with index options.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has designated this rule filing as non-controversial under Section 19(b)(3)(A) [18] of the Act and Rule 19b–4(f)(6) [19] thereunder. 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 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 and Rule 19b–4(f)(6) 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 under Section 19(b)(2)(B) [20] 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–CBOE–2021–059 on the subject line.

Paper Comments

- Send paper comments in triplicate to the Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2021–059. 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–CBOE–2021–059 and should be submitted on or before November 10, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22811 Filed 10–19–21; 8:45 am]

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[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f)(6).

[20] 15 U.S.C. 78s(b)(2)(B).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93314; File No. SR–ISE–2021–21)

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Pricing Schedule at Options 7, Section 6.A To Modify the QCC and Solicitation Rebate Program

October 14, 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 30, 2021, Nasdaq ISE, LLC (''ISE'' 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 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 proposes to amend the Exchange's Pricing Schedule at Options 7, Section 6.A to modify its Qualified Contingent Cross (''QCC'') and Solicitation rebate program, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.] [sic]

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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 purpose of the proposed rule change is to modify the Exchange's QCC [3] and Solicitation Rebate program in Options 7, Section 6.A by: (i) Providing a new additional rebate of $0.01 per originating contract side to qualifying Members, and (ii) amending the qualifications for the existing $0.01 additional rebate. The Exchange also proposes a technical amendment in Options 7, Section 4. Each change is discussed in detail below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on October 1, 2021.

Background

Today, Members using QCC and/or other solicited orders executed in the Solicitation [4] or Facilitation [5] Mechanisms (together with QCC, collectively, ''Solicited Orders'') receive rebates for each originating contract side in all symbols traded on the Exchange. Once a Member reaches a certain volume threshold in Solicited Orders during a month, the Exchange provides rebates to that Member for all of its eligible Solicited Order traded contracts for that month.[6] Rebates will be applied to Solicited Order traded contracts once the volume threshold is met. Members will receive the rebate for all Solicited Orders except for Solicited Orders between two Priority Customers.[7] Solicited Orders between two Priority Customers will not receive any rebate. The volume threshold and corresponding rebates are as follows:[8]

Originating contract sides	Rebate
0 to 99,999	$0.00
100,000 to 199,999	(0.05)
200,000 to 499,999	(0.07)
500,000 to 749,999	(0.09)
750,000 to 999,999	(0.10)
1,000,000+	(0.11)

For Members that achieve the highest volume threshold of 1,000,000 or more originating contract sides, the Exchange also currently provides an additional rebate of $0.01 per originating contract side on Solicited Orders that qualify for the QCC and Solicitation Rebate program if the Member achieves in a given month: (i) Combined Solicited Order volume of more than 1,750,000 originating contract sides and (ii) Priority Customer Complex Tiers 6–9 in Section 4 (the ''note * incentive'').[9] The purpose of this incentive is to encourage Members to provide high volumes of Solicited Order activity well above the highest QCC and Solicitation Rebate volume tier of 1,000,000 or more originating contract sides, and also provide significant complex order volume.

New QCC and Solicitation Incentive

To further encourage Solicited Order and complex order flow, the Exchange now proposes to provide a new additional incentive that will be structured similarly to the existing note * incentive, except the proposed incentive will also be applied to the lower QCC and Solicitation Rebate volume tiers (in addition to the highest volume tier). Furthermore, Members will be able to qualify for the proposed incentive by achieving less stringent Priority Customer Complex Tiers in Section 4. Specifically, the Exchange proposes that Members will receive an additional rebate of $0.01 per originating contract side on Solicited Orders that qualify for the QCC and Solicitation Rebate program if they achieve Priority Customer Complex Tier 2 or higher in a given month (the ''note & incentive'').

The note & incentive will be applied to all of the QCC and Solicitation Rebate volume tiers except for the lowest tier (for which the Exchange does not currently provide a QCC and Solicitation Rebate). This additional rebate opportunity will be cumulative of the base rebates so that qualifying Members could receive up to $0.06 in the second QCC and Solicitation Rebate volume tier, $0.08 in the third tier, $0.10 in the fourth tier, $0.11 in the fifth tier, and $0.13 in the sixth and highest tier (*i.e.,* the $0.11 base rebate, the $0.01 note * incentive, and the $0.01 note & incentive).

While structured similarly to the existing note * incentive, the proposed incentive will be less stringent in that it will require Members to send a lower amount of Solicited Order and complex order volume in order to qualify for the incentive. As such, the proposed note & incentive may be more readily accessible to Members. If more Members find this rebate is accessible to them, then more will seek to qualify for it by sending Solicited Order and complex order flow to the Exchange.

Existing QCC and Solicitation Incentive

As described above, the Exchange currently offers the $0.01 note * incentive to qualifying Members if they achieve in a given month: (i) Combined Solicited Order volume of more than 1,750,000 originating contract sides and (ii) Priority Customer Complex Tiers 6–9 in Section 4. When the Exchange adopted the note * incentive in 2019, there were only nine Priority Customer Complex Tiers in Section 4.[10] The Exchange has since amended its Pricing Schedule to adopt Priority Customer Complex Tier 10, and now proposes to update the existing Priority Customer Complex Tier qualification in the note * incentive accordingly.[11] As amended, the qualification will require Members to achieve Priority Customer Complex Tier 6 or higher. The amended qualification will therefore include Priority Customer Complex Tier 10 while also giving the Exchange flexibility to accommodate any similar changes to its Priority Customer Complex Tiers going forward. The Exchange notes that no Member is

[3] A QCC Order is comprised of an originating order to buy or sell at least 1000 contracts that is identified as being part of a qualified contingent trade, as that term is defined in Supplementary Material .01 to Options 3, Section 7, coupled with a contra-side order or orders totaling an equal number of contracts. *See* Options 3, Section 7(j).

[4] The Solicitation or Solicited Order Mechanism is a process by which an Electronic Access Member (''EAM'') can attempt to execute orders of 500 or more contracts it represents as agent against contra orders that it solicited. *See* Options 3, Section 11(d).

[5] The Facilitation Mechanism is a process by which an EAM can execute a transaction wherein the EAM seeks to facilitate a block-size order it represents as agent, and/or a transaction wherein the EAM solicited interest to execute against a block-size order it represents as agent. *See* Options 3, Section 11(b).

[6] All eligible volume from affiliated Members will be aggregated in determining QCC and Solicitation volume totals, provided there is at least 75% common ownership between the Members as reflected on each Member's Form BD, Schedule A.

[7] A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq ISE Options 1, Section 1(a)(37).

[8] Volume resulting from all Solicited Orders will be aggregated in determining the applicable volume tier.

[9] As set forth in Options 7, Section 4, Priority Customer Complex Tiers are based on Total Affiliated Member or Affiliated Entity complex order volume (excluding Crossing Orders and Responses to Crossing Orders) calculated as a percentage of Customer Total Consolidated Volume.

[10] *See* Securities Exchange Act Release No. 85647 (April 15, 2019), 84 FR 16300 (April 18, 2019) (SR–ISE–2019–09) (the ''2019 Filing'').

[11] *See* Securities Exchange Act Release No. 90501 (November 24, 2020), 85 FR 77328 (December 1, 2020) (SR–ISE–2020–39) (the ''2020 Filing'').

currently achieving both Priority Customer Complex Tier 10 and combined Solicited Order volume of more than 1,750,000 originating contract sides to receive the $0.01 additional incentive, so expects that the proposed changes will have minimal impact.

Technical Amendment

The Exchange proposes a minor, technical amendment in note 16 of Options 7, Section 4, which currently describes the Priority Customer Complex Tiers, to add a reference to Affiliated Entity [12] within the note's first sentence. The proposed change will simply align the note's language with corresponding language presently in the header of the Priority Customer complex rebates table.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[14] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange's proposed changes to its Pricing Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [15]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [16]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options security transaction services. The Exchange is only one of sixteen options exchanges to which market participants may direct their order flow. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

New QCC and Solicitation Incentive

The Exchange believes that its proposal to provide Members with an additional incentive of $0.01 per originating contract side on Solicited Orders that qualify for the QCC and Solicitation Rebate program if they achieve Priority Customer Complex Tier 2 or higher in a given month is reasonable because this incentive is intended to encourage Members to send more Solicited Order and complex order flow to the Exchange. As discussed above, the proposed note & incentive is similar to the existing note * incentive, except the proposed incentive will be less stringent in that it will require Members to send a lower amount of Solicited Order and complex order volume in order to qualify for the incentive. As such, the proposed note & incentive may be more readily accessible to Members. If more Members find this rebate is accessible to them, then more will seek to qualify for it by sending Solicited Order and complex order flow to the Exchange. All market participants benefit from increased order interaction when more order flow is available on ISE.

The Exchange further believes that the proposed note & incentive is equitable and not unfairly discriminatory because any Member may qualify for the proposed incentive by submitting the requisite volume of Solicited Orders and complex orders. Furthermore, the Exchange will uniformly apply the proposed incentive to all qualifying Members.

Existing QCC and Solicitation Incentive

The Exchange believes that the proposed changes to amend the existing qualification in the note * incentive is reasonable for the following reasons. First, the proposed changes would more closely align to the Exchange's original intent in the 2019 Filing to provide the note * incentive to qualifying Members that achieved anything above 1.000% of Total Affiliated Member or Affiliated Entity Complex Order Volume (Excluding Crossing Orders and Responses to Crossing Orders) calculated as a percentage of Customer Total Consolidated Volume (*i.e.,* Priority Customer Complex Tiers 6–9 at the time of the 2019 Filing).[17] The 2020 Filing amended, among other changes, the Priority Customer Complex Tiers by adding a new Tier 10 as the highest tier and adjusting the volume percentages in Tiers 8 and 9 accordingly.[18] The volume percentages in Tier 6, however, remained the same with the 2020 Filing, so even with the addition of Tier 10, corresponding changes should have been made to the note * incentive qualifications to include Tier 10 to align with the original intent of this incentive. Second, as noted above, the proposed changes to include Tier 10 in the incentive qualifications are expected to have minimal impact as no Member is currently achieving both Priority Customer Complex Tier 10 and combined Solicited Order volume of more than 1,750,000 originating contract

[12] An ''Affiliated Entity'' is a relationship between an Appointed Market Maker and an Appointed OFP for purposes of qualifying for certain pricing specified in the Schedule of Fees. Market Makers and OFPs are required to send an email to the Exchange to appoint their counterpart, at least 3 business days prior to the last day of the month to qualify for the next month. The Exchange will acknowledge receipt of the emails and specify the date the Affiliated Entity is eligible for applicable pricing, as specified in the Schedule of Fees. Each Affiliated Entity relationship will commence on the 1st of a month and may not be terminated prior to the end of any month. An Affiliated Entity relationship will terminate after a one (1) year period, unless either party terminates earlier in writing by sending an email to the Exchange at least 3 business days prior to the last day of the month to terminate for the next month. Affiliated Entity relationships must be renewed annually by each party sending an email to the Exchange. Affiliated Members may not qualify as a counterparty comprising an Affiliated Entity. Each Member may qualify for only one (1) Affiliated Entity relationship at any given time.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4) and (5).

[15] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[16] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[17] *See* 2019 Filing.

[18] *See* 2020 Filing.

sides to receive the $0.01 additional rebate.

Lastly, the Exchange believes that the proposed changes to the existing qualification are equitable and not unfairly discriminatory because any Member may qualify for the note * incentive by submitting the requisite volume of Solicited Orders and complex orders. The Exchange will apply the amended qualification to all qualifying Members uniformly.

Technical Amendment

The Exchange's proposal to amend note 16 in Options 7, Section 4 is reasonable, equitable, and not unfairly discriminatory. As discussed above, the Exchange is simply aligning the note's language corresponding language currently in the header of the Priority Customer complex rebates table. The Exchange believes that the proposed changes will bring clarity and transparency to the Exchange's Pricing Schedule.

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.

In terms of intra-market competition, the Exchange does not believe that its proposal will place any category of market participant at a competitive disadvantage. As discussed above, any Member may qualify for the QCC and Solicitation Rebates, including the note * incentive and the proposed note & incentive. The proposed changes are primarily aimed at attracting greater Solicited Order and complex order flow to the Exchange. To the extent the Exchange's proposal incentivizes Members to bring more order flow to ISE, the Exchange believes that the resulting additional volume and liquidity will benefit all market participants.

In terms of inter-market competition, 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, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other options exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of Members or competing exchanges to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or 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)(ii) of the Act.[19] 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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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–ISE–2021–21 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–ISE–2021–21. 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–ISE–2021–21 and should be submitted on or before November 10, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22807 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A)(ii).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93329; File Nos. SR–MIAX–2021–29, SR–EMERALD–2021–22, SR–PEARL–2021–30]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC, MIAX Emerald, LLC, and MIAX PEARL, LLC; Notice of Withdrawal of Proposed Rule Changes To Amend Fees for Purge Ports

October 14, 2021.

On July 1, 2021, Miami International Securities Exchange, LLC, MIAX Emerald, LLC, and MIAX PEARL, LLC (each an ''Exchange'') each 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 increase fees for purge ports. Each proposed rule change was immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.[3] The proposed rule changes were published for comment in the **Federal Register** on July 15, 2021.[4] The Commission received comment on the proposals.[5] On August 27, 2017, the Commission, pursuant to Section 19(b)(3)(C) of the Act,[6] temporarily suspended the proposed rule changes and instituted proceedings to determine whether to approve or disapprove the proposed rule changes.[7] Each Exchange withdrew its proposed rule change as of October 12, 2021 (SR–MIAX–2021–29, SR–EMERALD–2021–22, and SR–PEARL–2021–30).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22796 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93323; File No. SR–IEX–2021–12]

Self-Regulatory Organizations: Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Period for the Market-Wide Circuit Breakers to March 18, 2022

October 14, 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 October 13, 2021, the Investors Exchange LLC (''IEX'' 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

Pursuant to the provisions of Section 19(b)(1) under the Act,[4] and Rule 19b–4 thereunder,[5] IEX is filing with the Commission a proposed rule change to amend IEX Rule 11.280 to extend the pilot period for the market-wide circuit breaker to the close of business on March 18, 2022. IEX has designated this rule change as ''non-controversial'' under Section 19(b)(3)(A) of the Act [6] and requested that the Commission waive the five-day pre-filing notice required by Rule 19b–4(f)(6)(iii) thereunder.[7]

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.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 the 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 these statement may be examined at the places specified in Item IV below. The self-regulatory organization 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Market-Wide Circuit Breaker (''MWCB'') rules, including paragraphs (a) through (d) and (f) of IEX Rule 11.280, 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 [8] (the ''Pilot Rules,'' *i.e.,* for IEX, Rule 11.280(a)–(d) and (f) [9]). 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'').[10] 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'') [11],

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A). A proposed rule change may take effect upon filing with the Commission if it is designated by the exchange as ''establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization.'' 15 U.S.C. 78s(b)(3)(A)(ii).

[4] *See* Securities Exchange Act Release Nos. 92364 (July 9, 2021), 86 FR 37364 (July 15, 2021) (SR–MIAX–2021–29); 92360 (July 9, 2021), 86 FR 37373 (July 15, 2021) (SR–EMERALD–2021–22); 92363 (July 9, 2021), 86 FR 37376 (July 15, 2021) (SR–PEARL–2021–30).

[5] Comment on the proposed rule changes can be found at: *https://www.sec.gov/comments/sr-miax-2021-29/srmiax202129.htm; https://www.sec.gov/comments/sr-emerald-2021-22/sremerald202122.htm; https://www.sec.gov/comments/sr-pearl-2021-30/srpearl202130.htm.*

[6] 15 U.S.C. 78s(b)(3)(C).

[7] *See* Securities Exchange Act Release No. 92792 (August 27, 2021), 86 FR 49384 (September 2, 2021).

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6)(iii).

[8] *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).

[9] IEX's Pilot Rule has been effective since its approval for registration as a national securities exchange in 2016. *See* Securities Exchange Act Release No. 78101 (June 17, 2016), 81 FR 41142 (June 23, 2016) (File No. 10–222).

[10] 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).

[11] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012). An amendment to the LULD Plan adding IEX as a Participant was filed with the Commission on August 11, 2016, and became effective upon filing pursuant to Rule 608(b)(3)(iii) of the Act. *See* Securities Exchange Act Release No. 78703 (August

Continued

including any extensions to the pilot period for the LULD Plan.[12] In April 2019, the Commission approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[13] In conjunction with the proposal to make the LULD Plan permanent, the Exchange amended IEX Rule 11.280 to extend the Pilot Rules' effectiveness to the close of business on October 18, 2019.[14] The Exchange subsequently amended IEX Rule 11.280 to untie the Pilot Rules' effectiveness from that of the LULD Plan and extend the Pilot Rules' effectiveness for an additional year to the close of business on October 18, 2020,[15] and later, on October 18, 2021.[16]

The Exchange now proposes to amend IEX Rule 11.280 to extend the pilot to the close of business on March 18, 2022. This filing does not propose any substantive or additional changes to IEX Rule 11.280.

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.[17]

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 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'').[18] 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 ''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.[19]

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 New York Stock Exchange (''NYSE'') proposed a rule change to make the Pilot Rules permanent, consistent with the Working Group's recommendations.[20] On August 27, 2021, the Commission extended its time to consider the proposed rule change to October 20, 2021.[21] 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 the requirements of Sections 6(b)[22] and 6(b)(5) of the Act,[23] 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

26, 2016), 81 FR 60397 (September 1, 2016) (File No. 4–631). The LULD Plan provides a mechanism to address extraordinary market volatility in individual securities.

[12] *See, e.g.,* Securities Exchange Act Release No. 78703 (August 26, 2016), 81 FR 60397 (September 1, 2016) (File No. 4–631) (describing the several extensions of the LULD Plan pilot period).

[13] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019).

[14] *See* Securities Exchange Act Release No. 85576 (April 9, 2019), 84 FR 15237 (April 15, 2019) (SR–IEX–2019–04). *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).

[15] *See* Securities Exchange Act Release No. 87298 (October 15, 2019), 84 FR 56255 (October 21, 2019) (SR–IEX–2019–11).

[16] *See* Securities Exchange Act Release No. 90128 (October 8, 2020), 85 FR 65127 (October 14, 2020) (SR–IEX–2020–17).

[17] *See https://www.cmegroup.com/content/dam/cmegroup/market-regulation/rule-filings/2020/9/20-392_1.pdf*; *https://www.cmegroup.com/market-regulation/rule-filings/2020/9/20-392_2.pdf.*

[18] *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.*

[19] *See id.* at 46.

[20] *See* Securities Exchange Act Release No. 92428 (July 16, 2021), 86 FR 38776 (July 22, 2021) (SR–NYSE–2021–40).

[21] *See* Securities Exchange Act Release No. 92785A (August 27, 2021), 86 FR 50202 (September 7, 2021) (SR–NYSE–2021–40).

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

general to protect investors and the public interest. The MWCB mechanism under Rule 11.280 is an important, automatic mechanism that is invoked to promote stability and investor confidence during periods of significant stress when securities markets experience extreme broad-based declines. Extending the MWCB pilot for an additional five months would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. equity markets while the Commission reviews NYSE'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 the MWCB under Rule 11.280(a) through (d) and (f) should continue on a pilot basis because the MWCB will promote fair and orderly markets, and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change implicates any competitive issues 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 NYSE's proposed rule change to make the Pilot Rules permanent.

Further, IEX understands that the other SROs will file proposals to extend their rules regarding the MWCB 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

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 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 [24] and Rule 19b–4(f)(6) [25] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [26] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[27] 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 NYSE'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.[28]

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 under Section 19(b)(2)(B) [29] 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–IEX–2021–12 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–IEX–2021–12. This file number should be included in 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 will also be available for inspection and copying at the IEX's principal office and on its internet website at *www.iextrading.com.* All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–IEX–2021–12 and should be submitted on or before November 10, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22809 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

[24] 15 U.S.C. 78s(b)(3)(A).

[25] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization 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 Commission has waived this requirement.

[26] 17 CFR 240.19b–4(f)(6).

[27] 17 CFR 240.19b–4(f)(6)(iii).

[28] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[29] 15 U.S.C. 78s(b)(2)(B).

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93330; File No. SR–Phlx–2021–61]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Related to Clearly Erroneous Transactions Until April 20, 2022

October 14, 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 October 8, 2021, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the 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 proposes to extend the pilot related to Clearly Erroneous Transactions until April 20, 2022.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* 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 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 purpose of the proposed rule change is to extend the current pilot program related to Equity 4, Rule 3312, Clearly Erroneous Transactions, to the close of business on April 20, 2022. The pilot program is currently due to expire on October 20, 2021.

On September 10, 2010, the Commission approved, on a pilot basis, changes to Equity 4, Rule 3312 that, among other things: (i) Provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[3] Following this, on September 30, 2010, the Exchange adopted changes to conform its Rule 3312 to Nasdaq's and BX's rules 11890.[4] In 2013, the Exchange adopted a provision designed to address the operation of the Plan.[5] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) A series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[6]

These changes were originally scheduled to operate for a pilot period to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or ''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 light of that change, the Exchange amended Equity 4, Rule 3312 to untie the pilot program's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019.[9] Subsequently, the Exchange amended Rule 3312 to extend the pilot's effectiveness to the close of business on October 20, 2021.[10]

The Exchange now proposes to amend Equity 4, Rule 3312 to extend the pilot's effectiveness for a further six months until the close of business on April 20, 2022. If the pilot period is not either extended, replaced or approved as permanent, the prior versions of paragraphs (a)(2)(C), (c)(1), (b)(i), and (b)(ii) shall be in effect, and the provisions of paragraphs (g) through (i) shall be null and void.[11] In such an event, the remaining sections of Rule 3312 would continue to apply to all transactions executed on the Exchange. The Exchange understands that the other national securities exchanges and Financial Industry Regulatory Authority (''FINRA'') will also file similar proposals to extend their respective clearly erroneous execution pilot programs, the substance of which are identical to Rule 3312.

The Exchange does not propose any additional changes to Equity 4, Rule 3312. Extending the effectiveness of Rule 3312 for an additional six months will provide the Exchange and other self-regulatory organizations additional time to consider whether further amendments to the clearly erroneous execution rules are appropriate.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[12] in general, and Section 6(b)(5) of the Act,[13] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–NASDAQ–2010–076).

[4] *See* Securities Exchange Act Release No. 63023 (September 30, 2010), 75 FR 61802 (October 6, 2010) (SR–Phlx–2010–125).

[5] *See* Securities Exchange Act Release No. 68820 (February 1, 2013), 78 FR 9436 (February 8, 2013) (SR–Phlx–2013–12).

[6] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–Phlx–2014–27).

[7] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[8] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (approving Eighteenth Amendment to LULD Plan).

[9] *See* Securities Exchange Act Release No. 85632 (April 11, 2019), 84 FR 16057 (April 17, 2019) (SR–Phlx–2019–14).

[10] *See* Securities Exchange Act Release No. 91579 (April 15, 2021), 86 FR 20774 (April 21, 2021) (SR–Phlx–2021–23).

[11] *See* notes 3–6, *supra*. The prior versions of paragraphs (a)(2)(C), (c)(1), (b)(i), and (b)(ii) generally provided greater discretion to the Exchange with respect to breaking erroneous trades.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning review of transactions as clearly erroneous. The Exchange believes that extending the clearly erroneous execution pilot under Equity 4, Rule 3312 for an additional six months would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Based on the foregoing, the Exchange believes the amended clearly erroneous executions rule should continue to be in effect on a pilot basis while the Exchange and other self-regulatory organizations consider whether further amendments to these rules are appropriate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal would ensure the continued, uninterrupted operation of harmonized clearly erroneous execution rules across the U.S. equities markets while the Exchange and other self-regulatory organizations consider whether further amendments to these rules are appropriate. The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals to extend their respective clearly erroneous execution pilot programs. 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 either solicited or received.

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)(iii) of the Act[14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6)[16] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii)[17] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current clearly erroneous execution pilot program to continue uninterrupted, without any changes, while the Exchange and the other national securities exchanges consider a permanent proposal for clearly erroneous execution reviews. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[18]

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–Phlx–2021–61 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–Phlx–2021–61. 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–Phlx–2021–61 and should be submitted on or before November 10, 2021.

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization 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.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22797 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93331; File Nos. SR–NYSE–2021–14, SR–NYSEAMER–2021–10, SR–NYSEArca–2021–13, SR–NYSECHX–2021–03, SR–NYSENAT–2021–04]

Self-Regulatory Organizations; New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc.; Notice of Withdrawal of Proposed Rule Changes To Amend the Schedule of Wireless Connectivity Fees and Charges To Add Connectivity Services Available at the Data Center in Mahwah, New Jersey

October 14, 2021.

On February 12, 2021, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (collectively, the ''Exchanges'') each 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 (1) add circuits for connectivity into and out of the data center in Mahwah, New Jersey (''Mahwah Data Center''); (2) add services available to customers of the Mahwah Data Center that are not colocation Users; and (3) change the name of the Fee Schedule to ''Mahwah Wireless, Circuits, and Non-Colocation Connectivity Fee Schedule.''

The proposed rule changes were published for comment in the **Federal Register** on March 4, 2021.[3] On April 7, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule changes, disapprove the proposed rule changes, or institute proceedings to determine whether to disapprove the proposed rule changes.[5] On May 26, 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 changes.[7] On August 27, 2021, pursuant to Section 19(b)(2) of the Act,[8] the Commission designated a longer period for Commission action on the proceedings to determine whether to approve or disapprove the proposed rule changes.[9] The Commission has received comments on the proposed rule changes.[10] On October 12, 2021, the Exchanges withdrew the proposed rule changes (SR–NYSE–2021–14, SR–NYSEAMER–2021–10, SR–NYSEArca–2021–13, SR–NYSECHX–2021–03, SR–NYSENAT–2021–04).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22798 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93312; File No. SR–PEARL–2021–50]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by To Extend the Pilot Related to the Market-Wide Circuit Breakers in Exchange Rule 2622

October 14, 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 October 12, 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 extend the pilot related to the market-wide circuit breaker mechanism in Rule 2622.

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 extend the pilot related to the market-wide circuit breaker mechanism in Rule 2622 to the close of business on March 18, 2022.

Background

The Market-Wide Circuit Breaker (''MWCB'') rules, including the Exchange's Rule 2622, 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. In 2012 all U.S. cash equity exchanges and FINRA amended their cash equities uniform rules on a pilot basis[3] and, in

[19] 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 Nos. 91217 (February 26, 2021), 86 FR 12715 (March 4, 2021) (SR–NYSE–2021–14); 91218 (February 26, 2021), 86 FR 12744 (March 4, 2021) (SR–NYSEAMER–2021–10); 91216 (February 26, 2021), 86 FR 12735 (March 4, 2021) (SR–NYSEArca–2021–13); 91219 (February 26, 2021), 86 FR 12724 (March 4, 2021) (SR–NYSECHX–2021–03); and 91215 (February 26, 2021), 86 FR 12752 (March 4, 2021) (SR–NYSENAT–2021–04).

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 91490 (April 7, 2021), 86 FR 19313 (April 13, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 92033 (May 26, 2021), 86 FR 29601 (June 2, 2021).

[8] 15 U.S.C. 78s(b)(2).

[9] *See* Securities Exchange Act Release No. 92795 (August 27, 2021), 86 FR 49393 (September 2, 2021).

[10] Comments received on the proposed rule changes are available at: *https://www.sec.gov/comments/sr-nyse-2021-14/srnyse202114.htm.*

[11] 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. 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–

2020, the Exchange adopted the cash equities uniform rule under Exchange Rule 2622(a)–(d) to also operate on a pilot basis [4] (the ''Pilot Rules''). 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.

Exchange Rule 2622 was approved by the Commission to operate on a pilot basis set to expire on at the close of business on October 18, 2020.[6] The Exchange subsequently amended Rule 2622 to extend the Pilot Rules' effectiveness for an additional year to the close of business on October 18, 2021.[7]

The Exchange now proposes to amend Rule 2622 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 2622.

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.[8]

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 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'').[9] 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.[10]

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 New York Stock Exchange LLC (''NYSE'') proposed a rule change to make the Pilot Rules permanent, consistent with the Working Group's recommendations.[11] On August 27, 2021, the Commission extended its time to consider the proposed rule change to October 20, 2021.[12] The Exchange now proposes to extend the

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''). *See also* Securities Exchange Act Release No. 89563 (August 14, 2020), 85 FR 51510 (August 20, 2020) (SR–PEARL–2020–03) (''Equities Approval Order'') (approving, among other things, Exchange Rule 2622).

[4] *See* Equities Approval Order, *id.*

[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.,* Exchange Rule 504(a) *and* NYSE Arca Rule 6.65–O(d)(4).

[6] *See* Equities Approval Order, *supra note 3.*

[7] *See* Securities Exchange Act Release No. 90124 (October 8, 2020), 85 FR 65105 (October 14, 2020) (SR–PEARL–2020–20).

[8] 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.*

[9] *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.*

[10] *See id.* at 46.

[11] *See* Securities Exchange Act Release No. 92428 (July 16, 2021), 86 FR 38776 (July 22, 2021) (SR–NYSE–2021–40).

[12] *See* Securities Exchange Act Release No. 92785A (August 27, 2021), 86 FR 50202 (September 7, 2021) (SR–NYSE–2021–40).

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,[13] in general, and furthers the objectives of Section 6(b)(5) of the Act,[14] 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 MWCB mechanism under Rule 2622 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 MWCB 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 NYSE'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 MWCB pilot. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

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

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 after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [15] and Rule 19b–4(f)(6) [16] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [17] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[18] 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 NYSE'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.[19]

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.

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization 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.

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 240.19b–4(f)(6)(iii).

[19] For purposes only of waiving the 30-day operative delay, the Commission has also 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–PEARL–2021–50 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–PEARL–2021–50. 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–PEARL–2021–50 and

should be submitted on or before November 10, 2021. For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–22806 Filed 10–19–21; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17221 and #17222; Georgia Disaster Number GA–00131]

Administrative Declaration of a Disaster for the State of Georgia

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Georgia dated 10/13/2021.

Incident: Severe Flood Damage from Hurricane Ida.

Incident Period: 08/30/2021 through 09/01/2021.

DATES: Issued on 10/13/2021.

Physical Loan Application Deadline Date: 12/13/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 07/13/2022.

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 Administrator's disaster declaration, applications for disaster loans may be filed 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: Cobb

Contiguous Counties:

Georgia: Bartow, Cherokee, Douglas, Fulton, Paulding

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	3.125
Homeowners without Credit Available Elsewhere	1.563
Businesses with Credit Available Elsewhere	5.710
Businesses without Credit Available Elsewhere	2.855
Non-Profit Organizations with Credit Available Elsewhere	2.000
Non-Profit Organizations without Credit Available Elsewhere	2.000
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	2.855
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17221 8 and for economic injury is 17222 0.

The State which received an EIDL Declaration # is Georgia.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2021–22788 Filed 10–19–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17145 and #17146; New Jersey Disaster Number NJ–00063]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of New Jersey

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 4.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of New Jersey (FEMA–4614–DR), dated 09/05/2021.

Incident: Remnants of Hurricane Ida.

Incident Period: 09/01/2021 through 09/03/2021.

DATES: Issued on 10/13/2021.

Physical Loan Application Deadline Date: 11/04/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 06/06/2022.

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: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of New Jersey, dated 09/05/2021, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Warren

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021–22789 Filed 10–19–21; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 11567]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: "Revealing Krishna's Journey to Cambodia's Sacred Mountain" 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 ''Revealing Krishna: Journey to Cambodia's Sacred Mountain'' at the Cleveland Museum of Art, Cleveland, Ohio, 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

[20] 17 CFR 200.30–3(a)(12).

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. 2021–22794 Filed 10–19–21; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11564]

Review of Foreign Terrorist Organizations Designation for Liberation Tigers of Tamil Eelam

Pursuant to section 219(a)(4)(C) of the Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(4)(C)), the Department of State is undertaking a review of the designation of the Liberation Tigers of Tamil Eelam as a Foreign Terrorist Organization. In making its determination, the Department of State will accept written statements or other documentary materials submitted on behalf of interested parties and the above-named organization by its representatives. Such materials must be submitted by November 2, 2021, to: The Coordinator for Counterterrorism, United States Department of State, 2201 C Street NW, Washington, DC 20520.

This notice shall be published in the **Federal Register**.

Dated: October 7, 2021.

John T. Godfrey,

Acting Coordinator for Counterterrorism.

[FR Doc. 2021–22783 Filed 10–19–21; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 11565]

Determination Under Section 7014(b) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2020

SUMMARY: Pursuant to the authority vested in me by section 7014(b) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2020 (FY 2020 SFOAA), and Department of State Delegation of Authority 513, I hereby determine that a significant change in circumstances makes it unlikely that the following funds specifically designated for particular programs or activities by the FY 2020 SFOAA or any other Act can be obligated during the original periods of availability of such funds: $126,926,815 in the Economic Support Fund (ESF) account; $5,000,000 in the Global Health Programs (GHP)—USAID account; $14,000,000 in the International Narcotics Control and Law Enforcement (INCLE) account; and $18,000,000 in the Nonproliferation, Anti-terrorism, Demining, and Related Programs (NADR) account. This determination shall be published in the **Federal Register** and, along with the accompanying Memorandum of Justification, shall be transmitted to Congress.

Dated: September 30, 2021.

Brian McKeon,

Deputy Secretary of State for Management and Resources, Department of State.

[FR Doc. 2021–22775 Filed 10–19–21; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0862]

COVID–19 Related Relief Concerning Operations at Chicago O'Hare International Airport, John F. Kennedy International Airport, Los Angeles International Airport, Newark Liberty International Airport, New York LaGuardia Airport, Ronald Reagan Washington National Airport, and San Francisco International Airport for the Winter 2021/2022 Scheduling Season

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Extension of limited, conditional waiver of the minimum slot usage requirement for international operations only.

SUMMARY: The FAA has determined to extend through March 26, 2022, the Coronavirus (COVID–19)-related limited, conditional waiver of the minimum slot usage requirement at John F. Kennedy International Airport (JFK), New York LaGuardia Airport (LGA), and Ronald Reagan Washington National Airport (DCA) that the FAA has already made available through October 30, 2021, for international operations only. Similarly, the FAA has determined to extend through March 26, 2022, its COVID–19-related limited, conditional policy for prioritizing flights canceled at designated International Air Transport Association (IATA) Level 2 airports in the United States, for purposes of establishing a carrier's operational baseline in the next corresponding season, for international operations only. These IATA Level 2 airports include Chicago O'Hare International Airport (ORD), Newark Liberty International Airport (EWR), Los Angeles International Airport (LAX), and San Francisco International Airport (SFO). This relief is limited to slots and approved operating times used by any carrier for international operations only, through March 26, 2022, and will be subject to the same terms and conditions, with minor modifications, that the FAA has already applied to the relief that remains available through October 30, 2021.

DATES: The relief announced in this notice is available for the Winter 2021/2022 scheduling season, which runs from October 31, 2021, through March 26, 2022. Compliance with the rolling four-week return condition on the relief announced in this notice is required beginning on October 25, 2021. Compliance with all other conditions remains in effect without change from prior seasons.

FOR FURTHER INFORMATION CONTACT: Al Meilus, Manager, Slot Administration, AJR–G, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–2822; email *Al.Meilus@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On March 16, 2020, the FAA granted a limited waiver of the minimum slot usage requirements [1] to carriers operating at all slot-controlled airports in the United States (DCA, JFK, and LGA) [2] and related relief to carriers operating at designated IATA Level 2 airports in the United States (EWR, LAX, ORD, SFO) due to the extraordinary impacts on the demand for air travel resulting from the COVID–19 pandemic.[3] Since the initial slot usage waiver and related relief was

[1] The FAA has authority for developing ''plans and policy for the use of the navigable airspace'' and for assigning ''by regulation or order the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace.'' 49 U.S.C. 40103(b)(1). The FAA manages slot usage requirements under the authority of 14 CFR 93.227 at DCA and under the authority of Orders at JFK and LGA. *See* Operating Limitations at John F. Kennedy International Airport, 85 FR 58258 (Sep. 18, 2020); Operating Limitations at New York LaGuardia Airport, 85 FR 58255 (Sep. 18, 2020).

[2] Although DCA and LGA are not designated as IATA Level 3 slot-controlled airports given that these airports primarily serve domestic destinations, the FAA limits operations at these airports via rules at DCA and an Order at LGA that are equivalent to IATA Level 3. *See* FN 1. The FAA reiterates that the relief provided in the March 16, 2020, notice (85 FR 15018), the April 17, 2020, notice (85 FR 21500), the October 7, 2020, notice (85 FR 63335), and this policy statement, extends to all allocated slots, including slots allocated by exemption.

[3] Notice of Limited Waiver of the Slot Usage Requirement, 85 FR 15018 (Mar. 16, 2020).

provided, the FAA has taken action to extend the relief provided on three occasions subject to certain substantive changes, including the addition of conditions, as the COVID–19 situation continued to evolve.[4] The most recent limited, conditional extension of COVID–19-related relief was issued by the FAA on January 13, 2021, and is due to expire on October 31, 2021.[5]

The FAA issued a notice on September 16, 2021, inviting comment on its proposal to extend through March 26, 2022, the COVID–19-related limited, conditional waiver of the minimum slot usage requirement at United States (U.S.) slot controlled and IATA Level 2 airports that the FAA has already made available through October 30, 2021, for international operations only.[6] In its proposal the FAA explained it would generally evaluate any request for relief from U.S. carriers for the Winter 2021/2022 scheduling season based on historical levels of operations to foreign points as demonstrated in published schedules and that domestic carriers seeking relief for a particular operation under the waiver will need to provide the FAA, if not readily apparent from FAA records and historic published schedule data, alternative supplemental information that predates FAA's proposal to demonstrate intent to use a slot or approved operating time for an international destination. The notice explained that international operations eligible for a waiver at U.S. slot-controlled and IATA Level 2 airports under FAA's proposal would be subject to all of the same conditions and policies already in effect, with minor modifications.

In addition, the FAA invited comment and supporting information to demonstrate why the FAA should or should not finalize its proposed decision. In particular, U.S. carriers were invited to provide individualized responses to several questions concerning FAA's proposal and the continuing need for relief due to COVID–19.

[4] Notice of Extension of Limited Waiver of the Minimum Slot Usage Requirement, 85 FR 21500 (Apr. 17, 2020); Extension of Limited Waiver of the Minimum Slot Usage Requirement, 85 FR 63335 (Oct. 7, 2020); and FAA Policy Statement: Limited, Conditional Extension of COVID–19 Related Relief for the Summer 2021 Scheduling Season (Docket No. FAA–2020–0862–0302).

[5] FAA Policy Statement: Limited, Conditional Extension of COVID–19 Related Relief for the Summer 2021 Scheduling Season (Docket No. FAA–2020–0862–0302).

[6] Notice of proposed extension of a limited, conditional waiver of the minimum slot usage requirement for all international operations, 86 FR 52114 (Sep. 20, 2021).

Current COVID–19 Situation

Since FAA's January 13, 2021, policy statement granting a limited, conditional extension of COVID–19-related relief at slot-controlled airports and IATA Level 2 airports in the United States, COVID–19 has continued to cause disruption globally and the timeline for recovery from this global pandemic remains uncertain. The World Health Organization (WHO) reports COVID–19 cases in more than 200 countries, areas, and territories worldwide.[7] For the week ending October 10, 2021, the WHO reported 2.8 million new COVID–19 cases and just over 46,000 new deaths, bringing the cumulative total to more than 237 million reported COVID–19 cases and more than 4.8 million deaths globally since the start of the COVID–19 pandemic.[8]

The WHO reports that it is monitoring multiple variants globally; currently the WHO has classified four different variants as ''variants of concern'' and two different variants as ''variants of interest.'' [9] The Center for Disease Control (CDC) is monitoring all variants of COVID–19 in the United States.[10] The CDC has listed the Delta variant as a variant of concern and warns that it spreads more easily and quickly and may cause more severe cases than the other variants.[11] However, the CDC reports that so far, studies suggest that the current Food and Drug Administration (FDA)-approved or authorized vaccines do work against the circulating variants.[12]

On January 21, 2021, President Biden announced the National Strategy for the COVID–19 Response and Pandemic Preparedness, a national strategy to beat the COVID–19 pandemic.[13] The strategy is a comprehensive plan that starts with restoring public trust and mounting an aggressive, safe, and effective vaccination campaign while continuing with the steps that stop the spread like expanded masking, testing, and social distancing. On September 9, 2021, President Biden announced a six-pronged approach to expand vaccinations, provide booster shots, keep schools safely open, increase testing and masking, protect the economic recovery, and improve care for those with COVID–19.[14]

Currently three COVID–19 vaccines have been authorized for emergency use or approved by the FDA.[15] As of October 17, 2021, 57 percent of Americans are fully vaccinated and 65.9 percent of Americans have received at least one dose.[16] Increased rates of vaccination in the U.S., along with other measures to stop the spread have resulted in an overall decline of the U.S. COVID–19 infection rate since the previous COVID–19 waiver proceeding. However, cases increased again following the U.S. reaching its lowest rates of infection experienced since the week of March 16, 2020 (79,358 confirmed new cases for the week of June 14, 2021, reflected the lowest rate of infection since the week of March, 16, 2020).[17] When the FAA extended COVID–19-related relief on January 13, 2021, the number of confirmed new cases of COVID–19 in the U.S. for the week of January 11, 2021, based on WHO data, was 1,580,016.[18] For the week of October 3, 2021, which is the most recent week for which data is available, the WHO reports 653,837 confirmed new cases in the United States.[19]

The U.S. is attempting to distribute vaccines globally to help vaccination numbers improve.[20] On August 18, 2021, President Biden announced that in the months of June and July the United States had donated 100 million doses and that in the coming months of fall and early winter another 100 million boosters and 200 million

[7] *https://covid19.who.int/table.*

[8] COVID–19 weekly epidemiological update, October 13, 2021, available at: *https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports. See also https://covid19.who.int/ for WHO COVID–19 Dashboard with the most current number of cases reported.*

[9] *https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/.*

[10] Center for Disease Control (CDC), About Variants of the Virus that Causes COVID–19, available at: *https://www.cdc.gov/coronavirus/2019-ncov/variants/variant.html.*

[11] *Id.*

[12] *Id. See also https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/work.html.*

[13] *https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf.*

[14] President Biden's COVID–19 Plan | The White House.

[15] *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.*

[16] CDC, COVID–19 Vaccinations in the United States, updated October 17, 2021, available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

[17] *https://covid19.who.int/region/amro/country/us.*

[18] FAA Policy Statement: Limited, Conditional Extension of COVID–19 Related Relief for the Summer 2021 Scheduling Season. (Docket No. FAA–2020–0862–0302). *See also https://covid19.who.int/region/amro/country/us.*

[19] COVID–19 weekly epidemiological update, October 13, 2021, available at: *https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports See also https://covid19.who.int/region/amro/country/us.*

[20] *https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/03/statement-by-president-joe-biden-on-global-vaccine-distribution/.*

additional doses will be donated to other countries.[21]

The United States is moving to a system of vaccine verification to facilitate international travel to/from the United States. There remain a number of travel advisories and foreign government restrictions that are affecting the demand and operational flexibility of U.S. and foreign carriers that serve Level 2 and Level 3 airports from some international destinations.

Standard Applicable to This Waiver Proceeding

The FAA reiterates the standards applicable to petitions for waivers of the minimum slot usage requirements in effect at DCA, JFK, and LGA, as discussed in FAA's initial decision granting relief due to COVID–19 impacts.[22] At JFK and LGA, each slot must be used at least 80 percent of the time.[23] Slots not meeting the minimum usage requirements will be withdrawn. The FAA may waive the 80 percent usage requirement in the event of a highly unusual and unpredictable condition that is beyond the control of the slot-holding air carrier and which affects carrier operations for a period of five consecutive days or more.[24]

At DCA, any slot not used at least 80 percent of the time over a two-month period also will be recalled by the FAA.[25] The FAA may waive this minimum usage requirement in the event of a highly unusual and unpredictable condition that is beyond the control of the slot-holding carrier and which exists for a period of nine or more days.[26]

When making decisions concerning historical rights to allocated slots, including whether to grant a waiver of the usage requirement, the FAA seeks to ensure the efficient use of valuable aviation infrastructure while maximizing the benefits to airport users and the traveling public. This minimum usage requirement is expected to accommodate routine cancelations under all but the most unusual circumstances. Carriers proceed at risk if, at any time prior to a final decision, they make decisions in anticipation of the FAA granting a slot usage waiver.

Summary of Comments and Information Submitted

The FAA received comments on the proposal from 32 stakeholders and other persons including IATA, Airlines for America (A4A), the Cargo Airline Association (CAA), Airports Council International-North America (ACI–NA), Port Authority of New York and New Jersey (PANYNJ), Metropolitan Washington Airports Authority (MWAA), Exhaustless Inc. (Exhaustless), 4 U.S. carriers, 12 foreign carriers, 7 individuals, and 2 anonymous commenters.[27] A majority of commenters including IATA, A4A, and all commenting U.S. and foreign carriers except for CAA, generally support FAA's proposal though some commenting carriers have requested certain modifications. In addition, the FAA received one clarifying question from PaxEx.Aero.

Commenters Who Support FAA's Proposal

MWAA, EVA Air, Etihad Airways, Lot Polish Airlines, China Airlines, Singapore Airlines, Aer Lingus, Air New Zealand, British Airways, and Emirates commented supporting FAA's proposal. MWAA supports ''the FAA's decision to limit the continuation of the conditional waiver to international operations'' and that the ''restoration of the 80 percent slot utilization requirement for domestic operations recognizes that domestic air travel is rebounding.'' The foreign carriers that commented in support of FAA's proposal generally stated that international demand for air travel has not yet recovered from COVID–19-related impacts and that FAA's proposal provides the airline community needed flexibility and supports the long-term viability of airlines operations and networks.

Commenters Who Support FAA's Proposal With Requested Modifications

Avianca Airlines, Delta Air Lines (Delta), A4A, IATA, ACI–NA, Iberia Airlines, Tap Air Portugal, PANYNJ, Spirit Airlines (Spirit), United Airlines (United), Southwest Airlines (Southwest), and one individual support FAA's proposal but made additional requests or comments. IATA states that it agrees with the FAA that ''the industry has not seen any meaningful recovery from the circumstances it faced when the FAA last provided a waiver for the Summer 2021 season.'' IATA believes that this ''combined with the late notice of this relief so close to season start, warrants the full, conditional waiver to be extended for the Winter 2021–22 season.'' However, IATA states that it ''believes that the WASB offers the most sustainable solution.'' [28] In addition IATA asks the FAA to reconsider the proposed return date of October 4, 2021, and to instead set the return date ''two weeks after the publication of the final order in the **Federal Register**.''

A4A supports FAA's proposal stating that it provides ''operational certainty'', ''simplicity'', and ''fairness and equity.'' A4A submitted additional requests including that FAA ''maintain a reciprocity requirement'', ''incorporate flexibility into slot return rules to allow the initial slot return deadline to be 2 weeks from the Final FR publication'', ''clarify that the historic baseline is the Winter 2019 season'', and ''support international slot usage''. A4A requests the FAA ''permit a two-week slot return notice requirement for the first two weeks after a final notice is issued and thereafter revert to a four week slot return notice requirement'' given the timing of the final notice. A4A also asks the FAA to ''clarify that the Historic Baseline is the Winter 2019 Season.'' Specifically, A4A asks that the FAA to ''permit carriers to provide evidence that would demonstrate the W19 schedule and the historical international slot times to account for the many adjustments that must be made over time.'' In addition A4A asks that the FAA not use the Official Airline Guide data published at the time the final notice is issued because ''the U.S. is one of the last countries to finalize a W21 policy and carriers have already taken action to adjust some published schedules based on previous slot return deadlines imposed by foreign jurisdictions.'' Finally, A4A asks that the FAA support international slot usage by giving carriers ''the ability to utilize one-half of a historic international slot pair and waive the

[21] *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/08/18/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-2/*.

[22] *See* 85 FR 15018 (Mar. 16, 2020).

[23] Operating Limitations at John F. Kennedy International Airport, 85 FR 58258 (Sep. 18, 2020); Operating Limitations at New York LaGuardia Airport, 85 FR 47065 at 58255 (Sep. 18, 2020).

[24] At JFK, historical rights to operating authorizations and withdrawal of those rights due to insufficient usage will be determined on a seasonal basis and in accordance with the schedule approved by the FAA prior to the commencement of the applicable season. *See* JFK Order, 85 FR at 58260. At LGA, any operating authorization not used at least 80 percent of the time over a two-month period will be withdrawn by the FAA. *See* LGA Order, 85 FR at 58257.

[25] *See* 14 CFR 93.227(a).

[26] *See* 14 CFR 93.227(j).

[27] The FAA notes that two carriers submitted comments marked as containing proprietary information (PROPIN). The information contained within these comments was consistent with information submitted by other airline industry commenters. The FAA will maintain the confidentiality of this information to the extent permitted by law.

[28] A summary of the Worldwide Airport Slot Board (WASB) proposal for Winter 2021/2022 was included in an annex to IATA's June 4, 2021 petition, which has been placed in the docket for this proceeding.

other half to maximize utilization of planned operations.''

Delta supports the FAA's proposal stating that ''COVID–19 continues to cause disruption in global air travel and the timeline for recovery remains fluid and unpredictable.'' Noting that ''in contrast to the resurgence of domestic travel we are seeing in the United States, the global pandemic continues to depress international air travel demand—necessitating the extension of the existing slot waiver framework for international flying.'' While Delta fully supports the Department's proposal in principle, Delta asks ''the Department to modify the initial October 4, 2021 slot return deadline proposed in the notice to avoid compliance issues.'' Specifically, Delta asks for a two-week extension of the four-week advance slot return condition of the waiver. Finally, Delta provided responses to the individualized questions posed to carriers in FAA's proposal.

United commented that it adopts and incorporates by reference the comments filed by A4A as well as supports and endorses IATA's comments supporting the full season extension of FAA's existing conditional waiver. United supports FAA's proposal stating that ''the proposed COVID–19 Relief Notice continues to recognize the importance to international commerce of granting reciprocal waivers and the significance of affording parallel relief to Level 2 and Level 3 airports and promotes certainty, stability, and fairness across the industry.'' In addition, United urges the FAA ''to not grant slot historic status/historic precedence at Level 3 airports or priority consideration at Level 2 airports to ad hoc movements allocated during the Winter 2020 season unless the airport is below the declared capacity limit at the time of the ad hoc movement.'' Moreover, United disagrees that COVID–19 is causing structural and operational changes to the airline industry and asserts that ''the pandemic is not the new normal.'' Finally, United provided responses to the individualized questions posed to carriers in FAA's proposal.

Spirit comments that it supports FAA's proposal to end the ''limited, conditional waiver of the minimum slot usage requirement for domestic operations.'' Spirit notes that it does not oppose continuing the waiver ''for an additional season for international operations.'' However, Spirit states that it ''assumes the FAA will continue to approve operations by carriers that have been operating with otherwise unused international slots and authorizations during the current season to continue using those operating times if the holder does not reinstate service for the Winter 21–22 season.'' In addition, Spirit states that it ''supports the FAA's plan to require domestic carriers to establish that specific slot/authorizations were in fact used for international operations pre-pandemic.'' Spirit asks the FAA ''to remain vigilant to prevent large domestic slot holders to use loopholes to retain slots/authorizations using a range of anticompetitive tricks.''

Southwest supports FAA's proposal stating that ''recognizing that numerous COVID-related circumstances continue to inhibit international air travel uniquely, the DOT has wisely limited its proposed waiver of slot usage requirements to international operations.'' In addition, Southwest believes that FAA's decision not to grant further COVID-related usage waivers for domestic operations will increase competition which will benefit ''travelers, airports, communities, and the national economy.''

ACI–NA is supportive of FAA's proposal to ''restore slot utilization requirements for domestic flight beginning in W21.'' ACI–NA points out that the FAA has stated that ''there may come a point in time which ongoing waivers to preserve pre-COVID slot holdings could impede the ability of airports and airlines to provide services that may benefit the economy'' and ACI–NA believes ''the end of W21 is that point in time.''

PANYNJ supports FAA's decision to extend slot usage waivers for international operations only for the Winter 2021/2022 Scheduling Season. PANYNJ states that the decision to enforce utilization requirements for domestic flight ''reflects the strong recovery in domestic demand and will serve the public interest by ensuring valuable airport infrastructure is used to deliver crucial air service to our customers and help drive our region's economic recovery.'' PANYNJ requests ''greater visibility and information relative to returned capacity and reallocation under the usage waivers.'' In addition, PANYNJ asserts that ''carriers that have clearly and publicly communicated the indefinite discontinuation of operations at capacity constrained airports should not be waiver eligible without clear documentation to both FAA and the airport operator of plans to recommence operations within a reasonable timeframe'' and otherwise PANYNJ recommends ''the slots be returned to the pool for re-allocation.''

Avianca Airlines supports FAA's proposal however requests more flexibility in the usage threshold, such as a ''50/50'' minimum usage requirement, for slots newly allocated for W21. Iberia Airlines supports FAA's proposal and asserts that ''the recovery period has not yet arrived and that we are still in a period of uncertainty and waiting for demand.'' In addition, Iberia requests the reciprocity as a condition be removed. Tap Air Portugal supports FAA's proposal but notes that it will ''have to fight for the reciprocity in the EU, to have real benefits from the relief.''

Commenters Who Oppose the FAA's Proposal

CAA, seven individuals, two anonymous commenters, and Exhaustless oppose FAA's proposal to continue COVID–19-related relief for international operations only.

CAA opposes FAA's proposal to extend relief from minimum slot usage requirement for international operations. CAA submits that it is ''in the public interest for the FAA to require carriers that cannot use slots or timings in Winter 2021/2022 Season to return them to the FAA permanently.'' CAA states that it is ''fully aware of the daunting operating challenges facing both airports and airlines in an environment poisoned by COVID'' and that ''airlines should not be penalized for their temporary inability to fully utilize their slots and other operating rights as a result of government travel restrictions and drastically reduced passenger demand caused by the COVID pandemic.'' However, CAA believes that ''the high demand for air cargo and the location and time sensitive nature of the demand for e-commerce air cargo deliveries mean that air cargo services need the opportunity to secure slots and authorizations at peak times with historic rights to close in airports in the northeast as ever before.'' CAA states that ''the *ad hoc* slots and authorizations that waivers have made available do not substitute for slots or approved operating times that have a greater likelihood of securing long-term access for association members.'' In addition, due to the continued national emergency and the roll of all-cargo industry, CAA asserts that ''the slots or authorizations at Level 2 airports not needed by passenger airlines should be available for temporary allocation to cargo airlines rather than being un- or underused.'' Moreover, CAA urges the FAA to consider ''a longer-term solution to avoid serial, last-minute renewals of slot use waivers in the future'' and ''begin working toward a long-term plan on rights reallocation to account for the need for expansions and retiming of all-cargo services as an important component of competition.'' Finally,

CAA asks that if the FAA extends a limited waiver, that the FAA ''clearly define the basis any U.S. carrier might use to claim a waiver; describe how it will evaluate whether any individual slot or authorization will qualify for a waiver; and permit further public comment on those criteria.''

The individual and anonymous commenters believe that demand for domestic air travel has not recovered to a point that warrants discontinuing relief and that FAA's proposal will result in unnecessary flights that would be detrimental from an environmental perspective. However, one individual commenter states that they ''oppose continued slot usage relief'' because ''gate space is a scarce resource and the FAA should make every effort to utilize this space to maximize productivity and encourage economic recovery with airlines who believe they can successfully repurpose this space.'' This individual commenter states that they ''favor JetBlue's opinion that the DOT/FAA enable a case-by-case evaluation for limited exemptions based on extreme circumstances such as boarder [sic] closure or conditions of entry that represent de facto border closure.''

Exhaustless opposes FAA's proposal as unlawful, contending the FAA has no authority to administer runway slots or manage schedules and that ''[t]he only decision before the FAA is whether to voluntarily continue to violate the law or to extricate itself from this regulatory taking and illegal subsidy to a conspiracy.''

Clarifying Question

PaxEx.Aero sent an email to the FAA slot office on September 17, 2021, asking the FAA to clarify how the Agency will ''determine what slots are international service'' and if it will be ''from 2019/2020 scheduled levels.'' The FAA sent a response email on September 20, 2021, that quoted the portion of FAA's proposal that addressed PaxEx.Aero's question. A copy of the communication has been included in the docket of this proceeding.

Discussion of Continued Relief for International Operations Only for the Winter 2021/2022 Scheduling Season

At the present time, U.S. domestic air travel demand and U.S. vaccination rates have reached a level that the FAA believes no longer justifies COVID–19-related slot usage relief domestically. However, COVID–19 continues to present a highly unusual and unpredictable condition for international operations that is beyond the control of carriers. As demonstrated in comments submitted by carriers and industry advocates, passenger demand for international air travel continues to be depressed as a result of COVID–19. The continuing impacts of COVID–19 on global aviation are dramatic and extraordinary, with an unprecedented decrease in passenger demand for international air travel globally.

As with the proposal, the FAA acknowledges the need for slot holders to have some flexibility in decision-making, in regard to international operations, as the severe impacts of the COVID–19 pandemic continue globally, but note it is not the policy of the Department of Transportation (DOT) to use slot and Level 2 rules to reserve capacity for historic incumbent carriers until demand returns to predetermined levels. Instead, it is the policy of the DOT to encourage high utilization of scarce public infrastructure. Under the established standard, slot usage waivers are generally used to address short-term, unpredictable shocks to demand or capacity that are beyond carriers' control. After 19 months of experience, the DOT believes it is becoming apparent that COVID–19 is causing structural and operational changes to the airline industry; the industry is adapting; and the issuance of waivers should not hinder that adaptation. As previously stated, at some point in time, repeated waivers to preserve pre-COVID slot holdings will impede the ability of airports and airlines to provide services that benefit the overall national economy and make appropriate use of scarce public assets. Therefore, the FAA emphasizes that operators should not assume further relief on the basis of COVID–19 for international operations will be forthcoming beyond the end of the Winter 2021/22 scheduling season.

Based on the comments received in this proceeding, the FAA has determined to make available to slot holders at DCA, JFK, and LGA a waiver from the minimum slot usage requirements, for international operations only, due to continuing COVID–19 impacts through March 26, 2021, subject to the following conditions:

(1) All slots not intended to be operated must be returned at least four weeks prior to the date of the FAA-approved operation to allow other carriers an opportunity to operate these slots on an *ad hoc* basis without historic precedence. As explained further below, compliance with this condition is required for operations scheduled from November 22, 2021, through the duration of this relief; therefore, carriers must begin notifying the FAA of Winter returns by October 25, 2021. Slots operated as approved on a non-historic basis in Winter 2021/2022 will be given priority over new demands for the same timings in the next equivalent season (Winter 2022/2023) for use on a non-historic basis, subject to capacity availability and consistent with established rules and policies in effect in the United States.[29] [30] Foreign carriers seeking priority under this provision will be required to represent that their home jurisdiction will provide reciprocal priority to U.S. carrier requests of this nature.

(2) The waiver does not apply to slots newly allocated for initial use during the Winter 2021/2022 season. New allocations meeting minimum usage requirements remain eligible for historic precedence. The waiver does not apply to historic in-kind slots within any 30-minute or 60-minute time period, as applicable, in which a carrier seeks and obtains a similar new allocation (*i.e.,* arrival or departure, air carrier or commuter, if applicable); and,

(3) The waiver does not apply to slots newly transferred on an uneven basis (*i.e.,* via one-way slot transaction/lease) since October 15, 2020, for the duration of the transfer.[31] Slots transferred prior to this date may benefit from the waiver if all other conditions are met. Slots granted historic precedence for subsequent seasons based on this relief are not eligible for transfer if the slot holder ceases all operations at the airport.

In addition, an exception may be granted to these conditions based on any government restriction that prevents or severely restricts international travel to specific airports, destinations (including intermediate points) or

[29] Consistent with the FAA's final policy statement issued January 13, 2021, this priority applies to slot or schedule requests for Winter 2022/2023, which are comparable in timing, frequency, and duration to the non-historic ad hoc approvals made by the FAA for Winter 2021/2022. This priority does not affect the historic precedence or priority of slot holders and carriers with schedule approvals, respectively, which meet the conditions of the waiver during Winter 2021/2022 and seek to resume operating in Winter 2022/2023. The FAA may consider this priority in the event that slots with historic precedence become available for permanent allocation by the FAA.

[30] Although the FAA is extending the four-week rolling return policy consistent with the Summer 2021 waiver, any carrier returning full-season slots or schedule approvals at an airport outside the United States and associated with a route to the United States will generally be expected to similarly return the complementary full-season U.S. slot or schedule approval to the FAA for re-allocation on a non-historic or *ad hoc* basis.

[31] The FAA has determined not to revise this condition to include a buffer period for new transfers to be completed and still benefit from this waiver. Therefore, this policy will remain in effect continuously from the initial effective date of October 16, 2020.

countries for which the slot was held. This exception applies under extraordinary circumstances only in which a carrier is able to demonstrate that the ability to operate a particular flight or comply with the conditions of the proposed waiver is prevented or severely restricted due to an unpredictable official governmental action related to COVID–19. This exception includes minor modifications compared to the exception currently in effect for the Summer 2021 season.[32] The FAA seeks to provide greater flexibility in allowing exceptions under certain circumstances based on issues that have arisen in the course of implementing the relief currently available. Official government actions that may qualify for this exception, include—

- Government travel restrictions based on nationality, closed borders, government advisories related to COVID–19 that warn against all but essential travel, or complete bans on flights from/to certain countries or geographic areas.
- Government restrictions related to COVID–19 on the maximum number of arriving or departing flights and/or the number of passengers on a specific flight or through a specific airport.
- Government restrictions on movement or quarantine/isolation measures within the country or region where the airport or destination (including intermediate points) is located.
- Government-imposed closure of businesses essential to support aviation activities (*e.g.,* closure of hotels, ground handling suppliers, etc.).
- Governmental restrictions on airline crew, including unreasonable entry requirements or unreasonable testing and/or quarantine measures.

This exception is being administered by the FAA in coordination with the Office of the Secretary of Transportation (OST). The extraordinary circumstances exception in this slot usage relief is limited to the scope of the relief otherwise provided by this waiver; U.S. carriers should not expect to rely on the extraordinary circumstances exception for relief for domestic operations.

Moreover, the FAA has determined to extend through Match 26, 2021, its COVID–19-related policy for prioritizing flights canceled at designated IATA Level 2 airports in the United States (EWR, LAX, ORD and SFO), for purposes of establishing a carrier's operational baseline in the next corresponding season, subject to the following conditions:

(1) All schedules as initially submitted by carriers and approved by the FAA and not intended to be operated must be returned at least four weeks prior to the date of the FAA-approved operation to allow other carriers an opportunity to operate these times on an *ad hoc* basis without historic precedence. Compliance with this condition is required for operations scheduled from November 22, 2021, through the duration of this relief; therefore, carriers must begin notifying the FAA of Winter returns by October 25, 2021. Schedules operated as approved on an *ad hoc* basis in Winter 2021/2022 will be given priority over new demands for the same timings in the next equivalent season (Winter 2022/2023) for use on an *ad hoc* basis, subject to capacity availability and consistent with established rules and policies in effect in the United States. Foreign carriers seeking priority under this provision are required to represent that their home jurisdiction will provide reciprocal priority to U.S. carrier requests of this nature; and,

(2) The priority for FAA schedules approved for Winter 2021/2022 does not apply to net-newly approved operations for initial use during the Winter 2021/2022 season. New approved times will remain eligible for priority consideration in Winter 2022/2023 if actually operated in Winter 2021/2022 according to established processes.

Consistent with the final decision for slot-controlled airports, limited exceptions may be granted from either or both of these conditions at Level 2 airports under extraordinary circumstances due to any government restriction that prevents or severely restricts travel to specific airports, destinations (including intermediate points), or countries for which the slot was held, as discussed previously with respect to slot-controlled airports. If the exception is determined not to apply, carriers will be expected to meet the conditions for relief or operate consistent with standard expectations for the Level 2 environment.

The FAA believes a conditional extension of relief for international operations only, through March 26, 2022, is reasonable due to fluctuating travel restrictions and ongoing economic and health impacts of COVID–19 internationally. The proposed relief is expected to provide carriers with flexibility during this unprecedented situation and to support the long-term viability of international operations at slot-controlled and IATA Level 2 airports in the United States.[33] Continuing relief for this additional period is reasonable to mitigate the impacts on passenger demand for international air travel resulting from the spread of COVID–19 worldwide.

The current waiver policy was developed based on a balancing of various conflicting stakeholder interests to the extent permissible and within the bounds of the current slot rules and schedule policies in effect in the United States. None of the comments supporting alternative proposals have persuaded the FAA that this policy should be supplanted or discontinued at this juncture of the ongoing COVID–19 emergency. The FAA believes the conditions associated with the relief provided to date and in this decision are generally comparable to the WASB package and remain necessary to strike a balance between competing interests of incumbent carriers and those carriers seeking new or increased access at these historically-constrained airports, as well as to ensure the relief is appropriately tailored to reduce the potential to suppress flight operations for which demand exists.

Discussion of Comments Regarding Administering Relief Under This Waiver

The FAA received comment requesting clarification on how it will evaluate whether any individual slot or schedule approval will qualify for a waiver and whether the Winter 2019/2020 season would be used to establish a carrier's historic international operational baseline. The conditional relief described in this notice is available for international operations that would have been operated in the Winter 2021/2022 season, but for COVID–19 impacts. This conditional relief is available to domestic carriers on a scale that is generally comparable to each carrier's pre-COVID level of international service. The FAA will generally evaluate any request for relief from U.S. carriers for the Winter 2021/2022 scheduling season based on historical levels of operations to foreign points as demonstrated in published schedules from the Winter 2019/2020 scheduling season. Domestic carriers seeking relief for a particular operation

[32] *See* FAA Policy Statement: Limited, Conditional Extension of COVID–19 Related Relief for the Summer 2021 Scheduling Season (Docket No. FAA–2020–0862–0302).

[33] The FAA is responsible to develop plans and policy for the use of navigable airspace and assign by regulation or order the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. *See* 49 U.S.C. 40103(b)(1). The FAA manages slot usage requirements under the authority of 14 CFR 93.227 at DCA and under the authority of Orders at LGA and JFK. *See* Operating Limitations at John F. Kennedy International Airport, 85 FR 58258 (Sep. 18, 2020); Operating Limitations at New York LaGuardia Airport, 85 FR 58255 (Sep. 18, 2020).

under the waiver will need to provide the FAA, if not readily apparent from FAA records and historic published schedule data, alternative supplemental information that predates FAA's proposal (86 FR 52114) to demonstrate intent to use a slot or approved operating time for an international destination. The FAA will not accept evidence of intent to use a particular slot or approved operating time for an international flight during the Winter 2021/2022 season, if the information is dated after FAA's proposal issued September 16, 2021.

The FAA is persuaded by commenters that have requested the FAA modify the initial October 4, 2021, slot return deadline due to compliance issues attributable to the timing of FAA's final waiver decision. The slot return deadline, as proposed, would have required airlines to return slots associated with flights to be operated on November 1, 2021, by October 4, 2021 (*i.e.,* four weeks in advance). Due to the timing of this final notice, the FAA will require compliance with the 4-week advance slot return condition for operations scheduled from November 22, 2021 (instead of from October 31, 2021) through the duration of the Winter 2021/2022 season. Accordingly, carriers must begin notifying FAA of Winter returns by October 25, 2021 (instead of October 4, 2021). The FAA believes this change is reasonable because it would be impracticable for carriers to meet the proposed October 4, 2021, return deadline given the timing of the FAA's final waiver policy.

The FAA also received a comment requesting carriers be given flexibility to ''utilize one-half of a historic international slot pair and waive the other half to maximize utilization of planned operations.'' The FAA administers slots and schedule approvals on an individualized basis, not as slot pairs. Indeed, some slot allocations or schedule approvals are paired with operations outside of slot-controlled or schedule-facilitated hours. Due to slots not being administered in pairs the flexibility requested is already built into the underlying rules and waiver policy. Carriers therefore will have flexibility to and are encouraged to, operate any individual slot or schedule approval that does not necessitate this relief.

In addition, the FAA received a comment requesting that the FAA ''not grant slot historic status/historic precedence at Level 3 airports or priority consideration at Level 2 airports to ad hoc movements allocated during the Winter 2020 season unless the airport is below the declared capacity limit at the time of the ad hoc movement.'' The FAA notes that the conditions of this waiver provide that slots operated as approved on a non-historic basis in Winter 2021/2022 will be given priority over new demands for the same timings in the next equivalent season (Winter 2022/2023) for use on a non-historic basis, *subject to capacity availability and consistent with established rules and policies in effect in the United States* (emphasis added). However, the FAA further notes that this stated priority was initially added in FAA's Summer 2021 Policy Statement.[34] The FAA has flexibility under usual rules and procedures to apply the priority even in the absence of this.

Further, FAA received comment requesting that carriers that have ''clearly and publicly communicated the indefinite discontinuation of operations at capacity constrained airports should not be waiver eligible without clear documentation to both FAA and the airport operator of plans to recommence operations within a reasonable timeframe'' should be returned to the FAA for re-allocation. The FAA noted that the third condition for slot-controlled airports expressly states ''slots granted historic precedence for subsequent seasons based on this relief are not eligible for transfer if the slot holder ceases all operations at the airport.'' However, aside from the conditions provided in this relief, other established local rules in the United States continue to apply.

Furthermore, the FAA received comment requesting ''greater visibility and information relative to returned capacity and reallocation under the usage waivers.'' The FAA to date has accommodated all *ad hoc* requests for operations (passenger and cargo) under the current waiver based on continued depressed demand and associated returns before the four-week deadline. Generally, after the first weeks the Summer 2021 waiver was in effect, the majority of slot and schedule returns have been made in at least one-month increments. By June 2021, sufficient returns had been made to allow the FAA to accommodate most requests for *ad hoc* flights through the end of the season on October 30, 2021. Most of the *ad hoc* increases have been by domestic and foreign air carriers for cargo operations at JFK and by domestic carriers for passenger operations at EWR. In addition, cargo and passenger carriers at several airports requested and were approved for *ad hoc* retiming of some flights previously approved for different times. Some of those carriers indicated these changes are intended to reflect temporary adjustment to their network operations related to COVID–19 impacts. Other requests for *ad hoc* slots or flight approval have been primarily requests for restoration of short-term flights that were previously returned and additional flights often identified as repatriation or special cargo flights. Despite significant returns, the FAA has not received any requests for *ad hoc* flights at DCA and only a small number of requests for *ad hoc* flights at LGA beyond limited inquiries from carriers seeking permanent slot allocations.

Finally, the FAA received comments from some individuals and anonymous commenters suggesting that relief should be continued for domestic operations. The FAA notes that no U.S. carrier or industry advocate has petitioned the FAA for such continued relief for domestic operations. Indeed, comments from industry reflect a consensus view that demand in the United States for domestic travel is rebounding and further relief would be detrimental to recovery.

Discussion of Additional Issues Raised in Comments

The FAA received individualized responses from some carriers to the questions posed to carriers in FAA's proposal. This information will be useful in FAA's administration of this waiver and the additional information provided is consistent with the policy in this final notice. To the extent that some commenters question FAA's authority to manage slots and facilitate schedules or seek to supersede this proceeding entirely by encouraging the federal government to establish broader aviation industry recovery policies and/or change the regulatory policy landscape for managing slots and schedule facilitation in the United States, such comments are deemed to be outside the scope of this proceeding.

Decision

The FAA has determined to extend through March 26, 2022, the COVID–19-related limited, conditional waiver of the minimum slot usage requirement at JFK, LGA, and DCA that the FAA has already made available through October 30, 2021, for international operations only. Similarly, the FAA has determined to extend through March 26, 2022, its COVID–19-related limited, conditional policy for prioritizing flights canceled at designated IATA Level 2 airports in the United States (EWR,

[34] FAA Policy Statement: Limited, Conditional Extension of COVID–19-Related Relief for the Summer 2021 Scheduling Season (Docket No. FAA–2020–0862–0302).

LAX, ORD, and SFO), for purposes of establishing a carrier's operational baseline in the next corresponding season, for international operations only. This relief is limited to slots and approved operating times used by any carrier for international operations only, through March 26, 2022, and will be subject to the same terms and conditions, with minor modifications, as previously explained herein.

As of the date of issuance of this notice, U.S. domestic air travel demand and vaccination rates have reached a level that the FAA believes no longer necessarily justifies COVID–19-related slot usage relief domestically. However, COVID–19 continues to present a highly unusual and unpredictable condition for international operations that is beyond the control of carriers. Indeed, foreign carriers in many parts of the world are prevented from operating to the United States due to governmental restrictions resulting from COVID–19. The continuing impacts of COVID–19 on global aviation are dramatic and extraordinary, with an unprecedented decrease in passenger demand for international air travel globally.

Therefore, the FAA believes an extension of conditional relief for international operations only, through March 26, 2022, is reasonable due to fluctuating travel restrictions and ongoing economic and health impacts of COVID–19 internationally. The available relief is expected to provide carriers with flexibility during this unprecedented situation and to support the long-term viability of international operations at slot-controlled and IATA Level 2 airports in the United States.[35] Continuing relief for this additional period is reasonable to mitigate the impacts on passenger demand for international air travel resulting from the spread of COVID–19 worldwide.

While the FAA is providing continued, conditional, relief through the Winter 2021/2022 season for international operations, carriers should not assume that further relief will be forthcoming beyond the end of the Winter 2021/2022 scheduling season. The FAA will review the facts and circumstances at the time of any future waiver requests; however, the FAA will also continue to consider the importance of providing access to the Nation's congested airports where there is capacity available. Slots are a scarce resource. Slot usage waivers accordingly are reserved for extraordinary circumstances. Even during an extraordinary period such as the COVID–19 pandemic, carriers should utilize their slots and operating authorizations efficiently, in accordance with established rules and policy, or relinquish those slots and authorizations to the FAA so that other carriers willing and able to make use of them can do so. The FAA cautions all carriers against altering plans for usage at slot-controlled and Level 2 airports in reliance upon a presumption that additional relief will be forthcoming, which is a decision on which the FAA has not made at this time. The presumption that carriers should apply in preparing for operations in future scheduling seasons is compliance with standard slot management and schedule facilitation processes.

The FAA reiterates its expectation that foreign slot coordinators will provide reciprocal relief to U.S. carriers. To the extent that U.S. carriers fly to a foreign carrier's home jurisdiction and that home jurisdiction does not offer reciprocal relief to U.S. carriers, the FAA may determine not to grant a waiver to that foreign carrier. The FAA acknowledges that some foreign jurisdictions may opt to adopt more strict provisions in response to this policy than they had otherwise planned. However, as previously explained, the FAA believes the conditions associated with the relief provided in this policy are necessary to strike a balance between competing interests of incumbent carriers and those carriers seeking new or increased access at these historically-constrained airports, as well as to ensure the relief is appropriately tailored to reduce the potential for a long-term waiver to suppress flight operations for which demand exists. A foreign carrier seeking a waiver may wish to ensure that the responsible authority of the foreign carrier's home jurisdiction submits a statement by email to *ScheduleFiling@dot.gov* confirming reciprocal treatment of the slot holdings of U.S. carriers

The FAA emphasizes that it strongly encourages carriers to return slots and approved schedules voluntarily as soon as possible and for as long a period as possible during the Winter 2021/2022 season, so that other airlines seeking operations on an *ad hoc* basis may do so with increased certainty. The rolling four-week return deadline is only a minimum requirement, and FAA anticipates that carriers may often be able to provide notice of cancellations significantly further in advance than four weeks. In both the Level 2 and slot-controlled environments, the FAA seeks the assistance of all carriers to continue to work with the FAA to ensure the national airspace system capacity is not underutilized during the COVID–19 pandemic.

Carriers should advise the FAA Slot Administration Office of COVID–19-related cancellations and return the slots to the FAA by email to *7-awa-slotadmin@faa.gov* to obtain relief. The information provided should include the dates for which relief is requested, the flight number, origin/destination airport, scheduled time of operation, the slot identification number, as applicable, and supporting information demonstrating that flight cancellations directly relate to the COVID–19 pandemic. Carriers providing insufficient information to clearly identify slots that will not be operated at DCA, JFK, or LGA will not be granted relief from the applicable minimum usage requirements. Carriers providing insufficient information to identify clearly changes or cancellations from previously approved schedules at EWR, LAX, ORD, or SFO will not be provided priority for future seasons.

Issued in Washington, DC, on October 18, 2021.

Lorelei Dinges Peter,

Assistant Chief Counsel for Regulations.

Virginia T. Boyle,

Vice President, System Operations Services.

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[35] The FAA is responsible to develop plans and policy for the use of navigable airspace and assign by regulation or order the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. *See* 49 U.S.C. 40103(b)(1). The FAA manages slot usage requirements under the authority of 14 CFR 93.227 at DCA and under the authority of Orders at LGA and JFK. *See* Operating Limitations at John F. Kennedy International Airport, 85 FR 58258 (Sep. 18, 2020); Operating Limitations at New York LaGuardia Airport, 85 FR 58255 (Sep. 18, 2020).

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. DOT–NHTSA–2021–0039]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; State Data Transfer for Vehicle Crash Information

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for approval of an extension of a currently approved information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) summarized below will be submitted to

the Office of Management and Budget (OMB) for review and approval. The ICR describes the nature of the information collection and its expected burden. The State Data Transfer (SDT) program is a voluntary collection of motor vehicle crash data that State agencies collect for their own needs. NHTSA received emergency clearance to conduct the information collection until December 31, 2021. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on June 1, 2021. One comment from the Governors Highway Safety Association (GHSA) was received supporting NHTSA's SDT data collection and the request for emergency clearance to expedite this effort.

DATES: Comments must be submitted on or before November 19, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the Office of Management and Budget at *www.reginfo.gov/public/do/PRAMain.* To find this particular information collection, select ''Currently under Review—Open for Public Comment'' or use the search function.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Michael Frenchik, Office of Data Acquisitions (NSA–0100), (202) 366–0641, National Highway Traffic Safety Administration, Room W53–303, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), a Federal agency must receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. In compliance with these requirements, this notice announces that the following information collection request will be submitted to OMB.

Title: State Data Transfer (SDT) for Vehicle Crash Information.

OMB Control Number: 2127–0753.

Form Numbers: None.

Type of Request: Approval of an extension without modification of a currently approved information collection.

Type of Review Requested: Regular.

Length of Approval Requested: Three years.

Summary of the Collection of Information: The State Data Transfer (SDT) program is a voluntary collection of motor vehicle crash data. State agencies collect this information about motor vehicle crashes on Police Accident Reports (PARs) [1] for their own needs. In general, a PAR includes information about the vehicles and individuals involved in a crash, injuries or fatalities resulting from a crash, roadway information, environmental information, information to reconstruct the crash scenes, etc. The SDT is a process through which participating States transfer their PAR data to NHTSA. SDT has two components that NHTSA's National Center for Statistics and Analysis (NCSA) calls protocols:

1. The *State Data System (SDS)* protocol obtains PAR crash data from States that submit data on an annual basis to NCSA. The data is submitted via electronic media, such as encrypted CD–ROM/DVD, or through secured mail or a secure file transfer protocol (SFTP). Files submitted through the SDS protocol are referred to as ''annual crash files.''

2. The *Electronic Data Transfer (EDT)* protocol obtains PAR crash data, crash reports or crash images from participating State crash systems through an electronic data transfer. Generally, this transfer occurs on a nightly basis following State data quality control checks and acceptance from each State's centralized database. The information is transmitted using Extensible Markup Language (XML) or JavaScript Object Notation (JSON) files through a web service using Hypertext Transfer Protocol Secure (HTTPS) protocol between a State's crash data system and NHTSA.

The SDT process allows States to submit all of their PAR data to NHTSA. NCSA will then use this data to develop a census of the participating State's crashes. The dataset will help NCSA identify existing and emerging highway safety trends and assess the effectiveness of motor vehicle safety standards and new and emerging technologies on vehicle and highway safety programs. NHTSA will also use the dataset to support NHTSA's Corporate Average Fuel Economy (CAFE) program. Specifically, NHTSA will use the data to analyze the effects vehicle mass has on fatalities in cost benefit analyses for CAFE rulemakings.

Description of the Need for the Information and Proposed Use of the Information: NHTSA plans to utilize the SDT data to identify existing and emerging highway safety trends, assess the effectiveness of motor vehicle safety standards, and study the impact of new and emerging technologies on vehicles and highway safety programs. For example, NHTSA plans to combine data from the SDT with information about the type of advanced driver assistance systems (ADAS) on crash-involved vehicles to estimate the effectiveness of vehicles equipped with ADAS technologies such as lane keeping support, automatic emergency braking, blind spot detection, etc.

NHTSA also plans to use the SDT data to automatically pre-populate the motor vehicle crash data it collects for several other NHTSA data collection programs. The following are brief descriptions of these data collection programs:

- FARS (OMB Control No. 2127–0006) is a nationwide census of fatalities caused by motor vehicle traffic crashes. In addition to PAR data, FARS includes detailed information regarding the location of the crash, the vehicles, and the people involved. FARS cases can also include toxicology report data, medical records, medical examiner reports, etc.[2]
- CRSS (OMB Control No. 2127–0714) is a nationally representative sample of police-reported crashes involving all types of motor vehicles, pedestrians, and cyclists, ranging from property-damage-only crashes to those that result in fatalities. CRSS data elements are a subset of the data elements on each State's PAR.[3]
- CISS (OMB Control Number 2127–0706) is a nationally representative sample of minor, serious, and fatal crashes involving at least one passenger vehicle—cars, light trucks, sport utility vehicles, and vans—towed from the scene. CISS collects data at both the crash level through scene analysis and the vehicle level through vehicle damage assessment together with injury coding. Data collected through CISS expands upon the information that is collected in a PAR.[4]
- The SCI Program provides NHTSA with the most in-depth crash data collected by the agency. The data collected ranges from basic information contained in routine police and insurance crash reports, to comprehensive data from special reports

[1] Police Accident Reports are also known as Police Crash Reports (PCRs) in some jurisdictions.

[2] Additional details about FARS and how the agency collects this information are available in the supporting statements for the ICR with OMB Control No. 2127–0006.

[3] Additional details about CRSS and how the agency collects this information are available in the supporting statements for the ICR with OMB Control No. 2127–0714.

[4] Additional details about CISS and how the agency collects this information are available in the supporting statements for the ICR with OMB Control No. 2127–0706.

produced by professional crash investigation teams. Hundreds of data elements relevant to the vehicle, occupants, injury mechanisms, roadway, and safety systems are collected for each of the over 100 crashes designated for study annually.

• NTS is a virtual data collection system designed to provide counts and details regarding fatalities and injuries that occur in non-traffic crashes and in non-crash incidents. NTS non-traffic crash data is obtained through NHTSA's information collections for CRSS and FARS. NTS non-crash injury data is based upon emergency department records from a special study conducted by the Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS) All Injury Program. NTS non-crash fatality data is derived from death certificate information from the Centers for Disease Control's National Vital Statistics System.

• CIREN combines crash data collection with professional multidisciplinary analysis of medical and engineering evidence to determine injury causation in every crash investigation conducted. The mission of the CIREN is to improve the prevention, treatment, and rehabilitation of motor vehicle crash injuries to reduce deaths, disabilities, and human and economic costs.

Until recently, the transfer of vehicle crash data from a State's crash data system to NHTSA's FARS, CRSS and CISS required individuals to manually enter State vehicle crash data into each of the crash data systems operated by NHTSA. The SDT program will allow NHTSA to automate the transfer of State motor vehicle crash data into NHTSA's other data collection efforts that use this information. NHTSA's SDT program will reduce the burden for manual data entry and result in more accurate, high quality and timely data to help save lives, prevent injuries, and reduce economic costs due to motor vehicle crashes.

In addition, the SDT data will be made available to other DOT agencies, such as the Federal Highway Administration and the Federal Motor Carrier Safety Administration, to support their mission to save lives on our national roadways.

Request for Emergency Clearance: NHTSA requested emergency clearance from OMB for the SDT information collection. NHTSA requested emergency clearance for the maximum permissible period under 5 CFR 1320.13 (f) to allow NHTSA to collect the information while it completes the normal clearance procedures. NHTSA sought emergency clearance because the data collected through the SDT program are critical to several high priority projects for this administration. The SDT data will be used to analyze the effects vehicle mass has on fatalities in cost benefit analyses for CAFE rulemakings. Executive Order 13990 requires NHTSA to ''as appropriate and consistent with applicable law, [. . .] consider publishing for notice and comment a proposed rule suspending, revising, or rescinding'' the SAFE II Rule ''by July 2021.'' Following the normal clearance procedures will not allow NHTSA to receive approval to collect and use this data before the deadline.

The Partnership for Analytics Research in Traffic Safety (PARTS) also needs this data to help determine the effectiveness of automated driver assistance systems (ADAS) with Departmental leadership expecting initial analyses later this year.

Given the priorities identified above, this information is needed before NHTSA can complete the normal clearance procedures under 5 CFR part 1320. OMB approved the emergency clearance through December 31, 2021.

60-Day Notice: On June 1, 2021, NHTSA published a notice in the **Federal Register** with a 60-day comment period soliciting comments on this ICR.[5] NHTSA received one comment from the Governors Highway Safety Association (GHSA). In their comment, GHSA expressed support for NHTSA's SDT data collection and the request for emergency clearance to expedite this effort. GHSA stated that it appreciates that the data collection is voluntary and agrees with NHTSA ''that several States will likely continue to face participation barriers.'' GHSA further noted that it understands that the electronic transfer of Stata crash data reduces time and cost to States that participate and will continue to partner with NHTSA to promote SDT.

Affected Public: State Governments.

This voluntary information collection involves State governments, and specifically the State agencies that collect crash data.

Estimated Number of Respondents: 38.

Currently, 31 States are voluntarily submitting their annual crash database to NHTSA using the SDS protocol once the Annual file is complete and 19 States are voluntarily submitting their State's data using the EDT protocol where the transfer occurs on a nightly basis. NHTSA estimates that, on average, in each of the next three years, there will be 31 States submitting data using the SDS protocol and 23 States submitting data using the EDT protocol. NHTSA estimates that there will be 15 States submitting data through both EDT and SDS. Therefore, NHTSA estimates the total number of respondents to be 38.

Frequency: The frequency of this information collection varies State-by-State, potentially from daily to annually, as agreed upon by NHTSA and the individual States. States participating in the SDS protocol typically send a file to NHTSA once a year with all the crashes occurring during a calendar year. A State will send these files when it has completed its quality control process. For the EDT States, the data is usually transferred every night with the crash cases that have completed the quality control process since the last nightly transfer.

Number of Reponses: NHTSA estimates total annual responses based on NHTSA's estimate that SDS protocol States will submit files once a year and EDT protocol States will send data to NHTSA automatically on a nightly basis. Therefore, NHTSA estimates that it will receive 31 SDS responses a year (31 SDS States × 1 annual response) and 8,395 EDT responses a year (23 EDT States × 365 nightly responses).

Estimated Total Annual Burden Hours: 683 hours.

SDT receives the crash data from States in two different ways. SDS information is obtained annually from States submitted in a more traditional method via electronic media through secured mail or a Secure File Transfer Protocol (SFTP). NHTSA assumes a participating State already has a centralized electronic crash database. Currently, 31 States are voluntarily submitting their annual crash database to NHTSA, with five States sending electronic media and 26 states uploading the database to an SFTP site. Since NHTSA accepts the States' centralized electronic crash database without changes, NHTSA estimates that it will require eight hours for a State Database Administrator to save a copy of the State's annual crash database onto a SFTP site or electronic media. We estimate an additional four hours will be required for an administrative assistant to package and send the electronic media to NHTSA.

To estimate the labor cost associated with submitting the SDS information, NHTSA looked at wage estimates for the type of personnel involved with copying, packaging and sending the database. NHTSA estimates the total labor costs associated with copying the database by looking at the average wage for Database and Network Administrator

[5] 86 FR 29354.

and Architects. The Bureau of Labor Statistics (BLS) estimates that the average hourly wage for Database and Network Administrator and Architects (Standard Occupational Classification #15–1240, May 2020) is $47.80.[6] The Bureau of Labor Statistics estimates that State and local government workers' wages represent 61.9% of total labor compensation costs.[7] Therefore, NHTSA estimates the hourly labor costs for copying the database to be $77.22 ($47.80 ÷ 61.9%) for Database and Network Administrator and Architects. The cost associated with the eight hours of Database and Network Administrator labor is estimated to be $617.76 per respondent.

For the 5 States sending electronic media, NHTSA estimates the total labor costs for packing and sending the database by looking at the average wage for Secretaries and Administrative Assistants. The BLS estimates that the average hourly wage for Secretaries and Administrator Assistants (Standard Occupational Classification #43–6014, May 2020) is $19.43.[8] By using the same estimate that wages represent 61.9% of the total compensation cost of labor, NHTSA estimates the total labor hour for packing and sending the database on electronic media to be $31.39. Therefore, the cost associated with the four hours to send the electronic media is estimated to be $125.56 per respondent.

Combining these copying and packing and sending burden estimates for SDS, NHTSA estimates that the total burden hours associated with this collection will be 268 (248 + 20 hours) hours and total labor cost associated with the collection will be $19,151 ($617.76 × 31 States) for copying and $628 ($125.56 × 5 States) for packing and sending, for a total of $19,779 ($19,151 + $628) for the SDS protocol.

SDS Burden Estimate Summary

Burden type	Respondents	Burden hours per respondent	Total burden hours	Labor cost per burden hour	Labor cost per respondent	Total labor cost
SDS Copying	31	8	248	$77.22	$617.76	$19,150,56 19,151
SDS Packing and sending	5	4	20	31.39	125.56	627.80 628
Total			268			19,779

The EDT protocol burden hour estimate is based on the level of effort reported by the States that have fully implemented SDT. NHTSA estimates that in each of the next three years, there will be two new States joining the 19 States already participating in SDT program using the EDT protocol. Therefore, NHTSA estimates that there will be, on average, 23 EDT protocol States in each of the next three years. Cost and burden estimates for the EDT protocol are divided in two: a one-time implementation effort, and an annual maintenance effort. Both estimates assume a participating State already has a centralized electronic crash database. The burden for the one-time implementation of the SDT program is estimated at 200 hours. NHTSA estimates that these hours will account for work done by State IT (150 hrs.) and FARS program personnel (50 hrs.).

Once implemented, the hourly burden on States associated with SDT maintenance is estimated at five hours per year, based upon currently participating States' experiences. This time is generally used to troubleshoot any connection issues or refine mapping protocols for any data elements that have changed.

NHTSA estimates the cost for IT personnel burden hours using the Bureau of Labor Statistics' mean wage estimate for Software developers and Programmers (Standard Occupational Classification # 15–1250) of $52.86.[9] The Bureau of Labor Statistics estimates that for State and local government workers, wages represent 61.9% of total compensation.[10] Therefore, the total hourly cost associated with the IT burden hours is estimated to be $85.40 per hour. The cost associated with the 150 hours of IT personnel labor is estimated to be $12,810.00 per respondent. Initial SDT implementation is also expected to involve 50 hours of FARS program personnel time. There is no additional cost to the States associated with these hours because these costs may be charged to the Federal Government through the FARS cooperative agreements. Thus, total labor cost for EDT implication costs per State are estimated to be $12,810.00. The total annual implementation burden cost per year is estimated to be $25,620 ($12,810.00 × 2 new State respondents).

After initial implementation of a SDT interface, the ongoing cost burden to participating States is estimated at 5 hours per State annually, based on a survey of currently participating States. Per the loaded labor rates for State IT staff outlined above, 5 hours of work translates to an estimated total annual maintenance burden of $427.00 per State respondent maintaining participation in the SDT program. NHTSA estimates that there will be, on average, 23 States participating in EDT program in each of the next three years. Therefore, the annual maintenance cost for the States is a total of $9,821.00 ($427.00 × 23 States) per year.

Combining these implementation and maintenance burden estimates for the EDT protocol, NHTSA estimates that the total burden hours associated with this collection will be 415 hours and total labor cost associated with the collection will be $35,441.00.

[6] *See* May 2020 National Occupational Employment and Wage Estimates United States, available at *https://www.bls.gov/oes/current/oes_nat.htm* (accessed April 16, 2021).

[7] *See* Table 1. Employer Costs for Employee Compensation by ownership (Dec. 2020), available at *https://www.bls.gov/news.release/ecec.t01.htm* (accessed April 16, 2021).

[8] *See* May 2020 National Occupational Employment and Wage Estimates United States, available at *https://www.bls.gov/oes/current/oes_nat.htm* (accessed April 16, 2021).

[9] See May 2020 National Occupational Employment and Wage Estimates United States, available at *https://www.bls.gov/oes/current/oes_nat.htm* (accessed April 16, 2021).

[10] Employer Costs for Employee Compensation by ownership (Dec. 2020), available at *https://www.bls.gov/news.release/ecec.t01.htm* (accessed April 16, 2021).

EDT BURDEN ESTIMATE SUMMARY

Burden type	Respondents	Burden hours per respondent	Total burden hours	Labor cost per burden hour	Labor cost per respondent	Total labor cost
EDT IT Implementation	2	150	300	$85.40	$12,810.00	$25,620.00 25,620
EDT Maintenance	23	5	115	85.40	427.00	9,821.00 9,821
Total	.....	.....	415	.....	.....	35,441

The total estimated burden for SDT is 683 (268 SDS + 415 EDT) and total estimated labor cost is $55,220 ($19,779 SDS + $35,441 EDT).

A summary of the burden estimates is provided in the table below.

SDT BURDEN ESTIMATE SUMMARY

Burden type	Respondents	Total annual responses	Total burden hours	Average burden hours per respondent	Total labor cost	Labor cost per respondent
SDS	31	31	268	9	$19,779	$638
EDT	23	8,395	415	18	35,441	1,541
Total	.....	.....	683	.....	55,220	.....

Estimated Total Annual Burden Cost: $0.

NHTSA does not expect that participating states will incur any costs beyond the labor hour cost associated with the burden hours.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (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 proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including 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.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Chou-Lin Chen,

Associate Administrator, National Center for Statistics and Analysis.

[FR Doc. 2021–22824 Filed 10–19–21; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2021–0091]

Senior Executive Service Performance Review Boards Membership

AGENCY: Office of the Secretary, Department of Transportation (DOT).

ACTION: Notice of Performance Review Board (PRB) appointments.

SUMMARY: DOT published the names of the persons selected to serve on Departmental PRBs.

FOR FURTHER INFORMATION CONTACT: Anne B. Audet, Director, Departmental Office of Human Resource Management (202) 366–2478.

SUPPLEMENTARY INFORMATION: The persons named below may be selected to serve on one or more Departmental PRBs.

(Authority: 5 U.S.C. 4314(c)(4))

Issued in Washington, DC, on September 14, 2021.

Keith E. Washington,

Deputy Assistant Secretary for Administration.

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

ALONZI, ACHILLE
ARNOLD, ROBERT E
BAKER, SHANA V
BEZIO, BRIAN R
BIONDI, EMILY CHRISTINE
BRIGGS, VALERIE ANNETTE
BURROWS, SHAY K
CHRISTIAN, JAMES C
CRONIN, BRIAN P
CURTIS, STEPHANIE
EVANS, MONIQUE REDWINE
EVERETT, THOMAS D
FINFROCK, ARLAN E JR
FLEURY, NICOLLE M
FOUCH, BRIAN J
GIGLIOTTI, DANA
GRIFFITH, MICHAEL S
HARTMANN, JOSEPH L
HESS, TIMOTHY G.
HUGHES, CAITLIN GWYNNE
JENSEN, GARY ALAN
KALLA, HARI
KEHRLI, MARK R
KNOPP, MARTIN C
LEONARD, KENNETH
LEWIS, DAVID A
LUCERO, AMY C
MAMMANO, VINCENT P
MARQUIS, RICHARD J
MCLAURY, KEVIN L
OSBORN, PETER W
PETTY, KENNETH II
POLLACK, STEPHANIE LYNN
REGAL, GERALDINE K
RICHARDSON, CHRISTOPHER S
RICHTER, CHERYL ALLEN
RICO, IRENE
ROGERS, ANDREW CHARLES
RUSNAK, ALLISON B
SCHAFTLEIN, SHARI M
SHAFFER, RHONDA C
SHEPHERD, GLORIA MORGAN
SOSA, MAYELA
STEPHANOS, PETER J
TURNER, DERRELL E
WALKER, CHERYL J
WINTER, DAVID R

WRIGHT, LESLIE JANICE

Federal Motor Carrier Safety Administration

ADAMS, EARL STANLEY JR
DELORENZO, JOSEPH P
FROMM, CHARLES J
GRAYDON, AMY HEATHER
HERNANDEZ, SCOTT
HUG, CARRIE A
JONES, DARIN G
JOSHI, MEERA CATHERINE
KEANE, THOMAS P
KELLY, TAFT D
MINOR, LARRY W
PIDUGU, PAVANKUMAR
RIDDLE, KENNETH H.
RUBAN, DARRELL L
SCHREIBMAN, JACK L
SENTEF, JOSEPH
VAN STEENBURG, JOHN W

Federal Railroad Administration

ALEXY, JOHN KARL
ALLAHYAR, MARYAM
BOSE, AMITABHA
DYER, WILLIAM PATRICK
HAYWARD-WILLIAMS, CAROLYN
JORTLAND, BRETT ANDREW
KING, CHARLES PAT
KOUL, NEERAJ
LESTINGI, MICHAEL W.
LONG, MICHAEL T
NISSENBAUM, PAUL
PATTERSON, MARK A
RENNERT, JAMIE P.
REYES-ALICEA, REBECCA
RIGGS, TAMELA LYNN

Federal Transit Administration

AHMAD, MOKHTEE
ALLEN, REGINALD E
BROOKINS, KELLEY
BUTLER, PETER S
DALTON-KUMINS, SELENE FAE
GARCIA CREWS, THERESA
GEHRKE, LINDA M
GOODMAN, STEPHEN C
IYER, SUBASH SUBRAMANIAN
JAMES, FELICIA LANISE
LYSSY, GAIL C
NIFOSI, DANA C.
ROBINSON, BRUCE A
TAYLOR, YVETTE G
TELLIS, RAYMOND S
TERWILLIGER, CINDY E
WELBES, MATTHEW J

Great Lakes St. Lawrence Seaway Development Corporation

MIDDLEBROOK, CRAIG H
O'MALLEY, KEVIN P

Maritime Administration

BALLARD, JOHN R
BECKETT, COREY ANDREW
BROHL, HELEN A
BUONO, JOACHIM
CARTER, MICHAEL C
DAVIS, DELIA P
DUNLAP, SUSAN LYNN
FISHER, ANTHONY JR
HARRINGTON, DOUGLAS M
KUMAR, SHASHI N
LESSLEY, LUCINDA DAVIS
PAAPE, WILLIAM
PIXA, RAND R.
TOKARSKI, KEVIN M

National Highway Traffic Safety Administration

BAUMANN, ROLAND T III
BLINCOE, LAWRENCE J
CARLSON, ANN ELIZABETH
CHEN, CHOU-LIN
CLIFF, STEVEN SCOTT
COLLINS, ANNE L
DANIELSON, JACK H.
DOHERTY, JANE H
DOLAS, RAJEEV K
DONALDSON, K JOHN
HATIPOGLU, CEM
HINES, DAVID M
JOHNSON, TIM J
KOLLY, JOSEPH M
KOLODZIEJ, KERRY E
MARSHALL, JOHN W
MATHEKE, OTTO G III
PARKER, CYNTHIA D
PFISTER, JAMIE DURHAM
POSTEN, RAYMOND R
RIDELLA, STEPHEN A
RITTER, ROBERT G
SRINIVASAN, NANDA N
SUMMERS, LORI K
VALLESE, JULIETTE M.

Office of the Secretary of Transportation

ABRAHAM, JULIE
ALBRIGHT, JACK G
AUDET, ANNE H
AUGUSTINE, JOHN E
AYLWARD, ANNE D
BOHNERT, ROGER V
CALLENDER, DUANE A
CARLSON, TERENCE W
CHAVEZ, RICHARD M.
CHULUMOVICH, MADELINE M
COES, CHRISTOPHER ALEXAND
COGGINS, COLLEEN P
COHEN, DANIEL
COHN HUTCHESON, ROBIN M
CONNORS, SUSAN M
DOUGHERTY, BARBARA KAYE
FARAJIAN, MORTEZA
FLEMING, GREGG G
FUNK, JENNIFER S
GEIER, PAUL M
HAMPSHIRE, ROBERT CORNELI
HENDERSON, MAURICE ALEXAN
HERLIHY, THOMAS W
HOMAN, TODD M
HORN, DONALD H
HU, PATRICIA S.
HURDLE, LANA T
HUYNH, JULI C
IRVINE, PETER D
JACKSON, RONALD A
KALETA, JUDITH S
KING, DANIEL E.
LAWRENCE, CHRISTINE A
LEFEVRE, MARIA S.
LOHRENZ, MAURA C
MARCHESE, APRIL LYNN
MARION, IRENE BIANCA
MARTIN, HAROLD W III
MCCARTNEY, ERIN P
MCNAMARA, PHILIP ADAM
MORGAN, DANIEL S.
O'BERRY, DONNA
ORNDORFF, ANDREW R
PAIEWONSKY, LUISA M
PETROSINOWOOLVERTON, MARI
PETSONK, CAROL ANNETTE
POPKIN, STEPHEN M
PUTNAM, JOHN EDWARD
REAMY, LYNDA TRAN
RUIZ, KRISTIN RAE
SCHILLER, LAURA ELIZABETH
SCHMITT, ROLF R
SHAPIRO, MICHAEL PARIS
SHEIKH IBRAHIM, FIRAS
SHULMAN, SOPHIE MIKHAL
SIMONS, DANI LYNN
SIMPSON, JOAN
SMITH, WILLIE H
SPRAGUE, MARY G.
SZABAT, JOEL M
SZAKAL, KEITH J
SZATMARY, RONALD ALLEN JR
TAYLOR, BENJAMIN J
TIMOTHY, DARREN P
WASHINGTON, KEITH E
WASSMER, VICTORIA BAECHER
WISHNIA, ANDREW JAY
WORKIE, BLANE A
ZIFF, LAURA M

Pipeline and Hazardous Materials Safety Administration

BORENER, SHERRY S
BROWN, TRISTAN HILTON
DAUGHERTY, LINDA
DAVIS, CAREY THOMAS
FARLEY, AUDREY L.
GATTI, JONATHAN D
GORDON, STEPHEN N JR
MAYBERRY, ALAN K
MCMILLAN, HOWARD W
QUADE, WILLIAM A III
SCHOONOVER, WILLIAM S
TAHAMTANI, MASSOUD
TSAGANOS, VASILIKI B

[FR Doc. 2021–22821 Filed 10–19–21; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee: Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting: Correction.

SUMMARY: In the **Federal Register** notice that was originally published on October 12, 2021, (Volume 86, Number 194, Page 56790) the day for this meeting has been corrected from Thursday to Wednesday, November 10, 2021 at 2:00 p.m. Eastern Time. All other meeting details remain unchanged.

DATES: The meeting will be held Wednesday, November 10, 2021.

FOR FURTHER INFORMATION CONTACT: Fred Smith at 1–888–912–1227 or (202) 317–3087.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be held Wednesday, November 10, 2021 at 2:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Fred Smith. For more information please contact Fred Smith at 1–888–912–1227 or (202) 317–3087, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org*.

Dated: October 14, 2021.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2021–22793 Filed 10–19–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Improvements Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, November 9, 2021.

FOR FURTHER INFORMATION CONTACT: Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Improvements Project Committee will be held Tuesday, November 9, 2021, at 1:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Matthew O'Sullivan. For more information, please contact Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274, or write TAP Office, 1301 Clay Street, Oakland, CA 94612–5217 or contact us at the website: *http://www.improveirs.org*. The agenda will include various IRS issues.

Dated: October 14, 2021.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2021–22791 Filed 10–19–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Special Projects Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting: Correction.

SUMMARY: In the **Federal Register** notice that was originally published on October 12, 2021, (Volume 86, Number 194, Page 56759) the day for this meeting has been corrected from Thursday to Wednesday, November 10, 2021 at 11:00 a.m. Eastern Time. All other meeting details remain unchanged.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1–888–912–1227 or 202–317–4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be held Wednesday, November 10, 2021, at 11:00 a.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Antoinette Ross. For more information please contact Antoinette Ross at 1–888–912–1227 or 202–317–4110, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org*. The agenda will include various IRS issues.

Dated: October 14, 2021.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2021–22792 Filed 10–19–21; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 86 Wednesday,
No. 200 October 20, 2021

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 800, 801, 808, and 874
Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids; Proposed Rule
Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products: Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 800, 801, 808, and 874

[Docket No. FDA–2021–N–0555]

RIN 0910–AI21

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is proposing to establish a regulatory category for over-the-counter (OTC) hearing aids and to make related amendments to update the regulatory framework for hearing aids. Specifically, we propose to define OTC hearing aids and establish applicable requirements; amend existing rules for consistency with a new OTC category; repeal the conditions for sale applicable to hearing aids; amend the existing labeling requirements for hearing aids; and update regulations relating to decisions on applications for exemption from Federal preemption that would become obsolete as a result of changes to the hearing aid requirements. This action, if finalized, would more clearly define prescription hearing aids; however, it would not change the classification of existing device types. In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for these devices as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health.

DATES: Submit either electronic or written comments on the proposed rule by January 18, 2022. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by November 19, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 18, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–N–0555 for ''Establishing Over-the-Counter Hearing Aids.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) to the Office of Management and Budget (OMB) at *https://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. The title of this proposed collection is ''Medical Device Labeling Regulations.''

FOR FURTHER INFORMATION CONTACT: Srinivas Nandkumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20993, 301–796–5620, *Srinivas.Nandkumar@fda.hhs.gov.*

With regard to the information collection: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary

Purpose of the Proposed Rule

Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life. Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention. Several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price). FDA is proposing rules to address some of these concerns.

Moreover, the FDA Reauthorization Act of 2017 (FDARA) directs FDA to establish a category of OTC hearing aids through rulemaking, and FDARA sets forth various requirements for OTC hearing aids, including preemption provisions. In addition to protecting and promoting the public health, we have developed these proposed rules to establish the OTC category and implement the requirements of FDARA.

Summary of the Major Provisions of the Proposed Rule

FDA is proposing to establish a regulatory category for OTC hearing aids to improve access to hearing aid technology for Americans. OTC hearing aids will be intended to address perceived mild to moderate hearing loss in people age 18 or older. Alongside the OTC category, we are proposing multiple related changes to the overall regulatory framework for hearing aids to harmonize existing rules with the eventual OTC category. We believe the proposals set forth in this rulemaking will protect the public health by providing reasonable assurance of safety and effectiveness for hearing aids, as well as promote the hearing health of Americans by lowering barriers to access and fostering innovation in hearing aid technology.

Among other things, FDARA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by defining OTC hearing aids and providing the authorities to establish the OTC category of hearing aids among provisions that are, by definition, general controls. We are proposing general controls for OTC hearing aids consistent with FDARA. Moreover, because the FD&C Act specifies that OTC hearing aids are those that use the same fundamental scientific technology as air-conduction hearing aids, we would realign the existing classification regulations for hearing aids by sound conduction technology. However, the realignment would not affect the device class or premarket notification exemption status of any existing device. On the effective date of the final rule, we would realign current product codes to correspond with the revised regulations for consistency but would not otherwise change the codes.

This rulemaking also affects other existing regulations that apply to hearing aids. FDA has established device restrictions for hearing aids that include labeling requirements as well as conditions for sale. We are proposing to remove these device restrictions for hearing aids, and establish a new regulation for prescription hearing aid labeling. Further, FDA has by regulation granted or denied exemptions from Federal preemption for State requirements pertaining to hearing aids. The removal of the device restrictions on hearing aids, as well as certain provisions of FDARA, impact most of these previous exemption decisions, for example, by altering their scope. We are proposing to remove the regulations codifying these decisions and establish other regulations clarifying some of the effects of statutory preemption under FDARA.

Legal Authority

The FD&C Act establishes a comprehensive system for the regulation of devices intended for human use. Hearing aids are devices intended for human use and so are subject to, among other requirements, the device provisions of the FD&C Act. FDA has authority to establish regulatory controls needed to provide reasonable assurance of safety and effectiveness for these devices. As such, FDA is establishing regulatory controls for OTC hearing aids and amending regulatory controls for prescription hearing aids.

Specific to OTC hearing aids, the FD&C Act and FDARA authorize multiple controls, including authority for FDA to establish requirements for device labeling, output limits, conditions for sale and distribution, and other requirements that provide reasonable assurance of safety and effectiveness of OTC hearing aids. FDARA specifically directs FDA to establish a category of OTC hearing aids by regulation that must include the aforementioned requirements.

More generally, the FD&C Act further provides for labeling requirements as general controls such that devices (and other medical products) will not be misbranded. The FD&C Act also authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act. We are proposing the following regulations pursuant to these authorities and to fulfill the directive under FDARA.

Additionally, both the FD&C Act and FDARA include preemption provisions applicable to hearing aids.

Costs and Benefits

This proposed rule to establish OTC hearing aids and align other regulations, if finalized, would generate potential cost savings for consumers with perceived mild to moderate hearing loss who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance but who are currently unable to buy such products online because of State regulations or because they do not shop online. The proposed rule, if finalized,

would also generate costs for hearing aid manufacturers for changing labeling of existing hearing aids as well as for reading the rule and revising internal standard operating procedures in response to the rule. We estimate benefits of between $6 million and $147 million per year based on 5th and 95th percentile Monte Carlo results with a mean of $63 million per year. We estimate annualized costs of between $1 million and $2 million per year based on 5th and 95th percentile Monte Carlo results with a mean of $1 million per year. Combining benefits and costs, we used Monte Carlo analysis to estimate annualized net benefits of between $5 million and $145 million per year based on the 5th and 95th Monte Carlo percentile results with a mean of $62 million per year at both 3 percent and 7 percent discount rates.

TABLE OF ABBREVIATIONS AND ACRONYMS COMMONLY USED IN THIS DOCUMENT

Abbreviation/acronym	What it means
510(k)	A premarket notification for certain devices.
ANSI	American National Standards Institute.
ASA	Acoustical Society of America.
CFR	Code of Federal Regulations.
CTA	Consumer Technology Association.
dB	Decibel.
dBA	A-weighted decibel.
EA	Environmental assessment.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDARA	FDA Reauthorization Act of 2017.
FONSI	Finding of no significant impact.
FR	Federal Register.
GMPs	Good manufacturing practices.
Hz	Hertz.
ISO	International Organization for Standardization.
MSW	Municipal solid waste.
NASEM	National Academies of Sciences, Engineering, and Medicine.
NIOSH	National Institute for Occupational Safety and Health.
OMB	Office of Management and Budget.
OSPL90	Output sound pressure level with 90-dB input.
OTC	Over-the-counter.
PCAST	President's Council of Advisors on Science and Technology.
PRIA	Preliminary Regulatory Impact Analysis.
PSAP	Personal sound amplification product.
Pub. L	Public Law.
QS	Quality System.
SPL	Sound pressure level.
U.S.C	United States Code.

I. Background

FDA is proposing to define and establish general controls for an OTC category of hearing aids. We intend these proposals to provide for reasonable assurance of safety and effectiveness for these devices and improve access to and foster innovation in hearing aid technology for Americans, thereby promoting and protecting the public health. We would make various other revisions, as described in this document, to align existing regulations with statutory requirements and the new OTC category.

A. Need for the Regulation

Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life (Refs. 1 and 2). Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention (Ref. 3). The use of hearing aids has been linked to, among other health benefits, reductions in the incidence or severity of cognitive decline, depression, and other health problems in older adults (Ref. 3a and 3b). Additionally, benefits of hearing aid use can include improved social participation and a better quality of life.

Besides health benefits for individuals, more-widespread adoption of hearing aids could have broader effects. By increasing social participation, hearing aids could help to improve inclusion of individuals in family, economic, civic, and religious life. Thus, reducing barriers to hearing aid access might contribute to such improvements. This could be particularly true for people of color, rural Americans, low-income individuals, and others for whom barriers to hearing aid access may be especially burdensome.

Several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price) (Ref. 4). In addition, stakeholders have cited Federal regulations that require specific labeling and conditions for sale, initially implemented in the late 1970s, as barriers to access (*e.g.,* Refs. 5 to 7). This document proposes a number of changes to the regulatory framework for hearing aids to remove or reduce barriers to certain air-conduction hearing aids for perceived mild to moderate hearing impairment—a type of impairment often associated with aging—that have the potential to be of great benefit to the public health.

These proposals follow the enactment of FDARA, which included provisions directing FDA to establish regulatory requirements for a new category of OTC hearing aids and amended the FD&C Act to add section 520(q) (21 U.S.C. 360j(q); see Pub. L. 115–52). Section 520(q)(1) of the FD&C Act defines OTC hearing aids, in part, as devices available over-the-counter, without the supervision,

prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online. Section 520(q)(2) of the FD&C Act requires that such devices be subject to the regulations FDA issues for them in accordance with section 709(b) of FDARA.

Section 709(b) of FDARA requires that FDA establish a category of OTC hearing aids that includes, among other elements, requirements to provide reasonable assurances of the safety and effectiveness of these devices. We also make multiple proposals to prevent the sale of OTC hearing aids to or for people younger than age 18. This document does not, however, propose to create or classify a new device type.[1] Further, this document does not propose to exempt additional devices from the premarket notification requirements under section 510(k) of the FD&C Act, commonly referred to as ''a 510(k)'' (21 U.S.C. 360(k)). Section IV of this document discusses our findings regarding premarket notification in more detail.

We are simultaneously proposing related changes to the regulatory framework that currently applies to all hearing aids, as they are defined in § 801.420 (21 CFR 801.420), in light of the new OTC category and to ensure consistency across rules pertaining to hearing aids (see § 801.420(a)(1)). Detailed information about each proposal appears in section III.

B. Current Regulatory Framework for Hearing Aids

Hearing aids, as defined in § 801.420(a)(1), are currently restricted class I and class II devices of multiple types. A summary of the current regulatory framework for these devices appears in table 1.

TABLE 1—SUMMARY OF CURRENT REGULATORY FRAMEWORK

Classification regulation, 21 CFR section	874.3300	874.3305	874.3315	874.3325	874.3950
Device Restrictions	Restricted	Restricted	Restricted	Restricted	Restricted.
Class I, 510(k) exempt [1]	Air-conduction (''legacy'').				
Class II, 510(k) exempt [1]		Wireless air-conduction.			
Class II	Bone-conduction		Tympanic membrane contact hearing aid.	Self-fitting air-conduction.	Transcutaneous air-conduction hearing aid system.
Product codes	ESD, LXB, MAH, LRB, LDG.	OSM	PLK	QDD	NIX.

[1] 510(k) exemptions are subject to the limitations in 21 CFR 874.9.

1. Hearing Aid Classifications

Hearing aids are class I and class II wearable sound-amplifying devices intended to compensate for impaired hearing. They currently fall under five classification regulations (the following references are to sections in Title 21 of the CFR):

a. Hearing aid (§ 874.3300 (21 CFR 874.3300)). This device type includes air-conduction (class I, 510(k) exempt, subject to the limitations of exemption in § 874.9) and bone-conduction (class II) hearing aids. Class II bone-conduction hearing aids require a 510(k) notification. These are all restricted devices.

b. Wireless air-conduction hearing aid (§ 874.3305 (21 CFR 874.3305)). This device type is a hearing aid that incorporates wireless technology in its programming or use, for example, controls over Bluetooth. These devices are class II restricted, subject to the special controls that have been issued for these devices, and 510(k) exempt, subject to the limitations of exemption in § 874.9.

c. Tympanic membrane contact hearing aid (§ 874.3315 (21 CFR 874.3315)). This device type is a prescription device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane. These devices are class II restricted, subject to the special controls that have been issued for these devices, and require a 510(k) notification.

d. Self-fitting air-conduction hearing aids (§ 874.3325 (21 CFR 874.3325)). This device type is a hearing aid that incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fittings and settings. These devices are class II restricted, subject to the special controls that have been issued for these devices, and require a 510(k) notification.

e. Transcutaneous air conduction hearing aid system (§ 874.3950 (21 CFR 874.3950)). This device type consists of an air-conduction hearing aid attached to a surgically fitted tube system, which is placed through soft tissue between the post auricular region and the outer ear canal. These devices are class II restricted, subject to the special controls that have been issued for these devices, and require a 510(k) notification.

Devices of these types may be either prescription (for example, devices for insertion deep in the ear canal) or non-prescription devices (which include the majority of air-conduction hearing aids).[2] For the purposes of this rulemaking, we refer to non-wireless, non-self-fitting, air-conduction hearing aids as ''legacy hearing aids,'' which means all air-conduction hearing aids currently within § 874.3300 but not air-conduction hearing aids currently within §§ 874.3305, 874.3325, or 874.3950.

[1] ''Device type'' as used in this document has the same meaning as ''generic type of device'' in 21 CFR 860.3(i) (a ''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'').

[2] We use the term ''non-prescription'' because the FD&C Act, as amended by FDARA, defines OTC hearing aids and requires FDA to undertake rulemaking to establish the OTC category. As such, no hearing aid is yet OTC within the meaning of section 520(q) of the FD&C Act. We use ''non-prescription'' to avoid confusing the intended uses of current devices with devices that would eventually meet the OTC Hearing Aid Controls.

2. Hearing Aid Restrictions

Hearing aids are currently subject to a set of restrictions on sale, distribution, and use, established in accordance with section 520(e) of the FD&C Act. We will refer to those as ''Hearing Aid Restrictions,'' and they include requirements for professional and patient labeling, as a well as conditions for sale (see §§ 801.420 and 801.421 (21 CFR 801.420 and 801.421, respectively)). All legacy hearing aids, wireless air-conduction hearing aids, and self-fitting hearing aids (as well as other device types) fall within a separate, broader definition of hearing aids in § 801.420(a)(1), and therefore are currently subject to these restrictions.

Among other requirements, § 801.420 specifies that the User Instructional Brochure labeling for hearing aids contain a warning statement for hearing aid dispensers that prompts them to advise prospective purchasers to consult with a physician if any of the listed medical conditions are present (see § 801.420(c)(2)). We will refer to these medical conditions as ''red flag'' conditions in this proposal. The rule further prescribes a notice to prospective users and an additional statement about hearing loss in children (see § 801.420(c)(3)). It also requires the disclosure of technical data useful in selecting, fitting, and checking the performance of hearing aids (see § 801.420(c)(4)).

Currently, § 801.421 specifies a number of conditions for sale for hearing aids. Such conditions include that a prospective user must present to the dispenser a signed statement of medical evaluation from a physician prior to sale (see § 801.421(a)(1)). However, a prospective user who is 18 years of age or older may waive the medical evaluation requirement by signing a statement with a prescribed advisement (see § 801.421(a)(2)). A dispenser must provide an opportunity for the prospective user to review the User Instructional Brochure prior to signing a waiver and the sale of a hearing aid (see § 801.421(b)). Manufacturers and distributors must provide sufficient copies of User Instructional Brochures to dispensers, and upon written request, to prospective users; dispensers must similarly provide the brochures (or the name and address of a manufacturer or distributor to obtain a brochure) to prospective users upon request (see § 801.421(c)). Dispensers generally must retain a copy of a medical evaluation statement or signed waiver for 3 years (see § 801.421(d)).

However, we announced in a guidance entitled ''Conditions for Sale for Air-Conduction Hearing Aids'' that we do not intend to enforce the medical evaluation, waiver, or recordkeeping requirements of § 801.421 with respect to prospective purchasers who are 18 or older (Ref. 8).

In addition to other applicable misbranding and adulteration provisions in sections 501 and 502 of the FD&C Act (21 U.S.C. 351 and 21 U.S.C. 352, respectively), hearing aids are currently subject to misbranding provisions for restricted devices under section 502(q) and (r) of the FD&C Act. Section 704(a) of the FD&C Act (21 U.S.C. 374(a)) authorizes FDA to inspect, among other things, certain records relating to restricted devices.

3. State Requirements for Hearing Aids

Under certain circumstances, State requirements apply to hearing aids notwithstanding Federal requirements. In general, FDA's regulation of hearing aids preempts State law, meaning that a State or a political subdivision (*e.g.,* a city) may not establish or continue in effect its own requirement if that requirement is ''different from, or in addition to,'' a requirement under the FD&C Act (see section 521(a) (21 U.S.C. 360k(a))). Many States have established requirements equivalent to § 801.420 or § 801.421 (*i.e.,* not ''different from, or in addition to'' those regulations), which are not preempted by these Federal requirements.

However, for other State requirements, FDA has granted and denied exemptions from preemption under section 521(b) of the FD&C Act for some States that have applied. FDA responds to applications for such exemptions by regulation, codified in subpart C of part 808 (21 CFR part 808). Most of these regulations relate to hearing aids, and in some of these regulations, FDA has granted exemptions—meaning those States' requirements apply instead of, or in addition to, FDA's requirements—for:

- Specifying the physician expertise needed to examine prospective purchasers who are younger than 18 years of age;
- Advising purchasers when to seek medical attention based on ''red flag'' conditions;
- Providing purchasers with certain information and disclosures on receipts and other documentation;
- Recordkeeping requirements in addition to the Hearing Aid Restrictions; and
- Providing written notice of a money-back guarantee where a State court held the State requirement was preempted.

And FDA has denied exemptions—meaning the States could not establish or continue in effect requirements—for:

- Removing the waiver option for prospective purchasers who are 18 years of age or older;
- Lowering the age at which a waiver of medical examination prior to purchase was available;
- Changing the expertise for examinations, when conducted, for people 18 years of age and older;
- Prohibiting certain marketing claims about improving hearing; and
- Adopting different device testing standards.

FDARA added a separate Federal preemption provision for State and local laws, regulations, orders, or other requirements (for brevity, we will refer to ''State or local requirements'' in this rulemaking) specifically related to hearing products (FDARA section 709(b)(4)).[3] That provision may affect the applicability of State or local requirements for OTC hearing aids. Section III.G discusses the OTC hearing aid preemption provisions and the effects of this rulemaking.

4. Hearing Products Not Regulated as Hearing Aids

FDA does not consider personal sound amplification products (PSAPs) to be ''devices'' within the meaning of section 201(h) of the FD&C Act (21 U.S.C. 321(h)) when they are not intended to aid a person with, or compensate for, impaired hearing and do not otherwise meet the device definition. Such PSAPs are not subject to medical device regulations, nor would the proposed requirements of this rulemaking apply to such PSAPs.[4] Note that the name of a product on its own would not ordinarily demonstrate intended use. Thus, merely calling a product something besides ''hearing aid'' would not remove a product from device regulation under the FD&C Act if, for example, its labeling demonstrated that the product was intended to compensate for hearing loss.

C. History of This Rulemaking

Although this proposal is the first step in this rulemaking, FDA has taken other steps to initiate an update of the regulatory framework for hearing aids.

[3] Additionally, FDARA section 709(b)(5) addresses the effect of section 709 on certain private remedies.

[4] Section 520(q)(1)(B) of the FD&C Act also specifically excludes from the definition of OTC hearing aids products intended to amplify sound for nonhearing impaired consumers in situations including hunting and bird watching.

Prior to the enactment of FDARA, FDA had considered means to improve access to hearing aids. For example, we considered a report on the public health implications of hearing loss in adults that made recommendations to improve affordability and accessibility of hearing aids and to foster innovative hearing aid technology. The October 2015 report by the President's Council of Advisors on Science and Technology (PCAST) recommended, among other actions, that, ''FDA should approve [a] class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser'' (Ref. 7). In addition, the report concluded, among other things, that the Federal requirement for a medical examination, or a written waiver of such examination, ''provides little patient benefit, while acting as a barrier to access for the millions of Americans needing hearing assistance'' (Ref. 7).

Similarly, FDA, other Federal Agencies, and a consumer advocacy group co-sponsored a study entitled ''Hearing Health Care for Adults: Priorities for Improving Access and Affordability'' through the National Academies of Sciences, Engineering, and Medicine (NASEM). The resulting NASEM report, published on June 2, 2016, similarly recommends that FDA create a new category of OTC ''wearable hearing devices'' (using a term distinct from ''hearing aids'') and also that FDA remove the medical evaluation requirement for adults for hearing aids (Ref. 6). After a review of the literature and relevant clinical databases from the U.S. Department of Defense and the U.S. Department of Veterans Affairs, NASEM concluded that the health risk of missed diagnosis of treatable causes of hearing loss in adults is low, and ''[the] regulation [requiring a medical examination or waiver] provides no clinically meaningful benefit, and the waiver presents a barrier to access with no substantial enhancement of patient safety.''

Both PCAST and NASEM provided recommendations regarding FDA Quality System requirements (which set forth requirements for good manufacturing practices or GMPs) for the proposed category of OTC hearing aids. PCAST stated the following:

> FDA should exempt this class of hearing aids from QSR regulation in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer-electronics industry, developed by an appropriate third-party organization and approved by FDA. Similar actions should be taken with respect to diagnostic hearing tests used to dispense and fit Class I hearing aids.

However, NASEM recommended that these devices ''[b]e subject to quality system regulation (QSR) requirements, but be considered for exemption from certain QSR requirements as determined by FDA to be appropriate for this category.''

We held a public workshop on April 21, 2016, entitled ''Streamlining Regulations for Good Manufacturing Practices (GMPs) for Hearing Aids,'' (announced at 81 FR 784; see Ref. 9 for materials). FDA requested comments on several topics relating to hearing healthcare technology and improved access, including the appropriate level of GMP regulation (Quality System requirements) to ensure the safety and effectiveness of air-conduction hearing aid devices in consideration of the PCAST report recommendations.

FDA received hundreds of comments to the docket for this workshop prior to the (extended) deadline of June 30, 2016. In addition, 2 keynote speakers (from PCAST and NASEM), 12 invited speakers, and 24 public speakers offered comments or presentations at the workshop. Workshop speakers and submitters of docket comments were generally: Healthcare professionals (or healthcare professional organizations), members of industry, patients or consumers, academics, consensus standards developers, and science organizations.

Comments from this workshop ranged generally from strong opposition to strong support for the PCAST recommendations. Other comments were more nuanced. To summarize very broadly, all parties agreed that some combination of regulatory requirements and flexibility in compliance would provide reasonable assurance of safety and effectiveness. The differences in opinion lie in the preferred approach and its implementation to achieve these common goals. For example, some preferred amending the QS regulation and relying on inspections while others preferred allowing voluntary conformity to a consensus standard potentially relying on third-party certification.

In another effort to address the current regulatory framework, FDA also issued a guidance document, as noted above, related to the conditions for sale for air-conduction hearing aids. In that document, we announced our intent to reexamine and modify § 801.421 based on the PCAST and NASEM recommendations, as well as from other stakeholders, taking into consideration and addressing their recommendations as appropriate before adopting regulations for OTC hearing aids. The docket no. FDA–2016–D–3466 included commentary that expressed support for the creation of a ''basic'' category of hearing aids such as OTC hearing aids and provided recommendations for measures to support safe and effective use. We also received multiple telephone calls expressing similar interest in reducing regulatory burdens and questioning how the issuance of the guidance affected States' requirements.

In developing this proposed rule, we considered the input and questions we have received on the guidance, as well as the comments from the April 2016 public workshop and the recommendations from PCAST and NASEM.

D. Incorporation by Reference

FDA is proposing to incorporate by reference the Method and tables for clause 4.1 of ANSI/CTA–2051, ''Personal Sound Amplification Performance Criteria,'' dated January 2017, from the American National Standards Institute, 1889 L Street NW, 11th floor, Washington, DC 20036; *https://www.ansi.org,* 202–293–8020. You may download the standard from the web at *https://webstore.ansi.org/standards/ansi/cta20512017ansi.* The Method and tables for clause 4.1 describe how to measure frequency response and include technical data for adaptations for different circumstances. The Method and tables would provide a standardized way to quantify frequency response for OTC hearing aids and meet the related proposed requirements (see section III.E.1).

FDA is also proposing to incorporate by reference ANSI/ASA S3.22–2014, ''Specification of Hearing Aid Characteristics,'' dated November 2014, from the American National Standards Institute, 1889 L Street NW, 11th floor, Washington, DC 20036; *https://www.ansi.org,* 202–293–8020. ANSI/ASA S3.22–2014 describes tolerances and test methods used for certain measurements of hearing aid performance. The application of ANSI/ASA S3.22–2014 provides professional hearing aid fitters with standardized technical information to help them select the correct hearing aid and ensure optimal fit and performance for hearing aid users (see section III.H.2).

II. Legal Authority

The FD&C Act establishes a comprehensive system for the regulation of devices, as defined in section 201(h) of the FD&C Act, intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) defines three classes of devices, reflecting the regulatory

controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval) (see 21 U.S.C. 360c). Hearing aids are devices intended for human use and are subject to the FD&C Act. Currently, air-conduction hearing aids are generally either class I or class II devices.

FDARA amended the FD&C Act to apply requirements specific to certain hearing aids and defined the term ''over-the-counter hearing aid'' (see 21 U.S.C. 360j(q)). We are issuing these requirements for OTC hearing aids pursuant to section 709(b) of FDARA, which authorizes FDA to establish requirements for labeling, output limits, conditions for sale and distribution of OTC hearing aids, and other requirements that provide for reasonable assurance of safety and effectiveness of these devices.

In addition, the FD&C Act provides that a device is misbranded unless, among other requirements, its labeling bears adequate directions for use (see section 502(f)(1) of the FD&C Act). Consistent with section 502 of the FD&C Act, FDA has issued regulations that exempt certain kinds of devices from the requirement for adequate directions for use. Section 502(f)(2) further requires adequate warnings against use of a device in those pathological conditions, or by children, where use of the device may be dangerous to health. The labeling must also bear adequate warnings against unsafe dosage or methods or duration of administration or application (see section 502(f)(2) of the FD&C Act). Such warnings must be in such manner and form as are necessary for the protection of the users (see section 502(f)(2) of the FD&C Act).

A device is also misbranded if its labeling is false or misleading in any particular (see section 502(a) of the FD&C Act). Section 201(n) of the FD&C Act states that in determining whether labeling or advertising is misleading, there shall be taken into account not only representations made or suggested but also the extent to which labeling or advertising fails to reveal material facts.

Other misbranding provisions under the FD&C Act would apply as well, including section 502(c), which deems a device to be misbranded if any word, statement, or other information required by or under authority of the FD&C Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Additionally, section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act (21 U.S.C. 371(a)). The proposals in this rulemaking would be for the efficient enforcement of the FD&C Act because, if finalized, they will provide standards for the legal marketing of safe and effective hearing aid devices.

Violations of any final rules from this rulemaking, once in effect, would render the hearing aids adulterated and/or misbranded under sections 501 and/or 502 of the FD&C Act, and subject to enforcement action, for example, seizure (see section 304 of the FD&C Act (21 U.S.C. 334)), injunction (see section 302 of the FD&C Act (21 U.S.C. 332)), and criminal prosecution (see section 303 of the FD&C Act (21 U.S.C. 333)). Prohibited acts include, among others, introducing an adulterated or misbranded device into interstate commerce (see section 301 of the FD&C Act (21 U.S.C. 331)).

Under section 521 of the FD&C Act, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement that is different from, or in addition to, any requirement applicable under the FD&C Act to the device and that relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the FD&C Act (21 U.S.C. 360k). Section 521 of the FD&C Act also provides that FDA may grant an exemption from preemption under certain circumstances. Section 709(b) of FDARA also includes a preemption provision with respect to requirements for OTC hearing aids.

III. Description of the Proposed Rule

We are proposing multiple related actions in this rulemaking:

- Add to part 800, subpart B (21 CFR part 800, subpart B), definitions and other rules for OTC hearing aids;
- Remove § 801.420 and repeal § 801.421;
- Add to part 801, subpart H (21 CFR part 801, subpart H), § 801.422, labeling requirements for prescription hearing aids;
- Amend part 874, subpart D (21 CFR part 874, subpart D), in multiple places to update classification regulations for hearing aids and align hearing aid types by sound-conduction technology; and
- Amend part 808, subparts A and C (21 CFR part 808, subparts A and C), by updating the Scope and removing most of the current regulations codifying previous decisions for exemption from Federal preemption for certain States.

If this action is finalized, all non-OTC hearing aids will be prescription devices and would be subject to the labeling requirements in new § 801.422 as well as those in the existing § 801.109, but they would no longer be restricted devices. Note that a prescriber is any practitioner licensed by the law of the State in which the practitioner practices to use, or order the use of, the device. When the prescriber of a hearing aid need not be a physician, the labeling of a prescription hearing aid will describe other prescribers, for example, audiologists (see § 801.109(b)(1)).

We believe the proposed actions will, in combination, promote and protect the public health by, among other things, providing reasonable assurance of safety and effectiveness of OTC and prescription hearing aids. These actions would also help minimize the complexity of the applicable regulations, if finalized, through organization. We are proposing to add the OTC Hearing Aid Controls to 21 CFR part 800, subpart B, entitled ''Requirements for Specific Medical Devices,'' which would make them easy to locate. Labeling requirements for prescription devices would remain in part 801, Labeling, subpart H, ''Special Requirements for Specific Devices.'' Table 2 outlines the proposed hearing aid rules. Section III.I summarizes the proposed revisions to part 808.

TABLE 2—OUTLINE OF PROPOSED HEARING AID RULE

800.30	801.422	874.3301	874.3305
Over-the-counter hearing aid controls [1]	Prescription hearing aid labeling [1]	Bone-conduction hearing aid	Air-conduction hearing aid
(a) Scope. (b) Definitions.	(a) Scope. (b) Definitions.	(a) Identification. (b) Classification.	(a) Identification. (b) Classification.

TABLE 2—OUTLINE OF PROPOSED HEARING AID RULE—Continued

800.30	801.422	874.3301	874.3305
Over-the-counter hearing aid controls [1]	Prescription hearing aid labeling [1]	Bone-conduction hearing aid	Air-conduction hearing aid
(c) Labeling. • Package. • Labeling Inside the Package. • Labeling on the Device. • Technical Specifications. (d) Output Limits. (e) Electroacoustic Performance. • Distortion Control. • Self-generated Noise. • Latency. • Bandwidth. • Smoothness. (f) Design Requirements. • Insertion Depth. • Atraumatic Materials. • Proper Fit. • Tools, Tests, or Software. (g) Condition for Sale. (h) Effect on State Law. (i) Incorporation by Reference.	(c) Labeling. • Package. • Labeling Inside the Package. • Labeling on the Device. • Technical Specifications. • Misbranding. (d) Incorporation by Reference.	Product codes LXB, MAH.	• Legacy. • Wireless. • Self-Fitting. Product codes ESD, OSM, QDD, LRB, and LDG.

[1] These requirements would apply in addition to all other applicable requirements, including applicable labeling requirements in parts 801 and 830 (21 CFR parts 801 and 830). For example, for prescription devices, the labeling requirements in § 801.109 would continue to apply in addition to new § 801.422.

A. Scope (Proposed § 800.30(a))

The regulation would clarify which devices are subject to the OTC Hearing Aid Controls. Among other changes, FDARA amended the FD&C Act to define the term ''over-the-counter hearing aid,'' and section 709 of FDARA directs FDA to establish certain requirements for labeling, output limits, conditions for sale, and other requirements that provide reasonable assurances of the safety and effectiveness of OTC hearing aids. We propose to call this set of requirements ''Over-the-Counter Hearing Aid Controls'' and add § 800.30 to establish the OTC category of hearing aids and their requirements.

The scope, proposed paragraph (a), would specify the devices to which the regulation would apply, assisting with the determination of applicable requirements. This provision clarifies that a hearing aid is either in the prescription or OTC category and that, regardless of category, special controls found in the applicable classification regulation and other requirements in the FD&C Act apply.

B. Definitions (Proposed §§ 800.30(b) and 801.422(b))

FDA proposes to include the definition of an OTC hearing aid, consistent with the definition in section 520(q)(1) of the FD&C Act, and the definitions of other terms integral to understanding § 800.30. In several cases, we are proposing parallel definitions (sometimes slightly modified) under the proposed requirements for prescription hearing aid labeling in § 801.422.

Defining hearing aids. FDARA authorizes controls for devices that, among other characteristics, use the same fundamental scientific technology as air-conduction hearing aids under §§ 874.3300 or 874.3305. Section 520(q)(1)(A)(i) of the FD&C Act does not specifically refer to § 874.3325 because, at the time of FDARA's enactment, FDA had not classified that device type. However, we consider self-fitting hearing aids currently classified under § 874.3325 to be eligible for regulation as OTC hearing aids.

We consider them as such because, although self-fitting hearing aids under § 874.3325 differ from hearing aids under §§ 874.3300 and 874.3305 in that they incorporate technology, including software, that allows users to program their hearing aids, self-fitting hearing aids use the same air-conduction technology as hearing aids under §§ 874.3300 and 874.3305. Self-fitting hearing aids also meet the other elements of the OTC hearing aid definition in section 520(q)(1)(A) of the FD&C Act. For example, self-fitting hearing aids, through tools, tests, or software, allow the user to control the hearing aid and customize it to the user's hearing needs (see section 520(q)(1)(A)(iii) of the FD&C Act).

The proposed definitions of ''hearing aid'' (which is the current definition), ''air-conduction hearing aid,'' ''over-the-counter hearing aid,'' and ''prescription hearing aid'' help to delineate the different device categories.[5] As stated in section 520(q)(1)(B) of the FD&C Act, the definition of ''over-the-counter hearing aid'' does not include PSAPs. Similarly, the definition of ''hearing aid'' more generally excludes PSAPs that are not intended to aid with or compensate for impaired hearing. The proposed definition of ''prescription hearing aid'' in proposed § 801.422 is the same as that in the OTC Hearing Aid Controls except that the definition for prescription devices would cross-reference the OTC Hearing Aid Controls, proposed § 800.30.

Defining licensed persons. In that vein, OTC hearing aids will be available without the supervision, prescription, or other order, involvement, or intervention of a licensed person (section 520(q)(1)(A)(v) of the FD&C Act). A definition of ''licensed person'' would help delineate that a patient or consumer of OTC hearing aids will not need to consult an audiologist, a physician, or other licensed person prior to or after purchasing an OTC

[5] Although some have suggested the use of a different name for OTC hearing aids, for example, a ''wearable,'' we are proposing to continue referring to them as hearing aids to maintain consistency with the device type classifications and section 520(q) of the FD&C Act.

hearing aid. The proposed definition of ''licensed person'' also clarifies that FDA interprets ''licensed person'' to include businesses consistent with the broad definition of ''person'' in section 201(e) of the FD&C Act. For example, OTC hearing aids may be available for sale from businesses that are not specially licensed to distribute OTC hearing aids.[6]

FDA does not interpret section 520(q)(1)(A)(v) of the FD&C Act or section 709(b) of FDARA as preempting a State's ability to establish or continue in effect generally applicable State business or professional licensing requirements. In general, such requirements would not be ''specifically related to hearing products,'' so they are not subject to section 709(b)(4) of FDARA. If a person purports to be a licensed professional or business, then a State could regulate the person as such. Thus, for example, a person identifying as an ''audiologist'' would be subject to State professional or facility licensure requirements because an audiologist is a licensed professional.

However, unlike identifying as an ''audiologist,'' some descriptions for professions do not on their own imply licensure in relation to OTC hearing aids. Section 709(b)(4) of FDARA lists certain activities that may be undertaken with respect to OTC hearing aids without the supervision, prescription, or other order, involvement or intervention of a licensed person. FDARA specifically lists the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids. (For convenience, we will refer to these activities collectively as ''commercial activity'' in this document.) Thus, a person representing as a marketer, seller, dispenser, distributor, or customer support representative (or an equivalent description) of OTC hearing aids would not be a ''licensed person'' for the purposes of § 800.30 solely for that reason. Nor could a State require such persons to undertake special licensing or equivalent activities. In contrast, a person voluntarily identifying, for example, as a ''licensed dispenser'' (*i.e.,* not just a ''dispenser'') would be subject to corresponding State requirements for such dispensers to the extent that the State requirements do not restrict or interfere with commercial activity involving OTC hearing aids (see section 709(b)(4) of FDARA).

The proposed definition of ''licensed person'' specifies the descriptions of profession, consistent with section 709(b)(4) of FDARA, that would not, on their own, imply licensure relating to OTC hearing aids. Section III.G of this document describes other preemption scenarios in addition to licensed persons.

Defining tools, tests, or software. Another element of the definition of OTC hearing aids requires that users be able to control or customize the devices through tools, tests, or software (see section 520(q)(1)(A)(iii) of the FD&C Act). We interpret this requirement to refer to the ability for a layperson to perform such activities. As such, the proposed definition of ''tools, tests, or software'' clarifies that OTC hearing aids are those devices that allow lay users to control the device and customize it, such as the device's output, to meet their individual hearing needs.

Other definitions. The proposed definition of ''used hearing aid'' in both the OTC and prescription device provisions clarifies which hearing aids would be subject to certain proposed labeling requirements for used or rebuilt hearing aids. The proposed definitions are the same for OTC and prescription hearing aids, and they are derived from the current definition in § 801.420 except that we have revised the wording for clarity.

The proposal for prescription hearing aid labeling in § 801.422 retains the definition for ''dispenser'' that is currently applicable to all hearing aids. However, we propose to revise the wording to clarify that the definition applies only for purposes of prescription hearing aid labeling and propose other clarifying revisions to track the definition of ''person'' in section 201(e) of the FD&C Act more closely. We believe the definition will continue to be useful because the proposed requirements for prescription hearing aids refer to the dispenser.

FDA welcomes comments on the definitions pertinent to the regulation of OTC hearing aids (as well as any other portion of this proposal). In particular, we seek comments on the clarity of the definitions and ways to improve the definitions to encourage and support the broad availability of safe and effective devices.

C. Labeling (Proposed § 800.30(c))

We are proposing labeling requirements to provide consumers with essential information for the safe and effective use of OTC hearing aids. Section 709(b)(2)(C) of FDARA specifically directs FDA to include, among appropriate labeling requirements, a conspicuous statement that the device is only intended for adults age 18 and older, information on how consumers may report adverse events, information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss, and advisements to consult promptly with a licensed healthcare practitioner. In addition, section 709(b)(2)(A) of FDARA directs FDA to establish requirements that provide reasonable assurances of the safety and effectiveness of OTC hearing aids, and we intend the proposed labeling requirements to do so.

In considering which statements to require, we note the important role of information in supporting broader use of OTC hearing aids. As part of the 2016 FDA hearing aid workshop, the Hearing Loss Association of America presentation stressed the importance of clear labeling to inform consumers so that the consumer ''is empowered and knows what they're buying and knows the limitations and what's possible'' (Refs. 9 and 10). FDA agrees, and we have proposed labeling requirements to empower consumers.

Further the proposed conspicuous statement that OTC hearing aids are intended for people age 18 years and older is necessary because the use of OTC hearing aids in people younger than 18 presents risks to health beyond those typically associated with use in older people. Whereas hearing loss in older adults is most commonly related to noise exposure and aging, the etiology (causes) of hearing loss in younger people is varied and may result from conditions that warrant prompt diagnosis to avoid serious risks to health. These conditions may not be readily apparent and can include, but are not limited to:

- Congenital malformations (present since birth) of the external, middle, or inner ear;
- Infections, for example, otitis media (an inflammation of the middle ear) or congenital infections;
- Genetic causes, including hereditary syndromes that can involve cardiac, ophthalmic, renal, neurologic, and other organ systems (that is, syndromes that can involve the heart, eyes, kidneys, nerves, and other organs); or
- Certain exposures, for example, lead poisoning, hyperbilirubinemia (a buildup of a metabolic byproduct, bilirubin, in the blood), and drug ototoxicity (a toxic effect on the ear or its nerves).

The use of a hearing aid to treat hearing loss related to these conditions, without a medical evaluation, may delay diagnosis and treatment of the

[6] See section III.G, discussing the codification of the preemption provision, section 709(b)(4) of FDARA.

underlying condition. Further, prompt diagnosis is critical because, left untreated, these conditions may worsen, with potentially lifelong, adverse health effects. Because the use of OTC hearing aids in people younger than 18 presents risks to health beyond those typically associated with use in older people, the proposed conspicuous statements are appropriate and provide reasonable assurance of safety and effectiveness of OTC hearing aids.

The proposed labeling provisions include requirements for labeling on the package and inside the package, along with requirements for labeling on the device itself. These requirements would apply in addition to all other applicable labeling requirements in, for example, parts 801 and 830. In any of the labeling, manufacturers could continue to include additional truthful, non-misleading information provided it does not conflict with other requirements (such as those mentioned above).

In proposing where to place labeling statements—on the package or inside the package—we have considered when users, prospective users, and others should become aware of information (before or after purchase). We have also considered the limited space available on the packaging as well as simplicity of format.

FDA welcomes your comments on the proposed labeling requirements, including the placement or conspicuousness of statements, as well as whether the statements are clear and understandable. For example, in reviewing the proposals, did you find important information quickly? Did you find the information clear and easy to understand? We are particularly interested in your feedback about phrasing or formatting to convey information to people who are anticipated users, or more generally, who are not hearing health professionals. A rationale or evidence would make your feedback more useful. For example, if a proposed statement is unclear, telling us why is generally more helpful than saying only that you find the statement to be unclear.

1. Package Labeling

We are proposing that the outside of the package include information that consumers would need to know prior to purchasing the device, such as who is a candidate for the device, how to determine if you are a candidate, and when to seek professional help before trying the device. We believe this information empowers consumers and answers threshold questions about the suitability of purchasing an OTC hearing aid for their hearing needs. This proposal would also emphasize who the intended user is, to reduce the likelihood that people younger than 18 would purchase or use an OTC hearing aid.

To summarize, the proposed statements on the package describe:

- A conspicuous warning that the device is not for users younger than 18 years old;
- The symptoms of perceived mild-to-moderate hearing loss;
- Considerations for seeking a consultation with a hearing healthcare professional; and
- Red flag conditions: Warnings to consumers regarding signs and symptoms that should prompt a consultation with a licensed physician (preferably an ear specialist).

However, we are not proposing to require other information on the package, for example, mobile operating system compatibility or whether the package contains the necessary batteries. Further, we are proposing language that accurately conveys information to readers without relying on specialized knowledge (*i.e.,* for laypeople). We welcome your comments on whether to require other information on the package labeling and whether you had any difficulty understanding the information (and if so, your suggestions for improvements).

a. Symptoms suggesting perceived mild to moderate hearing loss. Prospective users may not know their definitive degree, configuration, or etiology of hearing loss. That is, they may not know the exact nature or cause, so commenters for the public meeting discussed various ways to communicate the signs of perceived mild to moderate hearing loss and reasons to seek medical evaluation. They generally agreed that such information should appear on the outside of the package. We agree with this sentiment and are proposing that the information be readily apparent prior to purchase to help people to determine whether an OTC hearing aid may benefit them.

To that end, we are proposing four scenarios that a person may recognize (symptoms) that suggest perceived mild to moderate hearing loss. We have selected these scenarios because they commonly present difficulties to people with perceived mild to moderate hearing loss and are situations in which users are likely to benefit from the use of OTC hearing aids. We have also based the selection on stakeholder input from the public workshops. Although people with normal hearing may sometimes experience these scenarios, people with perceived mild to moderate hearing loss will experience them more frequently, if not regularly. We have phrased the information to emphasize that the device is intended for people who are 18 or older, and the phrasing avoids medical and technical terms while describing everyday situations.

b. Considerations for seeking consultation with a hearing healthcare professional. However, because a prospective user may have hearing impairment beyond, or different from, perceived mild to moderate hearing loss, we are proposing a statement to assist people in evaluating the potential for increased benefit from an OTC hearing aid. We believe this information is important, and have titled it as such, and appropriate for users and prospective users who are not familiar with hearing aids.

c. ''*Red flag*'' *conditions.* In that vein, we are proposing to continue to require a statement advising users and prospective users to seek medical care if they exhibit any one of a number of conditions. We are not modifying the list of conditions from its present form except for phrasing and formatting changes to improve readability, as well as a change to the time periods (from 90 days to 6 months). We intend the change to the time periods to encourage consumers to consider a longer personal history, which may help them to identify the conditions without the involvement of a licensed person. The list includes reliable indicators of the possibility of an underlying medical condition that a hearing aid cannot treat. For example, fluid, pus, or blood coming out of the ear may indicate an active infection, as could sudden, quickly worsening, or fluctuating hearing loss. An examination by a physician, preferably an ear specialist, would determine whether such an underlying condition is present and treatable, potentially halting or reversing hearing loss.

d. Other information. We are also proposing to require that the outside package include a web address and telephone number for consumers to access a digital copy or request a paper copy of all labeling, including the labeling inside the package, for that OTC hearing aid. A website could provide easy access to the more comprehensive information found in the labeling inside the package and could allow the use of other media to convey information.

FDA is proposing to require that this labeling be available online or be able to be requested by phone prior to purchase to facilitate product familiarity to make a purchasing decision. We believe having the information found inside the package will help prospective users

choose a safe and effective device without the involvement of a licensed person. As proposed, this information would be available without the need for consumers to register for access, for example, by registering for a website member login.

Further, a download page could include, but would not be required to include, additional resources, for example, video explanations or tutorials to aid prospective users in selecting and using a device, as well as a mechanism for reporting complaints or adverse events. Since such additional resources would not be required under this proposal, accessing such resources could entail, for example, registering as a website member.

Please note that we are not proposing to require the distribution of paper copies for all OTC hearing aids because an analogous provision in the Hearing Aid Restrictions yielded little benefit—very few people requested a review of the paper copy—while adding to the regulatory burden. We are seeking comment on these proposed requirements (and any other portion of this proposed rule) regarding equitable access to the information and/or OTC hearing aids.

We are also proposing to require that the manufacturer disclose its return policy or, if none, state that it does not accept returns. Such a requirement would be appropriate, because prospective users of OTC hearing aids may be unsure whether an OTC hearing aid will meet their hearing needs. If an OTC hearing aid does not meet a user's hearing needs, the user may leave the device in the ''dresser drawer.'' (This is a common description of the phenomenon of relegating the device to disuse—putting it away, never to use it again—and foregoing the potential benefit of a more-satisfactory device). Thus, a statement of the return policy would be appropriate because, without the services of a licensed person, some users may be more dependent on the manufacturer's return policy (as opposed to the licensed person's) to avoid leaving an OTC hearing aid in the dresser drawer. A statement of the return policy would provide appropriate information to prospective users to help them determine the suitability of options given individual circumstances and preferences such as budget and willingness to try multiple OTC hearing aids. Additionally, consistent with the existing hearing aid requirement in § 801.420(c)(5), we are proposing that, when an OTC hearing aid is used or rebuilt, the outside package declare that fact. These requirements would advance the public health by facilitating the purchase of devices that meet users' hearing needs.

We are not proposing to require that manufacturers accept returns under these proposed Federal regulations. However, we likely would not consider a generally applicable State or local requirement to accept returns (*i.e.,* the requirement applies to any product) as a requirement specifically related to hearing products. Further, we believe that a State or local requirement for retailers (persons who sell to end users) to accept returned OTC hearing aids would likely promote—rather than restrict or interfere with—commercial activity involving the devices by reducing the financial risk to purchasers. As such, generally, State or local requirements for returns would continue to apply provided they do not conflict with the final rule based on this rulemaking. We are seeking comment on whether such a State or local requirement would promote, rather than restrict or interfere with, commercial activities involving OTC hearing aids.

Participants at the June 9, 2017, NASEM public workshop generally agreed with the importance and utility of requiring certain information on the package. Participants discussed potential labeling requirements such as these for OTC hearing aids (see Ref. 11). Numerous participants focused on the signs and symptoms of consumers who have mild-to-moderate hearing loss and might potentially benefit from OTC hearing aids. Specifically, participants expressed concerns that consumers would need information to help decide whether to purchase the products and/or whether to seek professional services. The proposed requirements in this document have taken these comments into account.

2. Labeling Inside the Package

We are proposing to require that manufacturers place labeling inside of the package with the information that consumers will need after purchasing an OTC hearing aid for its safe and effective use. The proposed content of this labeling includes:

- Warnings, cautions, and notes, including a conspicuous statement warning against the use of the OTC hearing aid in people younger than 18 years old as well as a warning regarding ''red flag'' medical conditions to prompt consumers to consult with a licensed physician and a note about how to report adverse events to FDA;
- Illustration(s) of and information about the controls, user adjustments, and the battery compartment;
- A description of any accessory that accompanies the OTC hearing aid;
- Adequate directions for use, consistent with § 801.5 (21 CFR 801.5), including but not limited to information on sizing and inserting the eartip as well as the tools, tests, or software that allow the user to control and customize the OTC hearing aid to the user's hearing needs (*e.g.,* to self-select, self-fit, and self-check the performance of the device);
- Technical specifications to allow users, prospective users, and others to evaluate and compare the performance of OTC hearing aids;
- Description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid;
- Identification of known physiological side effects associated with using the OTC hearing aid that may warrant consultation with a physician, including but not limited to skin irritation and accelerated build-up of ear wax (cerumen accumulation);
- Information on repair services; and
- If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the OTC hearing aid, a summary of all such studies.

We believe these labeling requirements for OTC hearing aids will help provide reasonable assurance of safe and effective use of OTC hearing aids for consumers with perceived mild-to-moderate hearing loss. We intend the proposed labeling requirements to provide lay consumers with adequate information, in particular, to ensure that those purchasing OTC hearing aids know when to seek professional intervention, how to use the device safely and effectively, and where and how to obtain additional information or assistance. The 2016 NASEM report supports FDA's proposal in that it similarly recommends that OTC hearing aids ''[i]nclude thorough consumer labeling, including information on:

- Frequency gain characteristics;
- adequate directions for use;
- communication challenges for which it may be helpful to seek professional consultation; and
- medical situations, symptoms, or signs for which to consult with a physician'' (Ref. 6).

We agree that thorough consumer labeling will assist users, potential users, and others with selecting, fitting, and wearing OTC hearing aids. Even so, the proposed requirements in this rulemaking are not intended as a substitute for other FDA regulations. Thus, for example, if adequate directions for use were to require additional information beyond that proposed in this rulemaking, manufacturers would need to include

that additional information (see § 801.5 regarding adequate directions for use).

As for the NASEM report's recommendations for OTC hearing aids regarding information about communication challenges and medical indicators, we agree that such information will help provide reasonable assurance of safety and effectiveness, and we have included that information, as well as the full-on gain value in our proposed labeling requirements. (Gain is a measure of amplification, and its full-on value is its maximum. We provide an explanation of gain in section III.D.2.)

We are not proposing to require additional technical information in the labeling for OTC hearing aids other than those in proposed § 800.30(c)(4); however, the labeling may optionally include such information if desirable. For example, technical information similar to what is currently required for all hearing aids may be useful in assisting audiologists offering services to users (see § 801.420(c)(4)). Multiple stakeholders voiced a similar view during the 2016 FDA workshop (Refs. 9, 10, and 12). Some added that scientific or technical information (in addition to the information we are proposing to require for OTC hearing aids) may be meaningful for consumers to make their decisions, especially if they are familiar with the technology. Although such additional information may be desirable for some consumers, FDA does not believe it is necessary to assist consumers in their selection.

FDA intends to issue at a later date a separate comprehensive guidance document that discusses, in part, labeling information and communicating that information with the goals of increasing transparency and choice to consumers. In accordance with 21 CFR 10.115, we will announce the availability of the draft of that guidance separately from this rulemaking, and the announcement will include information for submitting comments about that guidance, which will be separate and distinct from comments for this rulemaking. We do not intend to consider comments submitted to the docket for this rulemaking unless they pertain to the proposals in this document.

3. Labeling on the Device Itself

We are proposing to require that the labeling on the device itself include the serial number and symbol(s) for proper battery insertion orientation when applicable. If the device has been used or rebuilt, a tag indicating such would have to be physically attached to the device in addition to the statement on the outside of the package.

D. Output Limits (Proposed § 800.30(d))

FDA is proposing a maximum acoustic output limit requirement for an OTC hearing aid to provide reasonable assurance of safety and effectiveness. Section 709(b)(2)(B) of FDARA directs FDA to establish or adopt output limits appropriate for OTC hearing aids. A high output can be unsafe and further impair hearing. However, too low an output reduces device effectiveness and can lead to poor device performance, including clipping and distortion. In turn, poor performance would reduce consumer satisfaction and use of the devices. We believe that the proposed output limits balance the above considerations for these devices, so the limits are therefore appropriate for OTC hearing aids.

1. Overview of Proposed Output Limits

We propose a maximum OSPL90 output level of 115 dB sound pressure level (SPL) as a general rule to balance consumer safety with device performance.[7] However, we would permit a limit of 120 dB SPL for an OTC hearing aid that implements input-controlled compression and a user-adjustable device volume control (*i.e.,* volume adjustment). This is because a user-adjustable volume control allows the user to reduce the output below the maximum, in effect, further reducing the device's limit. Input-controlled compression is an automatic function that dynamically reduces the output of frequency ranges based on the input. Both of these design features thus reduce the likelihood that a user will experience high acoustic outputs, at the device's limit, at any given moment. Relatedly, we are proposing that the device labeling state the value of the maximum OSPL90 level (see section III.C.1).

We have proposed output limits to prevent injuries from exposure to loud sounds when amplified by OTC hearing aids while still allowing a sufficient dynamic range of outputs, called ''headroom,'' to provide effective amplification for users with perceived mild to moderate hearing loss. A device without sufficient headroom (when the output limit is too low) would not be as effective as a device with a higher output. However, a device with too high an output limit could further worsen hearing impairment.

2. Data and Stakeholder Perspectives on the Proposed Output Limit

We base the proposed limits on physiological data and stakeholder input, some of which appear in Clause 4.3 of ANSI/CTA–2051, a voluntary consensus standard (Ref. 13). Note that, although ANSI/CTA–2051 is a consensus standard for PSAPs, we believe that this standard is also relevant for OTC hearing aids, which provide personal sound amplification, albeit for purposes of aiding with or compensating for impaired hearing. The standard's basis for the output limit is a national workplace safety guideline, *Occupational Noise Exposure,* from the National Institute for Occupational Safety and Health (NIOSH) (Ref. 14). NIOSH developed this standard, which we will refer to as NIOSH–98, to define permissible exposure time depending on the intensity of the sound.

In general, the relationship between the loudness (SPL) and the time before damage to hearing is inversely related: The louder the sound, the shorter the time before hearing damage. Above about 85 dBA (A-weighted decibels), the exposure time is cut in half for every 3 dB increase in sound level (Ref. 14).[8] Thus, the difference between recommended exposure times for 115 dB SPL and 120 dB SPL is approximately 61 seconds, where 115 dB SPL provides approximately triple the permissible exposure time than 120 dB SPL (see the next section for a more detailed explanation of the ''3–dB exchange rate'').

Appendix A of ANSI/CTA–2051 describes this tradeoff between output level and exposure time, providing a rationale for a maximum OSPL90 output limit of 120 dB based on NIOSH–98. For the purposes of that standard, NIOSH found that 115 dBA SPL is acceptable for up to about 30 seconds. ANSI/CTA–2051 explains that this allows the user sufficient time to turn off or remove the hearing aid before the exposure becomes

[7] OSPL90 is an abbreviation for the sound output as measured in a standardized way. ANSI/ASA S3.22–2014 defines it as the SPL developed in the specified 2-cm^3 earphone coupler when the input SPL is 90 dB with the gain control of the hearing aid full-on. To simplify, this describes a way to simulate amplifying a sound into the ear canal, providing a standardized measurement for the amplified output.

[8] Weighting sound levels means that different frequency ranges have different values (weights) added or subtracted to them, so for example, lower frequencies may receive more weight than higher frequencies for the purpose of expressing the sound level. Different sets of weighting values have different purposes. A-weighting tries to account for the fact that the human ear is less sensitive to lower frequencies, which generally do not sound as loud to people as higher frequencies at the same SPL. Therefore, A-weighted decibels can be useful to express how a listener might perceive a sound level when considering the ear's variable sensitivity to different frequencies. This weighting method is common but is not the only one that accounts for human hearing perception. C-weighting is another.

unacceptably dangerous to hearing ability. ANSI/CTA–2051 observes that sound levels of desirable, ''real-life sonic events'' can approach the NIOSH–98 level, for example, a live symphony in which a user would want to experience ''occasional peaks'' undistorted. However, a lower output limit would not allow enough headroom for a faithful reproduction of such peaks and would lead to output clipping or distortion. Thus, a limit that allows desirable peaks, but sufficient time to react to undesirably loud sounds, would be ideal. As ANSI/CTA–2051 explains, 115 dBA is equivalent to an OSPL90 value of approximately 120 dB SPL with an allowance of 28 seconds to react.

FDA agrees that an OTC hearing aid should provide sufficient headroom to amplify relatively loud sounds such as those in a symphony, yet the device should not have an output so high that the user does not have time to act before sustaining injury. Further, the output should not be consistently at a limit of 120 dB SPL, accomplished through the inclusion of input-controlled compression and user-adjustable volume control.

In addition to considering the ANSI/CTA and NIOSH standards supporting the proposed limits, we considered stakeholder input. On June 9, 2017, NASEM held a public workshop meeting where participants discussed, among other topics, a 120-dB SPL maximum output limit for an OTC hearing aid (see Ref. 11). Numerous speakers commented that an OSPL90 output limit somewhat lower than 120 dB SPL for OTC devices would likely still provide sufficient amplification and headroom for individuals with perceived mild to moderate hearing loss while providing a safety margin in terms of sound-intensity exposure.

Additional comments during the NASEM workshop raised the importance of input-controlled compression and the inclusion of a user-adjustable volume control in order to help reduce overamplification. Each of those features can limit the device's output by dynamically reducing device gain as the input level increases, thus increasing the safety profile of a device: The user generally would not be listening at louder output levels as often as would occur without these features.

FDA has also reviewed numerous public comments on the risk of harm from excessive output, stemming from our 2016 public workshop, Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids (see Refs. 9, 15, and 16). We agree that excessive amplification from OTC hearing aids could pose a risk to individuals' health and thus are proposing that the maximum output (OSPL90) of OTC hearing aids not exceed a certain value, depending on device design features, that would provide users enough time to react to loud sounds to prevent injuries.

Some stakeholders have suggested inclusion of gain limits for OTC hearing aids. Gain is a measurement based on the ratio between the output and the input or, to simplify further, how much the device amplifies (or reduces) the input. A gain limit would further reduce the maximum device output because the device would sometimes reach the gain limit, providing no further amplification, before it reached the output limit. We are proposing not to limit the device gain because we believe that the proposed maximum output limit (together with the other proposed requirements) will provide reasonable assurance of safety and effectiveness without limiting the device gain also.

Moreover, a gain limit may unduly constrain the design of effective devices. Appropriate gain characteristics can depend on the implementation of the amplification circuit design (*e.g.,* linear amplification versus wide dynamic range compression). Thus, appropriate gain settings for one device may not be appropriate for another device of a different design. We believe that allowing flexibility in the gain settings will help maximize the effectiveness of the particular circuit design a manufacturer implements for a device to address perceived mild to moderate hearing loss. In light of this, and since a maximum output limit would also in effect limit gain, we do not believe a separate, additional gain limit is necessary to provide reasonable assurance of safety and effectiveness. We also note that the NASEM report does not recommend any limit on gain for OTC devices, only on maximum output (Ref. 6).

3. The Proposed Output Limit Requirements Help Provide Reasonable Assurance of Safety and Effectiveness

In further consideration of user-adjustable volume controls and input-controlled compression, we believe that these two design features together will sufficiently mitigate the risk of a higher maximum output limit (from 115 dB SPL up to and including 120 dB SPL) by reducing the likelihood that the user will experience excessive sound levels for periods long enough to sustain damage to hearing (Ref. 14). Input-controlled compression such as wide dynamic range compression is also associated with hearing performance benefits in realistic environments that have varying levels of sound intensity for persons with mild-to-moderate sensorineural hearing loss (see, *e.g.,* Refs. 17 to 21). That is, besides reducing the device's effective output limit, input-controlled compression also generally helps users hear better in daily situations.

In reaching this proposal on output limits, we note that hearing aids, including OTC hearing aids, are intended to be worn during all waking hours in a wide variety of listening environments and situations. Thus, user comfort is relevant to safety and effectiveness, and input-controlled compression and user-adjustable volume control increase comfort by dynamically adjusting gain and keeping outputs lower. This contributes to effectiveness and user satisfaction because users are generally more willing to wear a comfortable device consistently, maximizing the benefits of the device and the impact on public health.

We are not proposing to require input-controlled compression and a user-adjustable volume control for all OTC hearing aids, however. Thus, devices that do not have both of these features (which, in effect, reduce the device's output limit) would have to respect a 115 dB SPL limit, which would more than triple the safe exposure time compared to a 120 dB SPL limit (Ref. 14).[9] Users would have ample time to take appropriate action to mitigate unacceptably high sound levels, for example, by adjusting the volume (if the device has a user-adjustable volume control), turning the device off, removing the device from the ear, or moving out of the loud environment. As noted above, the device labeling would also be required to include a reminder to consumers that, if they are in a loud listening environment that warrants hearing protection, they should remove their hearing aid(s) and use hearing protection.

To summarize, we believe that a 115 dB SPL output limit would help provide reasonable assurance of safety and effectiveness for the intended population. However, we acknowledge that 120 dB SPL could have additional effectiveness potential in certain circumstances, for example, when listening to a symphony by a live orchestra (Ref. 13). As discussed above, we believe that achieving that potential would be safe only if the device also

[9] Based on the 3-dB exchange rate—above 85 dB SPL, the time halves for each 3-dB increase—of Clause 1.1.1 of NIOSH–98, which is used by ANSI/CTA–2051, exposure to 115 dB SPL is $2^{(5/3)}$ or 3.17 times the ANSI/CTA–2051 recommended exposure limit of 28 seconds for 120 dB SPL, equaling approximately 89 seconds.

includes input-controlled compression and a user-adjustable volume control. Overall, we believe this device-design contingent proposal for output limits helps provide reasonable assurance of safety and effectiveness of OTC hearing aids while providing ample design space for innovation.

E. Other Requirements (Proposed § 800.30(e) and (f))

Although certain labeling and output limits are necessary for reasonable assurance of safety and effectiveness of OTC hearing aids, these requirements alone are not sufficient to do so. FDA is therefore proposing that the devices must meet certain performance and design requirements in order to help provide reasonable assurance of safety and effectiveness, pursuant to section 709(b)(2)(A) of FDARA.

1. Electroacoustic Performance Requirements To Help Provide a Reasonable Assurance of Safety and Effectiveness

We are proposing to establish electroacoustic performance requirements to help ensure that the output of an OTC hearing aid safely and effectively compensates for perceived mild to moderate hearing loss in people age 18 and older. Electroacoustic performance describes how well a hearing aid converts an electrical signal, either digital or analog, into a sound (acoustic energy) or vice versa. Currently, hearing aid labeling must include technical data for certain performance characteristics gathered according to the test methods specified in ANSI/ASA S3.22–2003 (see § 801.420(c)(4)). We do not believe, however, that the data that conform to ANSI/ASA S3.22 are adequate for consumers to select their own hearing aid without the supervision, involvement, or intervention of a licensed person (among other reservations).

This is because ANSI/ASA S3.22 does not specify any minimum performance requirements. Instead, it specifies tolerances, which are acceptable ranges of deviation from manufacturer-stated specifications. The manufacturer, not a standard, determines how the hearing aid performs. As a result, achieving optimal hearing aid performance currently depends in part on interpreting the technical data supplied by the manufacturer for selection and adjustment. The interpretation of this information is highly technical, so the information is useful to a professional but generally not the lay user.

For OTC hearing aids, we believe that the devices must meet certain electroacoustic performance specifications so that any OTC hearing aid would perform safely and effectively for perceived mild to moderate hearing loss after the user customizes the device for individual needs. To that end, we are proposing to use several applicable specifications for device performance from ANSI/CTA–2051 for OTC hearing aids. A device that met these performance specifications would safely and effectively reproduce sounds without the need for professional involvement.

Specifically, an OTC hearing aid should provide amplification with high fidelity so that the user can accurately perceive daily social and environmental sounds. High-fidelity (accurate) output means that the device reproduces the input frequencies clearly, without distortion and without undue frequency shaping. We believe such an OTC hearing aid will have certain performance characteristics to achieve fidelity: The OTC hearing aid would have sufficiently low distortion, would not introduce excessive self-generated noise or time delays between input and output, and would provide a sufficient frequency response bandwidth and smoothness. An OTC hearing aid would have to achieve these, after customization to the individual's hearing needs, without the intervention of a licensed professional; that is, by design.

We have reviewed ANSI/CTA–2051:2017, which includes specifications for electroacoustic performance, and we believe that performance requirements based primarily on its Category 1 specifications would help provide reasonable assurance of safety and effectiveness of OTC hearing aids.[10] These specifications relate to the device's processing of the input sound (the sounds detected by the device) to generate the output sound (the amplified sound that the device produces to assist the user). To summarize, FDA believes that the specifications that would help provide reasonable assurance of safety and effectiveness, as well as set an objective baseline for device performance, are:

- Distortion control limits;
- Self-generated noise limits;
- Latency limit;
- Frequency response bandwidth; and
- Frequency response smoothness limits.

We believe that the above listed electroacoustic requirements would ensure that an OTC hearing aid can accurately reproduce daily speech and other environmental sounds without the need for professional involvement. We believe that this performance level is requisite for the device to meet the needs of people with perceived mild to moderate hearing loss. Likewise, the performance requirements would help ensure that undesirable effects (such as distortion) do not impair safety and effectiveness.

ANSI/CTA–2051 is, to FDA's knowledge, the first voluntary consensus standard to describe performance characteristics for hearing amplifiers (as opposed to standardized test methods and tolerances). Upon reviewing the voluntary consensus standard, and in consideration of related presentations during FDA's 2016 hearing aid workshop, we believe that the rationale and methodology of the standard are sound, and we believe that adhering to the specifications in this standard would yield high-fidelity OTC hearing aids. However, we are proposing to establish as requirements the subset of those specifications that we believe would help provide reasonable assurance of safety and effectiveness in conjunction with the other proposals in this rulemaking.

Whether to require such electroacoustic performance specifications for OTC hearing aids, and the specific values, were topics of discussion during the June 9, 2017, NASEM public workshop (Ref. 11). Additionally, public presentations of amplification measurements at FDA's hearing aid workshop showed performance differences and suitability in terms of frequency response bandwidth and smoothness across devices that presenters considered (Refs. 9, 15, 16, 22). After seeing such information, several participants opined that the Category 1 limits of ANSI/CTA–2051, together with the device latency limits (a Category 2 limit in ANSI/CTA–2051), would collectively help ensure safety and effectiveness of an OTC hearing aid with respect to its electroacoustic performance.

In addition to the performance aspects of the voluntary consensus standard, we recognize that aligning FDA regulations with a voluntary consensus standard may reduce administrative burdens while encouraging and facilitating greater availability of safe and effective OTC hearing aids. Note that we are not proposing to apply the electroacoustic performance requirements to

[10] Note that the consensus standard includes a maximum acoustic output as a Category 1 specification; however, we are proposing a different maximum output level rather than the consensus standard's (see section III.D). Additionally, we are proposing a latency limit, which the standard includes as a Category 2 specification.

prescription hearing aids, nor are we proposing to establish requirements for OTC hearing aids that mirror the technical data requirements under current § 801.420(c)(4). We expect that the involvement of a licensed professional for prescription hearing aids will help provide for reasonable assurance of safety and effectiveness for those devices. Similarly, although the technical data in current § 801.420(c)(4) will assist licensed professionals to select and fit a prescription hearing aid, we do not believe that the technical data are generally helpful for lay users of OTC hearing aids that meet electroacoustic performance requirements.

a. Distortion control limits. Distortion control limits describe how faithfully an OTC hearing aid reproduces a given frequency or range of frequencies at a given sound pressure level. An OTC hearing aid that produces less perceptible total harmonic distortion, plus hearing-aid-originated noise (*i.e.,* total harmonic distortion plus noise), will deliver a higher-fidelity sound to the user, meaning that the user will be able to perceive sounds more accurately or clearly than a device with higher perceptible total harmonic distortion plus noise. Total harmonic distortion plus noise can depend on both the input and output sound pressure levels and the corresponding (level-dependent) gain settings of the device if applicable. We believe that the proposed allowable levels of total harmonic distortion plus noise, when measured as proposed at the specified sound pressure levels, will help ensure accurate or clear amplification for the user of an OTC hearing aid.

b. Self-generated noise level limit. The self-generated noise level limit describes the maximum sound pressure level of noise that the OTC hearing aid may produce, where ''self-generated noise'' means sounds that are present in the output but not the input. Excessive self-generated noise can obscure or overwhelm softer output sounds, preventing the user from hearing such sounds. Excessive self-generated noise may also distract or annoy users. Appropriately limiting self-generated noise will therefore help users to hear softer output sounds as well as improve their experience by avoiding the production of perceptible noise or sounds that are not input sounds. We believe that the proposed rule will appropriately limit self-generated noise.

c. Latency limit. The latency limit describes how quickly an OTC hearing aid produces the output sound relative to the input sound. A shorter latency interval means that the device takes less time to produce the output, and when short enough, the user will not perceive a delay. A perceived delay is generally most noticeable when the device amplifies the user's own voice, causing an effect much like an echo that can be disorienting, distracting, or annoying. We believe that the proposed latency limit will help to avoid perceptible output delays that would reduce the benefit from an OTC hearing aid.

d. Frequency response bandwidth. The frequency response bandwidth of an OTC hearing aid is the range of frequencies that the device can reproduce for the user to hear. Cutoff frequencies, both lower and upper, are the limits of the bandwidth. The device would generally not sufficiently amplify signals with frequencies outside of these limits, meaning, below the lower cutoff or above the upper cutoff. A wider bandwidth means that the device can amplify a broader range of sound frequencies for users to hear. A bandwidth that is too narrow, especially if the upper cutoff is too low, will result in insufficient amplification of critical high-frequency sounds, including but not limited to speech sounds such as /s/,/z/,/t/, and/sh/. We believe that the proposed required frequency bandwidth, 250 Hz to 5 kHz, will ensure amplification of daily speech or other environmental sounds because almost all such sounds typically fall between these proposed lower and upper cutoff frequencies.

e. Frequency response smoothness limit. The frequency response smoothness limit describes how uniformly the OTC hearing aid amplifies different frequencies over its bandwidth. A uniform frequency response when graphed would correspond to a smooth and relatively uniform curve, which is the ''smoothness'' described by this limit. To describe this requirement, we divide the frequency range into multiple, narrower ranges called one-third octave bands. Any given peak in a one-third octave band would have to remain below a set level compared to neighboring bands, two bands above and two bands below, based on the averages. Meeting this requirement for frequency response smoothness means that the amplification performance is consistent across frequencies for users.

If a device does not amplify sounds uniformly across frequencies, the user would potentially perceive differences in intensity for different frequencies, reducing the audio fidelity and consequently the user's hearing perception. This may include a perceptibly altered speech quality (such as undue changes in the tone or timbre of the intended sound), which may be distracting or annoying. In addition, device output that is relatively excessive at lower frequencies (compared to higher frequencies) poses an increased risk for damaging a user's hearing at lower frequencies. This is because the typical user has more residual hearing (*i.e.,* better hearing thresholds) at lower frequencies, consistent with a typical sloping hearing loss, the kind of hearing loss associated with aging. We believe that the proposed frequency response smoothness limit will ensure consistent performance across frequency ranges and thereby help to provide reasonable assurance of device safety and effectiveness.

f. Performance test methods. For each of these proposed electroacoustic requirements, we are specifying performance test methods, including input and output sound pressure levels when appropriate. We are proposing specific performance test methods because different test methods could yield different results for the same metric of device performance. Thus, specifying test methods helps establish a common baseline to benchmark performance for any given device. Additionally, a common baseline would allow prospective users and others to compare electroacoustic performance across devices. Facilitating comparison shopping may also promote users' satisfaction with the OTC hearing aids that they decide to purchase.

2. Design Requirements To Ensure Proper Physical Fit and Prevent User Injury

We are proposing that the design of an OTC hearing aid must meet certain requirements for safety and effectiveness:

- Maximum insertion depth;
- Eartip made from atraumatic materials;
- Proper physical fit; and
- Tools, tests, or software allowing the lay user to control the device and customize it to the user's hearing needs.

The above listed requirements seek to balance effective fit and safe fit of an OTC hearing aid, accomplished by users themselves, without professional assistance. An OTC hearing aid eartip (the part of the OTC hearing aid that contacts and fits into the user's ear) must fit the user so the device performs optimally, but an OTC hearing aid must not damage the ear, including the ear canal and eardrum (tympanic membrane).

The device could damage the ear by scratching (abrading) the skin around the eartip parts, puncturing the eardrum, or exacerbating hearing loss if

the device is too close to the eardrum. In particular, the skin that lines the ear canal is especially thin and delicate. The lateral (outer) third of the canal is composed of cartilage, and the medial (inner) two-thirds, which ends at the ear drum, of bone. Each of these parts of the ear is therefore quite sensitive and easily injured. To provide reasonable assurance of safety and effectiveness, the design of an OTC hearing aid must allow insertion and prolonged contact with these sensitive areas while preventing injury to them. We believe the above listed requirements would ensure proper physical fit for optimal performance while avoiding injury to the user's ear canal skin, bony inner ear canal, the eardrum, or other middle ear structures.

a. Maximum insertion depth. We considered whether we could express a design requirement for manufacturers for maximum insertion depth as a given length. However, specific anatomical dimensions such as the length of the cartilaginous and bony portions of the external auditory canal and distance to the tympanic membrane can vary greatly among adults. That is, the distance to the eardrum differs greatly from person to person. A given length may be too long for one person (potentially resulting in injury with device insertion or placement) but too short for another (potentially impairing device performance by too shallow of an insertion). In contrast, we believe that the bony-cartilaginous junction is a readily identifiable and consistent anatomical landmark that can serve as a design limit for manufacturers of OTC hearing aids. That is, we believe a practical way to describe the depth limit is to base it on the area of the ear canal corresponding to where cartilage meets bone. However, we welcome comments, particularly those with support from peer-reviewed sources, about other design requirements (*e.g.,* in terms of absolute length) to limit the insertion depth and prevent damage to the tympanic membrane or other injuries while also promoting device effectiveness.

b. Construction from atraumatic materials. We are proposing that the eartip be encased by atraumatic materials, that is, materials that prevent injuries to the skin and bone, for example, because they are very flexible. The use of atraumatic materials reduces the chance that daily use or accidental contacts will cause damage to the delicate skin or bone of the ear.

c. Proper physical fit. We are proposing that the OTC hearing aid have features that enable users to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear. For example, the manufacturer may wish to provide interchangeable eartips of varying sizes. However, we are not proposing a specific design feature or strategy because such specificity may constrain the design of an OTC hearing aid and impede design innovations. This proposed requirement corresponds with the proposed labeling requirements to describe how users may obtain such a fit, including sizing or inserting the eartip to minimize the risk of injury.

d. Tools, tests, or software. We are proposing to codify the requirement that an OTC hearing aid must include tools, tests, or software through which a lay user can control the device and customize it to the user's hearing needs. Examples of tools, tests, or software include but are not limited to: A user-adjustable volume control, a user-adjustable tone control, the ability for a user to change preset listening programs manually, interactive software for self-selecting, testing, and fitting, or a switch to enable or disable automatically determined settings, such as acoustic environment sensing or noise cancellation. An OTC hearing aid would need to include tools, tests, or software, or some combination of those features, sufficient to customize the device to meet the user's hearing needs.

3. QS Requirements

We are soliciting further input on potential revisions to the applicable QS requirements for OTC hearing aids. The input that we have already received, while valuable, is sometimes contradictory and does not fully address FDA's concerns for the quality of medical devices. As described in section I.C, we received stakeholder input suggesting that FDA reduce the provisions of the QS regulation applicable to the devices as the provisions are overly burdensome. We also received input that the current requirements are important and not unduly burdensome (Ref. 9). While FDA wishes to minimize regulatory burdens, we must have reasonable assurance of safety and effectiveness, which a quality system helps to provide.

In considering the range of feedback already received, we note that the QS requirements are interdependent yet inherently flexible. This scheme relies on each of the provisions working together. Further, because hearing aids are medical devices, a quality system for medical devices specifically, as opposed to a quality system for consumer electronics more generally, is necessary to provide reasonable assurance of safety and effectiveness. This is because medical device quality systems address regulatory concerns regarding safety and effectiveness that systems for consumer electronics do not.

While the use of the quality system described in part 820 would be more appropriate for OTC hearing aids and straightforward to implement than another standard with various reservations, exceptions, and modifications, FDA is open to considering alternatives to the existing QS requirements. Any such changes would be proposed in a separate rulemaking proceeding, and interested parties would have an opportunity to comment during that rulemaking. However, we welcome proposals for how the QS requirements could be modified, or an alternate approach implemented, to ensure the quality of OTC hearing aids and provide a reasonable assurance of safety and effectiveness.

Finally, with regard to the QS requirements, FDA is undertaking other separate efforts to minimize regulatory burdens for manufacturers by proposing the harmonization of part 820 with an international consensus standard.

In light of the foregoing—including contradictory input already received, the inherent flexibility of the QS requirements, the need for a quality system suited to medical devices, and other changes that FDA is proposing—we are seeking further input on potential modifications to the QS requirements that would be applicable to OTC hearing aids to inform future rulemaking.

F. Condition for Sale (Proposed § 800.30(g))

FDA is proposing to establish a condition for sale of OTC hearing aids to prevent sale to people younger than 18, helping to provide reasonable assurance of safety and effectiveness. We are proposing the condition for sale pursuant to section 709(b)(2)(D) of FDARA, which directs FDA to describe the requirements under which the sale of OTC hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online. For the purposes of this provision, we interpret ''sale'' broadly to include, among other transactions, leases and rentals.

The proposed condition for sale is consistent with 709(b)(2)(C) of FDARA and section 520(q)(1)(A)(ii) of the FD&C Act, which establish that OTC hearing aids are only intended for people age 18 and older. As described above, the use of OTC hearing aids in people younger

than 18 presents risks to health beyond those typically associated with use in older people. Accordingly, we are proposing to prohibit the sale of an OTC hearing aid to or for a person younger than 18 years.

FDA has considered whether other conditions for sale for OTC hearing aids are necessary in addition to the proposed labeling that includes conspicuous statements that OTC hearing aids are only intended for people age 18 and older. This proposed condition for sale provides a basis for comments on the subject.

FDA also considered whether requirements on sellers to verify the age of purchasers or, in the case of online or mail-order sales, the age of the recipient, would promote the public health. However, mindful that the current conditions for sale have been criticized as described above, we believe that a requirement to obtain proof of age could make hearing aids more difficult to obtain. For example, people with limited means or mobility may not have a government-issued photographic identification that shows their birthdate. Similarly, age verification for online or mail-order sales could impede delivery of OTC hearing aids or reduce the number of willing sellers, which could disproportionately affect OTC hearing aid access in remote or rural areas. Moreover, FDA does not expect high demand for OTC hearing aids from or for people younger than 18. Thus, a requirement for age verification could impose a barrier to access, particularly for underserved populations, without a corresponding benefit to the public health.

FDA welcomes your comments on whether a prohibition of sales to or for people younger than 18 years, without the need to verify age, would best promote access to OTC hearing aids while protecting the hearing health of people younger than 18 years. Alternatively, we welcome your comments on what other conditions for sale may protect the hearing health of people younger than 18 years. In the case of alternative conditions for sale, FDA is particularly interested in conditions that would not disproportionately burden underserved communities. FDA is also interested in your comments on whether labeling, without the prohibition on sales, adequately protects the health of people younger than 18.

We intend to minimize burdens and provide flexibility for sellers, while also protecting the hearing health of people younger than 18, helping to promote the public health by promoting the availability of OTC hearing aids for people who are 18 and older.

G. Preemption Provisions (Proposed § 800.30(h))

FDA is proposing to codify the provisions regarding preemption and private remedies under section 709(b)(4) and (5) of FDARA to assist stakeholders in understanding the legal framework for OTC hearing aids. These provisions are not codified in the FD&C Act, meaning they do not appear under Title 21 of the U.S. Code, but apply nonetheless. We believe that including these provisions in the Code of Federal Regulations will assist our stakeholders, who may not be as familiar with requirements that are not codified in the FD&C Act, such as these, by consolidating applicable requirements in one location that is more familiar.

This may be particularly helpful because FDARA added to the existing preemption framework for devices. In general, under section 521(a) of the FD&C Act, device requirements established by a State (or a political subdivision) are preempted when the requirements are different from, or in addition to, requirements applicable to the device under the FD&C Act and which relate to the safety or effectiveness of the device or to any other matter included in the requirements applicable to the device. FDA may by regulation grant or deny exemptions to this preemption in response to an application from a State (or political subdivision) under certain conditions specified in section 521(b) of the FD&C Act. Prior to the enactment of FDARA, FDA issued regulations in response to such applications, most of them relating to hearing aids, which are codified in part 808.

However, section 709(b)(4) of FDARA established preemption specific to OTC hearing aids that is different from the general rule for preemption under section 521(a) of the FD&C Act. Although FDARA did not explicitly address the existing exemptions from preemption related to hearing aids, section 709(b)(4) of FDARA applies preemption to any requirement of a State (or local government) specifically related to hearing products, that would restrict or interfere with commercial activity involving OTC hearing aids (which, as mentioned above, we will use as shorthand in this document for the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online), that is different from, in addition to, or otherwise not identical to, FDA's regulations issued under FDARA section 709(b). We are therefore proposing to amend the scope of part 808 to reflect the additional preemption set by FDARA (see section III.I.1).

1. FDARA Preempts State Regulation of OTC Hearing Aids

Under FDARA section 709(b)(4), the OTC Hearing Aid Controls that are the subject of this rulemaking, proposed § 800.30, if finalized, would preempt any State or local requirement specifically related to hearing products that would restrict or interfere with commercial activity involving OTC hearing aids, that is different from, in addition to, or otherwise not identical to, the OTC Hearing Aid Controls, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids.

FDA interprets section 709(b)(4) of FDARA, including the terms therein, as consistent with its purpose that State or local government requirements specifically related to hearing products not restrict or interfere with commercial activity involving OTC hearing aids. For example, we interpret this provision as preempting State or local requirements specifically related to hearing products that would restrict or interfere with leases, consignments, or deliveries of OTC hearing aids, though not explicitly mentioned in FDARA, because such activities fall within the commercial activity involving OTC hearing aids covered by the provision, in this example, within the marketing, sale, dispensing, use, and/or distribution. Further, the FDARA preemption provision applies to requirements specifically related to hearing products generally, as opposed to devices or hearing aids more specifically, where such requirements restrict or interfere with commercial activity involving OTC hearing aids.

As explained, we do not interpret section 709(b) of FDARA as necessarily preempting State requirements regulating professional services such as speech pathology, audiology, or fitting. A State could, for example, continue to regulate such professional services generally. However, to the extent State or local governments require that purchasers of OTC hearing aids seek those services, such requirements would be preempted by section 709(b)(4) of FDARA as interfering with or restricting commercial activity involving OTC hearing aids. The same would be true were a State, for example, to require providers to undertake an activity, such as certification and examination specific

to hearing aids, in order to sell OTC hearing aids.

2. Generally Applicable State and Local Requirements Are Not Necessarily Preempted Under FDARA

As noted in section III.B, FDA does not interpret FDARA to preempt generally applicable requirements. By ''generally applicable,'' we mean that the requirement relates to other products in addition to hearing products, to services not specific to hearing products, or to unfair trade practices in which the requirements are not limited to hearing products.[11] Requirements that apply to any place of business that offers goods or services for sale would likely be generally applicable and therefore not preempted (see also § 808.1(d)(1)). Similarly, requirements that apply to certain places of business may be generally applicable provided the requirements do not attach on account of selling, or other commercial activity involving, hearing products. State or local requirements that make compliance with Federal regulations enforceable by State or local authorities would also not generally be preempted. The examples below focus only on the FDARA preemption provision that applies to OTC hearing aids.

a. Example 1. For example, any given pharmacy may be subject to certain State licensing requirements that apply regardless of whether the pharmacy sells OTC hearing aids; it would not be exempt from such licensing requirements merely because it sells OTC hearing aids. Similarly, a requirement to include terms of sale or return on the receipt that applied also to the sales of other (non-hearing) products would not be preempted.

b. Example 2. In contrast, requirements that attach on account of the sale of hearing products (or would not attach but for the sale of hearing products), would not be ''generally applicable.'' For example, a requirement that any place of business must obtain a license or certification to sell OTC hearing aids would be a requirement specifically related to hearing products. In addition, it would serve to restrict or interfere with commercial activity involving OTC hearing aids and would be different from, in addition to, or not otherwise identical to, the regulations issued under section 709(b) of FDARA. Therefore, it would be preempted.

A requirement may attach on account of the sale of hearing products in a more indirect manner as well, and if it was in effect different from, in addition to, or not otherwise identical to the terms of the statute or Federal regulations, and if it restricted or interfered with commercial activity involving OTC hearing aids, it would be preempted. That is, a State or local requirement may appear on its face to be generally applicable, but if in practice it was specifically related to hearing products and would restrict or interfere with commercial activity involving OTC hearing aids, the State or local requirement would be preempted.

c. Example 3. A requirement that a retailer may only sell OTC hearing aids when it has an audiologist on premises would require the involvement of a licensed person in at least some cases. This requirement would restrict or interfere with commercial activity involving OTC hearing aids, including by requiring the involvement of a licensed person, and would be preempted.

d. Example 4. Similarly, a requirement that sellers advise purchasers of any hearing aids, whether prescription or OTC, of specific medical information not required in the OTC Hearing Aid Controls would be preempted with respect to the sale of OTC hearing aids. Although the requirement attaches on account of the sale of hearing aids more generally (not just OTC devices), it is ''specifically related to hearing products'' and would operate as a condition of sale that is different from, in addition to, or otherwise not identical to those proposed in this rulemaking. The requirement would also restrict or interfere with commercial activity involving OTC hearing aids. Therefore, the requirement would be preempted as applied to the sale of OTC hearing aids.

e. Example 5. A professional or ethical requirement that deemed a sale to be professional malpractice if the dispenser permitted the sale of any hearing aid without consultation would be preempted under FDARA. It specifically relates to hearing products and by requiring consultation prior to the sale of an OTC hearing aid, it would restrict or interfere with commercial activity involving OTC hearing aids even though the requirement on its face applies only to the dispenser (who must meet licensing requirements).

f. Example 6. A requirement that a seller maintain a statement of medical examination, in connection with the sale of a hearing product, would be preempted under FDARA because such a condition of sale would restrict or interfere with commercial activity involving an OTC hearing aid. Moreover, the requirement for a statement of medical evaluation would restrict or interfere with commercial activity involving OTC hearing aids by requiring the involvement of a licensed person during the course of the commercial activity.

3. Requirements for Professionals and Establishments

As with generally applicable requirements, we do not interpret section 709 of FDARA as generally prohibiting the regulation of professionals or establishments or exempting them from applicable professional requirements, even in the case that the professional or establishment only undertakes activities related to OTC hearing aids. Thus, a person that purports to be a specially licensed professional or establishment would be subject to applicable State and local requirements. Such requirements may include periodic professional examination or mandating the availability of testing equipment.

FDA does, however, interpret section 709 of FDARA as preempting certain kinds of professional or establishment requirements. To use one specific example, many States have established definitions for hearing aid fitters, dispensers, or other sellers and servicers. In some cases, State or local requirements may deem an individual or establishment to be a dispenser (or other defined term) by virtue of engaging in the sale of or providing services for hearing aids. That status in turn incurs legal obligations. As explained, we interpret section 709 of FDARA as preempting such requirements to the extent that they would require the involvement of a licensed person for consumers to access OTC hearing aids or would otherwise restrict or interfere with commercial activity involving (the servicing, marketing, sale, dispensing, use, customer support, or distribution of) OTC hearing aids.

For the reasons explained in section III.B regarding the definition of ''licensed person,'' we are specifying certain related terms that would not on their own, as they relate to OTC hearing aids, indicate professional or specialized obligations. For example, under the proposed definition of ''licensed person,'' identifying as a

[11] We refer to hearing products more generally, not just OTC hearing aids. We wish to make clear that a State or locality may not establish requirements for hearing products if those requirements would restrict or interfere with commercial activity involving OTC hearing aids. However, we do not interpret section 709 of FDARA as preempting requirements that apply only to prescription hearing aids (provided they do not restrict or interfere with commercial activity involving OTC hearing aids) but such requirements could be preempted under section 521 of the FD&C Act.

hearing aid ''dispenser'' would not imply licensure. Note that we would consider a person identifying as a ''licensed dispenser'' to be subject to State or local requirements applicable to licensed dispensers and therefore considered a ''licensed person'' under section 709(b)(4) of FDARA.

The examples below focus only on the FDARA preemption provision that applies to OTC hearing aids.

a. Example 7. In contrast to identifying as a dispenser (without using the word ''licensed''), as proposed, identifying as an audiologist or hearing aid fitter, for example, may imply licensure, depending on State and local requirements. Thus, a person who advertises as an audiologist or hearing aid fitter—professional services that may be provided, but cannot be required to be provided, to sell OTC hearing aids—would be subject to State requirements that apply to audiologists or hearing aid fitters. This would be true even if such an audiologist or fitter only sold OTC hearing aids.

b. Example 8. In contrast, a person who advertises as a hearing aid dispenser or seller, and who only sells OTC hearing aids, cannot be required to obtain specialized licenses to engage in commercial activity involving OTC hearing aids.

c. Example 9. As in Example 7, a person who only sells OTC hearing aids but advertises as a licensed dispenser even though such licensing is not required to sell OTC hearing aids—the person purports to be a licensed person, not a ''dispenser'' more generally—would be subject to State or local requirements that apply to licensed dispensers.

We are proposing a preemption provision that speaks specifically to professional requirements in order to clarify in the regulations that the servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids, on its own, does not obligate a person to obtain specialized licenses, certificates, or any other State or local sanction.

H. Proposed Repeal of Conditions for Sale and Modifications for Prescription Labeling (§§ 801.420, 801.421, 801.422)

FDA is proposing to repeal the conditions for sale for hearing aids, § 801.421, because these would no longer be necessary. Currently, those conditions apply to all hearing aids, but section 520(q)(2) of the FD&C Act specifies that OTC hearing aids will be exempt from §§ 801.420 and 801.421 or any successor regulations. Instead of continuing to apply those conditions to non-OTC hearing aids, FDA is proposing to repeal them. Additionally, FDA is proposing to remove the current labeling requirements for hearing aids in § 801.420 and issue prescription labeling requirements under § 801.422, which would be in addition to the prescription labeling requirements in § 801.109.

The repeal of § 801.421 and the amendments to the labeling requirements (amending the current labeling requirements, moving them to a new section, and removing § 801.420) would have further regulatory implications. In proposing new § 801.422, FDA is not relying on its restricted device authority in section 520(e) of the FD&C Act. Therefore, if this proposed rule is finalized, class I and class II hearing aids would no longer be ''restricted devices'' under section 520(e) of the FD&C Act. As such, certain Federal requirements related to restricted devices would no longer apply to class I and class II hearing aids. Further, the basis for some of FDA's exemption decisions about preempted State requirements would change. The next section of this document discusses those changes along with the additional Federal preemption implications of FDARA and how we would remove, update, or clarify those regulations. Repeal of the conditions for sale would also obviate the need for the guidance entitled ''Conditions for Sale for Air-Conduction Hearing Aids''; if the repeal of the conditions for sale is finalized, we would withdraw that guidance (Ref. 8).

1. Repeal of Conditions for Sale § 801.421

As summarized in section I.C.2, the conditions for sale of hearing aids under § 801.421 require a statement of medical evaluation, unless waived by a user 18 years of age or older; the availability of a user instructional brochure and an opportunity to review it; and records of the statements of medical evaluation or waiver. The conditions also provide an exemption from the requirements in § 801.421 for auditory trainers.

In light of the fact that FDA is proposing to clarify that non-OTC hearing aids would be prescription devices, such hearing aids would be subject to State and local requirements for obtaining written or oral authorization of a practitioner licensed by State law to administer the use of the devices. For example, some States license audiologists to administer the use of prescription hearing aids for an adult, so adults could obtain a prescription for hearing aids from an audiologist in those States. In the case of people younger than age 18, the proposed prescription labeling statements described in the next section of this document would in manner and form emphasize the importance of medical evaluations. Because prescription hearing aids will require a written or oral authorization from a practitioner licensed by law to administer the device, and because we are proposing certain labeling requirements in a certain manner and form, FDA is proposing to repeal the conditions for sale (including the requirement for a medical evaluation and for providing a user instructional brochure) because they would no longer be necessary to provide reasonable assurance of safety and effectiveness of prescription hearing aids. Thus, hearing aids that do not meet the definition of, or the requirements for, OTC hearing aids would all be prescription hearing aids, but they would no longer be restricted devices. We expect that the application of prescription requirements with the removal of device restrictions will not increase the burden to obtain non-OTC hearing aids, and that the change will promote consistency with other products, easing the burden on purchasers. Specifically, hearing aids will be either prescription or OTC; users and other interested people would not also need to inquire whether a device is restricted.

Additionally, repeal of the requirements discussed above would obviate the need for the exemption for group auditory trainers, which we are correspondingly proposing to repeal.

2. Revised Labeling for Prescription Hearing Aids

We continue to believe that the labeling requirements are necessary to provide reasonable assurance of safety and effectiveness of prescription hearing aids. As such, we are proposing to retain most of the required information currently in § 801.420 in substance, except as revised below, and place the proposed revised labeling requirements that would be specific to prescription hearing aids in § 801.422, thereby removing § 801.420. These proposed revisions are to ensure that the wording is consistent with and similar to the proposed labeling statements for OTC hearing aids when appropriate. In particular, we are proposing to revise the labeling statements to be more understandable and, when addressed to users and prospective users, less technical.

In general, as summarized in section II, a device's labeling must bear adequate directions for use and certain adequate warnings in the manner and form necessary to protect the user (see section 502(f) of the FD&C Act). We

have defined ''adequate directions for use,'' in part, as directions by which a layperson can use the device safely and for the purposes for which it is intended (see § 801.5). However, we have exempted prescription devices from the requirement for labeling to bear adequate directions for use provided they meet certain conditions (see § 801.109). For prescription devices, labeling must bear, among other statements, information for use under which practitioners licensed by law to administer the device can use it safely and for the purpose for which it is intended (see § 801.109(c)). In any case, the labeling for a device must not be false or misleading in any particular (see section 502(a)(1) of the FD&C Act). Labeling may be false or misleading because, among other reasons, it fails to reveal facts material to its use (see section 201(n) of the FD&C Act). Therefore, prescription hearing aid labeling must include certain adequate warnings as well as information for the licensed professional to use the device safely and for the purpose for which it is intended, and the labeling must not fail to reveal certain material facts.

To determine whether those requirements are met, we consider the sale, distribution, and use of prescription hearing aids. In the case of prescription hearing aids, a prospective user would obtain one from a practitioner licensed by law in that State. However, the professional qualifications for fitters and other licensed practitioners, as well as dispensers more generally, vary widely. Therefore, we are proposing to require information for dispensers to ensure necessary warnings are conveyed in an adequate manner and form for every device. The proposal includes warnings: (1) Of possibilities for underlying pathological conditions, (2) against use in people younger than 18 without a medical evaluation, and (3) of injury potential from high output.

We are further proposing to require the disclosure of certain technical specifications, which is necessary to provide fitters and dispensers information for the safe and effective use of the device. This information is material to the use of the device, as this information would be necessary for a hearing health professional to select an appropriate device. Without this information, a hearing health professional would be unable to determine a safe and effective device for the user without unnecessarily increasing the risks to health to the user. This provision includes a proposed requirement that measurement of the specifications conforms to ANSI/ASA S3.22–2014, ''Specification of Hearing Aid Characteristics,'' to provide for uniformity in testing and measurement, which in turn aids hearing health professionals in selecting or fitting an appropriate prescription hearing aid.

The proposed user labeling requirements are also intended to provide adequate warnings against use in certain pathological (''red flag'') conditions, and by children, where the use would be dangerous to health; as well as adequate warnings against unsafe dosage or methods or duration of administration or application. We propose that this manner and form are necessary for the protection of the users.

Once a user obtains a prescription hearing aid, use of the device occurs without direct supervision of a licensed professional, and notably, such use is generally intended to occur over long periods each day, every day. Therefore, in addition to the proposed information for hearing health professionals summarized above, we are proposing warnings and information specifically for users. We intend this information to be more understandable for laypeople while communicating warnings against use in certain pathological (''red flag'') conditions, against use in children without a medical evaluation, and in a manner and form that are necessary for the protection of the users.

For the reasons explained above, we believe that the proposed labeling requirements for prescription hearing aids are necessary to provide reasonable assurance of safety and effectiveness. This proposal also maximizes consistency with OTC hearing aid labeling to reduce the burden on manufacturers that wish to offer both categories of hearing aids. Although we are proposing the foregoing warnings and information in manner and form as are necessary for the protection of users, the specificity of this proposal would also encourage uniformity while conveying essential information appropriate for the type of hearing healthcare delivery. By minimizing burdens and fostering familiarity, the specificity and consistency would also help promote availability and use of prescription devices.

To provide for clarity and efficient enforcement of the FD&C Act, FDA is proposing to provide explicitly that a prescription hearing aid that does not satisfy the labeling requirements of proposed § 801.422, if finalized, would be misbranded under sections 201(n), 502(a), and 502(f) of the FD&C Act. Moreover, as explained, we believe that the labeling statements as we propose to revise them are material to and necessary for the safe and effective use of prescription hearing aids. Thus, we believe that an explicit misbranding provision in the prescription labeling requirements will provide for clarity as well as the efficient enforcement of the FD&C Act.

If we finalize the repeal of the conditions for sale under § 801.421, we would correspondingly withdraw the guidance document entitled ''Conditions for Sale for Air-Conduction Hearing Aids'' because that guidance announces our policy regarding certain provisions of § 801.421 and would cease to be relevant (Ref. 8).

I. Proposed Amendments to Previous Exemption Decisions (Part 808)

A State or a political subdivision (*e.g.,* a city) may not establish or continue in effect its own requirement with respect to a device for human use if that requirement is different from, or in addition to, a requirement applicable under the FD&C Act to the device (see section 521(a) of the FD&C Act). Under section 521(b) of the FD&C Act, upon application of a State or political subdivision of a State, FDA may, by regulation, exempt from preemption a State or political subdivision requirement applicable to a device if: (1) The requirement is more stringent than a requirement under the FD&C Act that would be applicable to the device if an exemption were not in effect or (2) the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of the FD&C Act. FDA has granted some exemption requests and most, if not all, of FDA's decisions to grant exemption from preemption were based on the State or local requirement being more stringent.

FDA's decisions on States' applications for exemption from Federal preemption under section 521 of the FD&C Act are codified in regulations under part 808, subpart C. The regulations codifying these decisions include both granting and denial of exemption from preemption. Therefore, ''exemption decisions'' as used in this document include both types of decisions. Most of the applications for exemption from Federal preemption related to State medical device requirements that apply to hearing aids, as they existed at the time of the exemption decisions, and that were different from or in addition to the requirements in §§ 801.420 and/or 801.421. Because FDARA directs FDA to establish different requirements for some hearing aids that are not subject to section 521(b) of the FD&C Act, many of the current exemption decisions would not accurately reflect the regulatory

framework for hearing aids under FDARA and the FD&C Act as amended. Moreover, if we finalize the changes we are proposing to the existing requirements for hearing aids in §§ 801.420 and 801.421, the previous exemption decisions based on those requirements may no longer apply.

1. Exemption Decisions Under Section 521(b) Are Affected by FDARA (Proposed § 808.1(g))

As explained in section III.G of this document, and as indicated above, some decisions on exemption from Federal preemption under section 521(b) of the FD&C Act would no longer accurately reflect the applicability of State requirements after the enactment of FDARA and upon establishing the OTC category of hearing aids. To assist stakeholders to understand the changes effected by FDARA, we are proposing to codify how FDARA limits the scope of exemption decisions under section 521(b) of the FD&C Act. We believe this proposal will provide a concise reference for stakeholders to ascertain the changes effected by FDARA.

Note that we are not considering exemptions from section 709(b)(4) of FDARA for State or local requirements. This is because FDARA does not provide a parallel mechanism to exempt State or local requirements regarding hearing products that would restrict or interfere with commercial activity involving OTC hearing aids. We refer to preemption under section 709(b)(4) simply to clarify how FDARA affects State and local requirements.

2. Removal of Regulations Codifying Exemption Decisions Affected by Amendments to § 801.420 and Repeal of § 801.421 if Finalized

As explained above, FDA's exemption decisions are codified in regulations under part 808, subpart C. These decisions were issued in the 1980s and apply to the specific State provisions identified in the regulations and the specific Federal requirements in effect at the time. As mentioned above, most of the exemption decisions related to State medical device requirements that apply to hearing aids and that were different from or in addition to the requirements in §§ 801.420 and/or 801.421. We are proposing to remove all of the regulations in part 808 related to hearing aids; that is, almost all regulations codifying the previous decisions in §§ 808.53 through 808.101, except for the portions of § 808.55 (California) that do not relate solely to hearing aids. We are proposing this because the exemption decisions codified in those regulations may no longer apply due to changes to the Federal hearing aid requirements as proposed in this rulemaking and changes to the specific State provisions we have identified in those regulations since the decisions were made over 30 years ago.

In particular, the repeal of the conditions for sale would eliminate specific Federal requirements that preempt certain State or local requirements. As such, whether we previously granted or denied exemptions, the exemption decisions would no longer apply because the State or local requirements that differed from, or were in addition to, § 801.421 would no longer be preempted. Therefore, we are proposing to remove the State-specific regulations in part 808 codifying exemption decisions pertaining to the conditions for sale for hearing aids because those decisions would no longer be applicable if the conditions for sale are repealed.

Also, the proposed amendments to the hearing aid labeling requirements may affect the exemption decisions relating to § 801.420. Although the proposed § 801.422 is similar to § 801.420 in that it too would address labeling for hearing aids, the labeling requirements are not identical to those in § 801.420 and include substantive changes. Moreover, FDA is aware that several States have modified their requirements that were the subject of the exemption decisions since they applied for exemptions, in which case the exemption decision may no longer be applicable. Thus, not only will the Federal requirements change, but the State requirements that were the subject of the exemption decisions may have changed too since the decisions were made.

Given that the exemption decisions were based on specific Federal requirements and specific State requirements that existed at the time of the decision, changes in either may affect those decisions such that they are no longer applicable. Because the exemption decisions relating to hearing aid labeling requirements may no longer be applicable, we are proposing to remove the regulations codifying these decisions. We specifically seek comments from the States regarding the proposed removal of the regulations in part 808, subpart C, codifying these exemption decisions. For example, if a State disagrees with the proposed removal of the regulation(s) in part 808, subpart C, because the State believes the exemption decision still applies, a statement and explanation why in the comments may be helpful.

We note that when § 801.422 is finalized and in effect, no State or political subdivision of a State may establish or continue in effect with respect to prescription hearing aids, any requirement which is different from, or in addition to, any requirement in § 801.422 (see section 521(a) of the FD&C Act). However, a State or political subdivision thereof may apply for an exemption from preemption by following the process in part 808 for any requirement that is preempted by § 801.422 (see also section 521(b) of the FD&C Act).

J. Other Proposed Amendments

FDA is proposing several amendments to provide for consistency, including with the proposals in this rulemaking, if finalized, and to improve clarity. We are proposing the following:

- To realign the hearing aid classification regulations by sound conduction mode so that legacy air-conduction hearing aids, wireless air-conduction hearing aids, and self-fitting air-conduction hearing aids would be under one classification regulation; bone-conduction hearing aids would be under a separate classification regulation.
- To clarify that air-conduction hearing aids are subject to § 800.30 or § 801.422, as applicable, and bone-conduction hearing aids are subject to § 801.422.
- To revise the special control currently in § 874.3305(b)(1) for consistency with the special control currently in § 874.3325(b)(3). Although the proposed revision to § 874.3305(b)(1) would require demonstration of electrical safety and thermal safety, we believe that generally manufacturers of wireless air-conduction hearing aids regulated under § 874.3305 have been evaluating these safety aspects for their devices and therefore, this proposed revision would have little to no impact on these manufacturers.
- To revise the special controls for wireless hearing aids currently in § 874.3305(b) and for self-fitting hearing aids currently in § 874.3325(b) to eliminate redundancy, for example, removing special controls that would be addressed by the proposed labeling requirements for both OTC and prescription hearing aids.
- To revise §§ 874.3315 and 874.3950 to clarify that these devices are subject to the prescription hearing aid labeling requirements, including in proposed § 801.422.
- To clarify that a tympanic membrane contact hearing aid under § 874.3315 is a wearable device for

purposes of prescription hearing aid labeling.

We are also proposing non-substantive modifications to the decisions regarding exemption from Federal preemption in part 808 to assist stakeholders to understand the subject matter of the individual exemption decisions.

1. Realignment of Hearing Aid Classification Regulations by Sound Conduction Mode

To increase clarity and to reduce administrative burdens associated with interpreting regulations, we are proposing to separate the classification regulations for bone-conduction and air-conduction hearing aids. We believe this will increase clarity because air-conduction devices are technologically more similar to each other than they are to bone-conduction devices. In addition, section 520(q)(1)(A)(i) defines an OTC hearing aid as a device that, among other criteria, uses the same fundamental scientific technology as air-conduction hearing aids that are wearable devices. Therefore, bone-conduction hearing aids do not fall within the scope of the OTC hearing aid definition and moving them to a separate classification regulation (proposed § 874.3301) will help make that clear. Tympanic membrane contact hearing aids also do not fall within the scope of the OTC hearing aid definition because, among other reasons, they do not use the same fundamental scientific technology as air-conduction hearing aids, and as specified in § 874.3315, they will continue to be regulated as prescription devices.

The proposed realignment of the air-conduction hearing aid types would also locate all OTC hearing aids within the same classification regulation; however, not all air-conduction hearing aids would be OTC hearing aids. For example, high-output air-conduction devices would be prescription. Further, transcutaneous air conduction hearing aid systems entail surgical implantation of a tube to conduct sound, so we do not consider them suitable for OTC availability; the devices will continue to be regulated under § 874.3950. The realignment will not affect any device that does not use the same fundamental scientific technology, such as cochlear implants (product code MCM) or implantable middle ear hearing devices (product code MPV).

In realigning the regulations by sound conduction mode, we are not proposing to reclassify any device or change the exemption status under section 510(m)(2) of the FD&C Act for premarket notification for any device type (see 21 U.S.C. 360(m)(2)). For example, wireless air-conduction hearing aids regulated under § 874.3305 would continue to be class II exempt, subject to the limitations of exemption in § 874.9, and special controls would continue to apply to these devices in addition to the general controls. (The proposed general controls under § 800.30 or § 801.422, if finalized, would also apply.) As of the effective date of the final rule, we would realign current product codes to correspond with the revised regulation numbers for consistency but would not otherwise change the codes. Also, we would change the name of each classification regulation to reflect the sound conduction mode.

Note that the regulation for air-conduction hearing aids would embody a split classification, where different devices under the regulation would have different classifications and special controls depending on the technology and design. As discussed above, we would also amend the wireless hearing aid special controls to provide for consistency with the special controls for self-fitting hearing aids, and we would amend the special controls for wireless hearing aids and self-fitting hearing aids to eliminate redundancy.

2. Non-Substantive Revisions to Exemption Decisions for Clarity and Ease of Use

In addition to the amendments in part 808 explained in section III.I., we are proposing to amend the remaining State-specific regulation in part 808 to include paragraph headings that would appear in italics. Currently, the regulations do not include paragraph headings and, as such, require stakeholders to look elsewhere to understand the content of the State or local requirements as they were at the time FDA made an exemption decision. The paragraph headings will assist stakeholders by briefly describing the subject of the individual exemption decisions, thereby providing additional information and context for stakeholders.

IV. Findings Regarding Premarket Notification

FDA may, in appropriate circumstances, exempt a class II device from premarket notification requirements under section 510(m)(2) of the FD&C Act. Section 709(b)(3) of FDARA directs FDA to make such findings, that is, to determine whether OTC hearing aids require a report under section 510(k) to provide reasonable assurance of safety and effectiveness. As described in section I.B, legacy and wireless air-conduction hearing aids are exempt from section 510(k) subject to the limitations of exemption, and we are not proposing to alter the exemption status of such devices.

Self-fitting air-conduction hearing aids are not currently exempt. FDA classified this device type in October 2019 (see 84 FR 57610), and the Agency does not have sufficient information or experience with this device type to exempt these devices from premarket notification. Accordingly, FDA has determined that, at this time, reports under section 510(k) continue to be necessary to provide reasonable assurance of safety and effectiveness. We therefore do not propose to exempt them at this time.

V. Proposed Effective and Compliance Dates

A. Effective Date

FDA proposes that this rule, if finalized, be effective 60 days after the publication of the final rule in the **Federal Register**. We propose the following compliance dates:

B. Compliance Date for Hearing Aids Not Legally Offered for Sale Prior to the Effective Date

For hearing aids that have not been offered for sale prior to the effective date of the final rule, or have been offered for sale but are required to submit a new 510(k) under 21 CFR 807.81(a)(3), compliance with the new or revised requirements applicable to the hearing aid, and obtaining 510(k) clearance if applicable, must be achieved before marketing the device on or after the effective date of the final rule. If a person (*e.g.,* manufacturer) markets such a device without complying with the new or revised requirements or if applicable, receiving 510(k) clearance, then FDA would consider taking action against such person under our usual enforcement policies.

C. Compliance Date for Hearing Aids Legally Offered for Sale Prior to the Effective Date

For hearing aids that have been legally offered for sale prior to the effective date of the final rule, including those that already have a 510(k) clearance, compliance with the new or revised requirements that apply to the hearing aid must be achieved 180 days after the effective date of the final rule (*i.e.,* 240 days after the publication of the final rule). After that date, if a person (*e.g.,* manufacturer) continues to market such a device but does not comply with the new or revised requirements that apply to the device, then FDA would consider taking action

against such person under our usual enforcement policies.

At present, legacy and wireless air-conduction hearing aids are exempt from section 510(k) of the FD&C Act, subject to the limitations of exemption described in § 874.9. (Legacy hearing aids are class I devices and are 510(k) exempt under section 510(*l*)(1) of the FD&C Act.) However, self-fitting air-conduction hearing aids are not exempt and, therefore, are subject to premarket notification requirements. We believe that modifications to hearing aids, including labeling changes, to comply with the proposed OTC Hearing Aid Controls may exceed the limitations of exemption, for example because the device was formerly intended for use by healthcare professionals only. We believe that labeling changes for such hearing aids to comply with the proposed prescription hearing aid labeling requirements are less likely to exceed the limitations of exemption.

VI. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed 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). Based on our preliminary analysis, OMB's Office of Information and Regulatory Affairs has determined that this proposed rule is an economically 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 believe we can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. The estimated annualized cost over 10 years is $0.009 million per firm, which is unlikely to represent more than 3 percent to 5 percent of the revenue of an affected manufacturer. However, we note that some uncertainty exists as to these impacts, so we have chosen to draft an initial regulatory flexibility analysis. We request comments relating to the effect of this proposed rule on small manufacturers.

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 proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The proposed rule, if finalized, would define a new regulatory category for OTC hearing aids and make corresponding changes to the existing regulatory framework, including defining hearing aids not meeting the proposed OTC requirements as prescription medical devices, as well as providing new labeling requirements for both OTC and prescription hearing aids. This proposed rule, if finalized, would generate potential cost savings for consumers with perceived mild to moderate hearing loss who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance but who are currently unable to buy such products online because of State regulations or because they do not shop online. The proposed rule, if finalized, would also generate costs for hearing aid manufacturers for changing labeling of existing hearing aids as well as for reading the rule and revising internal standard operating procedures in response to the rule. Table 3 summarizes our estimate of the annualized costs and the annualized benefits of the proposed rule, if finalized.

TABLE 3—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year.	$63 63	$6 6	$147 147	2020 2020	7 3	10 10	
Annualized Quantified					7 3		
Qualitative	Potential increase in hearing aid and hearing technology use, leading to associated health benefits, potential fostering of innovation in hearing aid technology.						
Costs:							
Annualized Monetized $millions/year.	1 1	1 1	2 2	2020 2020	7 3	10 10	
Annualized Quantified					7 3		
Qualitative	Potential loss of consumer utility from inability to buy existing hearing aids under existing conditions						
Transfers:							
Federal Annualized Monetized $millions/year.					7 3		
From/To	From:			To:			

TABLE 3—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Other Annualized Monetized $millions/year.	.....	.....	.....	.....	7 3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government:
Small Business:
Wages:
Growth:

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 23) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental impact of this proposed rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of increased use and eventual disposal of OTC hearing aids that will need to be handled if the proposed rule is finalized.

The environmental assessment (EA) considers environmental impacts related to additional waste to landfills at municipal solid waste (MSW) facilities. The proposed action would increase the availability and use of hearing aid devices, which would result in additional waste from increased disposal of these devices and their associated batteries and an increase in industrial waste associated with any domestic production to meet market demand for the new devices. Overall, given the current limited use of these devices, projected slow growth with increase in availability, and the small mass of waste material to be disposed or recycled, the proposed action is not expected to have a significant impact on MSW, landfill facilities, and the environment.

The Agency has concluded that the proposed rule will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40, are on display with 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 invites comments and submission of data concerning the EA and FONSI.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual recordkeeping and third-party disclosure 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.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medical Device Labeling Regulations; OMB Control Number 0910–0485—Revision.

Description: FDA is proposing to establish a regulatory category and related rules for OTC hearing aids to improve access to hearing aid technology for Americans. FDARA amended the FD&C Act by placing the authorities to establish the OTC category of hearing aids among provisions that are, by definition, general controls, which is what these rules would be. Alongside the OTC category, we are proposing multiple related changes to the overall regulatory framework for hearing aids to harmonize existing rules with the eventual OTC category while continuing to provide a reasonable assurance of safety and effectiveness. We believe the proposals set forth in this rulemaking will promote the hearing health of Americans by lowering barriers to access and fostering innovation in hearing aid technology. The set of general controls we are proposing, Over-the-Counter Hearing Aid Controls, would apply to all hearing aids that meet the definition of an OTC hearing aid under the FD&C Act, regardless of the device's class. Among other provisions, the controls would include requirements for labeling and device design, as well as a condition for sale to prevent the sale and use of the devices by people younger than age 18. We are also proposing to remove the labeling requirements in the existing restrictions but establish a new regulation for labeling specific to prescription hearing aids. The new prescription labeling requirements would be similar to the current labeling requirements but maintain consistency with the new labeling requirements for OTC hearing aids (for example, so that ''red flag'' conditions, as revised, will be the same). We are proposing to repeal the other existing restrictions, *i.e.,* the conditions of sale, because, if this rule is finalized as proposed, the new labeling requirements for prescription hearing aids, the requirement for a prescription, and other existing requirements would provide reasonable assurance of safety and effectiveness.

Description of Respondents: Respondents to the information collection are manufacturers of hearing aids.

We estimate the burden of the collection of information as follows:

TABLE 4—ESTIMATED ONE-TIME BURDEN [1] [2]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Total capital costs
Understanding and implementing new regulatory requirements from hearing aids rule	105	1	105	284	29,820	$4,100,000
Hearing aids relabeling; one-time burden	105	8	840	68	57,120	6,000,000

[1] There are no operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded to the nearest whole number.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Proposed labeling disclosures under 800.30(c)(2) and 801.422(c)(2); Hearing aids; electronic version of user instructional brochure	105	8	840	1	840

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded to the nearest whole number.

TABLE 6—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1] [2]

Activity; 21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
OTC Hearing Aid Controls—800.30	105	7	735	19	13,965
Prescription Hearing Aid Labeling—801.422	105	1	105	19	1,995
Total	.....	.....	.....	.....	15,960

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded to the nearest whole number.

Our burden estimate is based on FDA Uniform Registration and Listing System data; FDA's Operational and Administrative System for Import Support data; informal communications with industry; and our knowledge of and experience with information collection pertaining to medical device labeling. We intend the burden estimates to be consistent with our Preliminary Regulatory Impact Analysis (PRIA) for this rulemaking (Ref. 23).

Estimated One-Time Burden: OTC Hearing Aids proposed rule—one-time burden (Recordkeeping): As noted in the PRIA for this proposed rule, we estimate it will take 3 hours each for an executive, a lawyer, and a marketing manager to read and understand the rule. Also included in our estimate is time for revising guidelines or standard operating procedures. We assume this may take up to 25 hours for one executive, up to 100 hours for one marketing manager, and up to 150 hours for one technical writer. Therefore, we estimate a one-time recordkeeping burden of 284 hours for each manufacturer.

OTC Hearing Aids proposed rule—one-time relabeling burden (Third-Party Disclosure):

The proposed rule would necessitate the relabeling of all current hearing aids (approximately 840). The labeling cost model used in the PRIA suggests, based on a compliance period of 6 months, a one-time estimated third-party disclosure burden for relabeling of about 68 hours per product.

We request comments on these estimates.

Estimated Annual Burden: Over-the-Counter Hearing Aid Controls—§ 800.30 (Recordkeeping and Third-Party Disclosure): Proposed § 800.30 sets forth labeling requirements for OTC hearing aids. Proposed § 800.30(c)(1) describes the warnings and other important information that the outside package must bear. Additionally, manufacturers must include on the outside package label a weblink to all labeling and any additional resources, their return policy or lack thereof, and, if the OTC hearing aid is used or rebuilt, they must declare that fact.

Proposed § 800.30(c)(2) describes device-specific requirements for labeling, inside the package. Among the labeling requirements listed are a user instructional brochure, an electronic version of which is to be made available for download; additional warnings; caution and notices for users; other specified information; and any other information necessary for adequate directions for use as defined in § 801.5. Also required under proposed § 800.30(c)(2) is the identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician; the technical specifications required by § 800.30(c)(4); a description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid; if applicable, information regarding repair service; and, if applicable, a summary of all clinical or non-clinical studies

conducted to support the performance of the OTC hearing aid.

Proposed § 800.30(c)(3) provides requirements for the labeling on an OTC hearing aid itself, specifically, name of the manufacturer, model name or number, serial number, and year of manufacture and if applicable, information regarding the battery. Also, if the OTC hearing aid is used or rebuilt, the manufacturer must physically attach a removable tag to the hearing aid declaring that fact.

We include no estimate for provisions under proposed § 800.30(c)(1)(i)(A) through (D), (c)(2)(i)(A) and (B), and (c)(2)(iii)(A) through (D) because we consider the labeling to be ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public,'' consistent with 5 CFR 1320.3(c)(2). Thus, those labeling provisions are not within the definition of collection of information.

The PRIA for this proposed rule estimates that 105 firms manufacture air-conduction hearing aids sold in the United States, based on FDA Medical Device Registration data. We estimate that each manufacturer has an average of eight products that would need relabeling.

For each hearing aid product, we assume a 1-hour annual recordkeeping burden for maintaining the electronic version of the user instructional brochure (under proposed §§ 800.30(c)(2) and 801.422(c)(2)).

The proposed rule would necessitate the relabeling of all current hearing aids (approximately 840) according to either the proposed OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the PRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.

We request comments on these estimates and assumptions.

Prescription Hearing Aid Labeling—§ 801.422 (Third-Party Disclosure):

Proposed § 801.422(c) sets forth labeling requirements for prescription hearing aids. However, as with some of the provisions under proposed § 800.30(c), we include no estimate for provisions under proposed § 801.422(c)(1)(i)(A) and (B), (c)(2)(i)(A) through (C), and (c)(2)(ii)(A) through (E) because we consider the labeling to be ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public,'' consistent with 5 CFR 1320.3(c)(2).

Proposed § 801.422(c)(1) provides the warnings that must be on the outside package labeling and, if applicable, that the prescription hearing aid is used or rebuilt.

Proposed § 801.422(c)(2) describes requirements for prescription hearing aid labeling, inside the package. Among the labeling requirements listed are a user instructional brochure, an electronic version of which is to be made available for download; additional warnings; caution and notices for users; and additional information that must be included in the user instructional brochure.

Proposed § 801.422(c)(3) provides the requirements for the labeling on a prescription hearing aid itself, specifically, name of the manufacturer, model name or number, serial number, and year of manufacture; as well as information regarding the battery if applicable; and if the prescription hearing aid is used or rebuilt, the manufacturer must physically attach a removable tag to the hearing aid declaring that fact.

Proposed § 800.422(c)(4) provides the technical specification elements that must appear in the user instructional brochure or in separate labeling that accompanies the device.

The PRIA estimates that 105 firms manufacture air conduction hearing aids sold in the United States, based on FDA Medical Device Registration data. We estimate that each manufacturer has an average of eight products that would need relabeling.

For each hearing aid product, we assume a 1-hour annual recordkeeping burden for maintaining the electronic version of the user instructional brochure (under proposed §§ 800.30(c)(2) and 801.422(c)(2)).

The proposed rule would necessitate the relabeling of all current hearing aids (approximately 840) according to either the proposed OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the PRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.

We request comments on these estimates and assumptions.

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through *https://www.reginfo.gov/public/do/PRAMain* (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

IX. Federalism

FDA has analyzed this proposed 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 where 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.'' Federal law includes an express preemption provision that preempts certain state requirements ''different from, or in addition to, any requirement applicable under'' chapter V of the FD&C Act that is applicable to devices. (See section 521 of the FD&C Act; *Medtronic* v. *Lohr,* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic,* 552 U.S. 312 (2008)). Federal law also preempts State or local laws ''specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of [OTC hearing aids] through in-person transactions, by mail, or online, that [are] different from, in addition to, or otherwise not identical to, the regulations promulgated under'' section 709(b) of FDARA (see section 709(b)(4) of FDARA).

Section 521(b) of the FD&C Act provides that the Commissioner of Food and Drugs may, upon application of a State or local government, exempt a requirement from preemption, if the State or local requirement for the device is more stringent than the requirement

under the FD&C Act, or if the requirement is necessitated by compelling local conditions and compliance with it would not cause the device to be in violation of a requirement under the FD&C Act.'' Following this process, and if this rule becomes final, a State or local government may request an exemption from preemption for those State or local requirements pertaining to hearing aid products that are preempted by the Agency's final rule under section 521 of the FD&C Act. However, because FDARA does not provide a parallel mechanism to exempt State or local requirements from its express preemption provision, FDA is not considering exemptions under section 709(b)(4) of FDARA for OTC hearing aids.

Thus, if this proposed rule is made final, the final rule would create requirements that fall within the scope of section 521 of the FD&C Act and/or section 709(b)(4) of FDARA. If made final, it would also amend § 801.420 and repeal § 801.421, and such changes would affect many of the decisions on applications for exemption from preemption that were issued in relation to these two regulations under section 521(b) of the FD&C Act, resulting in the removal of the regulations codifying such decisions, as discussed further in section III.I. above. The scope of preemption of this proposed rule, if finalized, is discussed in more detail in sections III.G through I, above.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XI. 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 are also 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 with 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 800

Administrative practice and procedure, Incorporation by reference, Medical devices, Ophthalmic goods and services, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 801

Incorporation by reference, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 808

Intergovernmental relations, Medical devices.

21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 800, 801, 808, and 874 be amended as follows:

PART 800—GENERAL

■ 1. The authority citation for part 800 is revised to read as follows:

Authority: 21 U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360j, 360k, 361, 362, 371.

Section 800.30 also issued under Sec. 709, Pub. L. 115–52, 131 Stat. 1065–67.

■ 2. Add § 800.30 to subpart B to read as follows:

§ 800.30 Over-the-Counter Hearing Aid Controls.

(a) *Scope.* This section specifies the requirements for over-the-counter (OTC) air-conduction hearing aids. Air-conduction hearing aids that satisfy the requirements in paragraphs (c) through (f) of this section are considered ''available'' over the counter as section 520(q)(1)(A)(v) of the Federal Food, Drug, and Cosmetic Act uses the term. Air-conduction hearing aids that do not meet the definition in section 520(q) of the Federal Food, Drug, and Cosmetic Act and do not satisfy the following requirements are prescription hearing aids. Unless otherwise specified, the requirements in this section are in addition to other applicable requirements, including but not limited to special controls found in the applicable classification regulation.

(b) *Definitions for the purposes of this section.* This section uses the following definitions:

Air-conduction hearing aid. An air-conduction hearing aid is a hearing aid that conducts sound to the ear through the air.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Licensed person. A licensed person is a person as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act that holds a license or degree for the diagnosis, assessment, or treatment of hearing loss; or that holds a license to sell or distribute hearing aids. A person that must meet generally applicable licensing or operating requirements such as annual health and safety inspections, provided the generally applicable licensing or operating requirement is consistent with this section and other applicable requirements under the Federal Food, Drug, and Cosmetic Act, is not a ''licensed person'' solely for that reason. A person that represents as a marketer, seller, dispenser, distributor, or customer support representative (or an equivalent description) is not a ''licensed person'' solely by making such representations.

Over-the-counter hearing aid. An over-the-counter (OTC) hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements in this section.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section.

Sale. Sale includes a lease, rental, or any other purchase or exchange for value.

Tools, tests, or software. Tools, tests, or software are components of the device that, individually or in combination, allow a lay user to control the device and customize it sufficiently, such as the device's output, to meet the user's hearing needs.

Used hearing aid. A hearing aid is ''used'' if a user has worn it for any period of time. However, a hearing aid shall not be ''used'' merely because a prospective user wore it as part of a bona fide hearing aid evaluation to determine whether to select that particular hearing aid for that prospective user. A hearing aid evaluation is ''bona fide'' if it was conducted in the presence of the dispenser or a hearing health professional selected by the dispenser to assist the prospective user in making a determination.

(c) *Labeling.* An OTC hearing aid shall bear all of the following in the labeling.

(1) *Outside package labeling.* The outside package of an OTC hearing aid shall bear all of the following:

(i) *Warnings and other important information.* All of the following shall appear on the outside package:

BILLING CODE 4164–01–P

(A) *Warning against use in people younger than 18.*--

WARNING: If you are younger than 18, do not use this.

You should go to a doctor because your condition needs specialized evaluation and management. Over-the-counter hearing aids are only for users who are age 18 or older.

(B) *Symptoms suggesting perceived mild to moderate hearing loss.*--

This hearing aid is designed and intended for perceived mild to moderate hearing loss in adults. If you experience any of the following, you may have this kind of hearing loss:

- Difficulty hearing or understanding conversations, especially in groups or noisy places, or when you can't see who is talking
- Difficulty hearing while using a telephone
- Fatigue due to greater listening effort
- Needing to turn up the volume of television, radio, or music louder than normal or loud enough for others to complain

(C) *Advice of availability of professional services.*--

Important Information: You can seek assistance from a hearing healthcare professional.

This device may not be useful for more significant hearing loss or complicated hearing needs. If you cannot hear conversations in a quiet environment, or you have trouble hearing loud sounds—for example, loud music, motor vehicles, power tools, noisy appliances—this device may not help you hear better. If you try this device and continue to struggle with or remain concerned about your hearing, you should seek a consultation with a hearing healthcare professional.

(D) *"Red flag" conditions.*--

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(E) *Notice of weblink and telephone number for information.*--

This information and other labeling, including the user instructional brochure, are available on the internet at: [weblink to all labeling and any additional resources]

You may also call [telephone number] to request a paper copy of this information and other labeling.

(F) *Notice of manufacturer's return policy.*--

Manufacturer's return policy: [succinct, accurate statement of return policy or absence of return policy]

(ii) *Statement of build condition.* If the OTC hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.

(2) *Labeling, inside the package.* The manufacturer or distributor of an OTC hearing aid shall include a user instructional brochure inside the package and shall make an electronic version available for download without site or customer registration and without requiring purchase of any product or service. The user instructional brochure shall include all of the following:

(i) The following warnings, which shall appear in the following order and prior to any content except the cover page:

(A) *Warning against use in people younger than 18.*--

WARNING: If you are younger than 18, do not use this. You should go to a doctor because your condition needs specialized evaluation and management. Over-the-counter hearing aids are only for users who are age 18 and older.

This over-the-counter hearing aid is for users age 18 and older to compensate for perceived mild-to-moderate hearing impairment. A younger person with hearing loss should see a licensed physician, preferably an ear specialist, for diagnosis of potential associated medical conditions. Furthermore, children should receive a formal hearing evaluation and rehabilitation since hearing loss may cause problems in language development and educational and social growth of a child.

(B) *"Red flag" conditions.*--

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(C) *Warning about pain from device placement.*--

WARNING: This hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when inserting or placing it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. You may also report this to FDA as an adverse event according to the instructions that appear later.

(ii) Any additional warnings the manufacturer may include prior to the caution and notices to users in paragraph (c)(2)(iii) of this section.

(iii) The following caution and notices for users, which shall appear prior to any content except the cover page and the warnings under paragraphs (c)(2)(i) and (ii) of this section:

(A) *Caution about hearing protection.*--

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, either of short or long duration. You should use appropriate hearing protection in loud environments. As a general rule, if you would use ear plugs in a loud environment, you should remove this device and use ear plugs in that environment.

(B) *Caution about excessive sound output.*--

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful.

(C) *Advice to seek professional services.*--

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

(D) *Note about user expectations.*--

Note: Expectations about what a hearing aid can do

A hearing aid will not restore normal hearing and may not completely eliminate difficulty hearing over noise. Further, a hearing aid will not prevent or improve a hearing impairment resulting from a medical condition(s).

For many people, the use of a hearing aid may be more satisfactory with training or counseling because the device is only one part of hearing habilitation.

Also, if you have hearing loss in both ears, use of hearing aids for both ears (bilateral hearing aids) may provide more benefit than just one hearing aid, especially in demanding listening situations—for example, noisy environments.

(E) *Note about reporting adverse events to FDA.*--

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report an adverse event, you should submit the information to FDA as soon as possible after the event. Adverse events can include: ear canal or outer ear skin irritation, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device lodged in your ear canal, sudden increased severity in hearing loss with device use, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088.

(iv) An illustration(s) of the OTC hearing aid that indicates operating controls, user adjustments, and the battery compartment.

(v) Information on the function of all controls intended for user adjustment.

(vi) A description of any accessory that accompanies the OTC hearing aid, including but not limited to wax guards and accessories for use with a computer, television, or telephone.

(vii) Specific instructions for all of the following:

(A) Instructions for sizing or inserting the eartip of the OTC hearing aid to prevent insertion past the bony-cartilaginous junction of the external auditory canal and damage to the tympanic membrane.

(B) The tools, tests, or software that allow the user to control the OTC hearing aid, including self-select, self-fit, and self-check the performance of the OTC hearing aid, and customize it to the user's hearing needs, including information about properly fitting eartips.

(C) Use of the OTC hearing aid with any accompanying accessories.

(D) Maintenance and care of the OTC hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(E) If the battery is replaceable or rechargeable, how to replace or recharge the battery, including a generic designation of replacement batteries.

(F) Expected battery life.

(G) Any other information necessary for adequate directions for use as defined in § 801.5.

(viii) Identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

(ix) The technical specifications required by paragraph (c)(4) of this section.

(x) A description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid, including but not limited to ear wax buildup, drops, immersion in water, or exposure to excessive heat.

(xi) If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.

(xii) If the manufacturer provides a repair service or licenses or certifies third-party repair services, information on how and where to obtain repair service, including at least one specific address where the user can go or send the OTC hearing aid to obtain such repair service.

(xiii) If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the OTC hearing aid, a summary of all such studies.

(3) *Labeling on the device.* The labeling on an OTC hearing aid itself shall bear all of the following clearly and permanently, except as provided in paragraph (c)(3)(iii) of this section:

(i) The serial number.

(ii) If the battery is removable, a ''+'' symbol to indicate the positive terminal for battery insertion unless the battery's physical design prevents inserting the battery in the reversed position.

(iii) If the OTC hearing aid is used or rebuilt, the manufacturer shall physically attach a removable tag to the hearing aid declaring that fact.

(4) *Technical specifications.* All of the following technical specifications shall appear in the user instructional brochure that accompanies the device. You may additionally include it on the outside package.

(i) The maximum output limit value (OSPL90).

(ii) The full-on gain value, which is the gain with a 50 dB SPL pure-tone input and volume set to full on.

(iii) The total harmonic distortion value.

(iv) The self-generated noise value.

(v) The latency value.

(vi) The upper and lower cutoff frequencies for bandwidth.

(d) *Output limits.* The output limit for an OTC hearing aid shall be the device maximum acoustic output sound pressure level (SPL) in a 2-cubic centimeter (cm^3) coupler when the device input is a 90 dB SPL pure-tone, and the gain/volume control is full on. An OTC hearing aid shall not exceed the following limits:

(1) *General output limit.* An OTC hearing aid shall not exceed an output limit of 115 dB SPL at any frequency except as provided in paragraph (d)(2) of this section.

(2) *Output limit for a device with input-controlled compression and user-adjustable volume control.* An OTC hearing aid that includes input-controlled compression and a user-adjustable volume control shall not exceed an output limit of 120 dB SPL at any frequency.

(e) *Electroacoustic performance limits.* An OTC hearing aid shall perform within all of the following electroacoustic limits. Measure each electroacoustic performance characteristic using a 2-cm^3 coupler where applicable.

(1) *Output distortion control limits.* Test the output distortion of the OTC hearing aid as follows to ensure that it does not exceed the limit specified in paragraphs (e)(1)(i) through (iii) of this section.

(i) The total harmonic distortion plus noise shall not exceed 5 percent for output levels within one of the following sets of levels, depending on the test method:

(A) Using sine wave-based testing, measure at 70 dB SPL and 100 dB SPL; or

(B) Using a 500-Hz one-third-octave pulsed-noise signal, measure at 67 dB SPL and 97 dB SPL.

(ii) You must measure the total harmonic distortion using a 500-Hz input tone with an analyzer that has a bandwidth at least as wide as the frequency limits of the OTC hearing aid.

(iii) You must measure the output distortion at the OTC hearing aid's maximum volume and the input sound level to the OTC hearing aid adjusted to produce the required outputs.

(2) *Self-generated noise level limits.* Self-generated noise shall not exceed 32 dB SPL. You must disable any methods that artificially lower the apparent noise floor for the measurement. Such methods would include but are not limited to auto-muting and downward expansion.

(3) *Latency.* Latency shall not exceed 15 ms. You must measure the latency with a method that is accurate and repeatable to within 1.5 ms.

(4) *Frequency response bandwidth.* The lower cutoff frequency shall extend to 250 Hz or below, and the upper cutoff frequency shall extend to 5 kHz or greater. You must measure the frequency response bandwidth as specified in the Method for clause 4.1 in ANSI/CTA–2051:2017.

(5) *Frequency response smoothness.* No single peak in the one-third-octave frequency response shall exceed 12 dB relative to the average levels of the one-third-octave bands, two-thirds octave above and below the peak. You must measure the frequency response smoothness using values for a diffuse field and the corrected one-third-octave frequency insertion response as specified in the Method for clause 4.1 in ANSI/CTA–2051:2017.

(f) *Design requirements.* An OTC hearing aid must conform to all of the following design requirements.

(1) *Insertion depth.* The design of an OTC hearing aid shall limit the insertion of the eartip to the bony-cartilaginous junction of the external auditory canal and no deeper.

(2) *Use of atraumatic materials.* The material for the eartip of an OTC hearing aid shall be atraumatic.

(3) *Proper physical fit.* The OTC hearing aid shall be designed to enable consumers to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear.

(4) *Tools, tests, or software.* The OTC hearing aid shall, through tools, tests, or software, permit a lay user to control the device and customize it to the user's hearing needs.

(g) *Condition for sale of an OTC hearing aid.* The sale of an OTC hearing aid to or for a person younger than 18 years of age is prohibited.

(h) *Effect on State law.* Any State or local government requirement for an OTC hearing aid is preempted to the following extent.

(1) *Preemption.* No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations issued under section 709(b) of the FDA Reauthorization Act of 2017, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids.

(2) *Professional requirements.*—(A) *General rule.* The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids, or an equivalent activity, whether through in-person transactions, by mail, or online, shall not cause, require, or otherwise obligate a person providing such services to obtain specialized licensing, certification, or any other State or local sanction unless such requirement is generally applicable to the sale of any product or to all places of business regardless of whether they sell OTC hearing aids. However, although a State or local government may not require the order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids, a licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.

(B) *Sale of OTC hearing aids is not an exemption.* The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids does not exempt a person from any State or local government's professional or establishment requirements that are consistent with this section.

(C) *Representations may create professional obligations.* A person shall not incur specialized obligations by representing as a servicer, marketer, seller, dispenser, customer support representative, or distributor (or an equivalent description) of OTC hearing aids. However, a person representing as any other defined professional or establishment, or as a State licensed dispenser, is subject to applicable State and local requirements even if the person undertakes commercial or professional activities only in relation to OTC hearing aids.

(3) *Private remedies.* This section does not modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

(i) *Incorporation by reference.* (A) The standard required in this section is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available from the sources indicated below. It is also available for inspection 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/code_of_federal_regulations/ibr_locations.html*.

(B) *ANSI.* The American National Standards Institute, 1889 L Street NW, 11th floor, Washington, DC 20036, *storemanager@ansi.org, https://www.ansi.org,* 202–293–8020.

(*1*) ANSI/CTA–2051, ''Personal Sound Amplification Performance Criteria,'' clause 4.1, dated January 2017.

(*2*) [Reserved]

(ii) [Reserved]

PART 801—LABELING

■ 3. The authority citation for part 801 is revised to read as follows:

Authority: 21 U.S.C. 321, 331–334, 351, 352, 360d, 360i, 360j, 371, 374.

§ 801.420 [Removed]

■ 4. Remove § 801.420.

§ 801.421 [Removed]

■ 5. Remove § 801.421.

■ 6. Add § 801.422 to subpart H to read as follows:

§ 801.422 Prescription hearing aid labeling.

(a) *Scope.* This section specifies the labeling requirements for prescription hearing aids. Any hearing aid that does not satisfy the requirements of § 800.30 of this chapter shall be a prescription device. Unless otherwise specified, the requirements in this section are in addition to other applicable requirements, including but not limited to special controls found in the

applicable classification regulation. This section does not apply to group auditory trainers.

(b) *Definitions for the purposes of this section.* This section uses the following definitions:

Dispenser. A dispenser is any person, as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act, engaged in the sale of prescription hearing aids to any member of the consuming public or any employee, agent, salesperson, and/or representative of such a person.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an over-the-counter (OTC) hearing aid as defined in § 800.30 of this chapter or a hearing aid that does not satisfy the requirements in § 800.30 of this chapter.

Sale. Sale includes a lease, rental, or any other purchase or exchange for value.

Used hearing aid. A hearing aid is ''used'' if a user has worn it for any period of time. However, a hearing aid shall not be ''used'' merely because a prospective user wore it as part of a bona fide hearing aid evaluation to determine whether to select that particular hearing aid for that prospective user. A hearing aid evaluation is ''bona fide'' if it was conducted in the presence of the dispenser or a hearing health professional selected by the dispenser to assist the prospective user in making a determination.

(c) *Labeling.* A prescription hearing aid shall bear all of the following labeling.

(1) *Outside package labeling.* The outside package of a prescription hearing aid shall bear all of the following:

(i) *Warnings.* All of the following shall appear on the outside package:

BILLING CODE 4164–01–P

(A) *Warning against use in people younger than 18 without prior medical evaluation.*--

WARNING – Medical evaluation for people younger than 18: The use of a hearing aid in people younger than 18 years old without a medical evaluation may worsen impairment or disability. A prospective hearing aid user who is younger than 18 should have a recent medical evaluation from a licensed physician, preferably an ear specialist. Prior to purchase, a physician should determine that the person is a candidate for the use of a hearing aid.

(B) *"Red flag" conditions.*--

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(ii) *Notices.* All of the following shall appear on the outside package:

(A) *Note about device trial options.*--

Note: Ask about trial-rental or purchase-option programs.

If you are unsure about your ability to adapt to using a hearing aid, you should ask about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers offer programs that allow you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

(B) *Statement of build condition.* If the prescription hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.

(2) *Labeling, inside the package.* The manufacturer or distributor of a prescription hearing aid shall include a user instructional brochure inside the package and shall make an electronic version available for download without site or customer registration and without requiring purchase of any product or service. The user instructional brochure shall include all of the following:

(i) The following warnings, which shall appear in the following order and prior to any content except the cover page:

(A) *Warning against use in people younger than 18 without prior medical evaluation.*--

WARNING – Medical evaluation for people younger than 18: The use of a hearing aid in people younger than 18 years old without a medical evaluation may worsen impairment or disability. A prospective hearing aid user who is younger than 18 should have a recent medical evaluation from a licensed physician, preferably an ear specialist. Prior to purchase, a physician should determine that the person is a candidate for the use of a hearing aid.

(B) *"Red flag" conditions, addressed to dispensers.*--

WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a licensed physician, preferably an ear specialist, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodic vertigo or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

(C) *Warning to dispensers about very high-output devices.*--

WARNING to Hearing Aid Dispensers, Outputs in excess of 132 dB SPL:

You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

(ii) The following caution and notices for users, which shall appear prior to any content, except the cover page and the warnings under paragraph (c)(2)(i) of this section:

(A) *Caution about hearing protection.*--

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, either of short or long duration. You should use appropriate hearing protection in loud environments. As a general rule, if you would use ear plugs in a loud environment, you should remove this device and use ear plugs in that environment.

(B) *Caution about excessive sound output.*--

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful.

(C) *Note about user expectations.*--

Note: Expectations about what a hearing aid can do

A hearing aid will not restore normal hearing and may not completely eliminate difficulty hearing over noise. Further, a hearing aid will not prevent or improve a hearing impairment resulting from a medical condition(s).

For many people, the use of a hearing aid may be more satisfactory with training or counseling because the device is only one part of hearing habilitation.

Also, if you have hearing loss in both ears, use of hearing aids for both ears (bilateral hearing aids) may provide more benefit than just one hearing aid, especially in demanding listening situations—for example, noisy environments.

(D) *Note about reporting adverse events to FDA.*--

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report an adverse event, you should submit the information to FDA as soon as possible after the event. Adverse events can include: ear canal or outer ear skin irritation, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device lodged in your ear canal, sudden increased severity in hearing loss with device use, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088.

(E) *Note about hearing loss in people younger than 18 and fitting devices.*--

Note: Hearing loss in people younger than 18

- If you're younger than 18, you should see a doctor first, preferably an ear specialist.
- The doctor will identify and treat medical conditions when appropriate.
- The doctor may refer you to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the right hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a licensed physician, preferably an ear specialist, before the purchase of a hearing aid. Licensed physicians who specialize in the ear are often called otolaryngologists, otologists, or otorhinolaryngologists. The purpose of a medical evaluation is to identify and treat all medical conditions that may affect hearing before the hearing aid is purchased for the person.

Following the medical evaluation and if appropriate, the physician will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The physician may refer you to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the hearing aid candidate's ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist to select and fit a hearing aid to the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

BILLING CODE 4164–01–C

(iii) An illustration(s) of the prescription hearing aid that indicates operating controls, user adjustments, and the battery compartment.

(iv) Information on the function of all controls intended for user adjustment.

(v) A description of any accessory that accompanies the prescription hearing aid, including but not limited to wax guards, and accessories for use with a computer, television, or telephone.

(vi) Specific instructions for all of the following:

(A) Use of the prescription hearing aid with any accompanying accessories.

(B) Maintenance and care of the prescription hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(C) If the battery is replaceable or rechargeable, how to replace or recharge the battery, including a generic designation of replacement batteries.

(D) Expected battery life.

(vii) Identification of any known physiological side effects associated with the use of the prescription hearing aid that may warrant consultation with a physician, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) The technical specifications required by paragraph (c)(4) of this section unless such specifications appear in separate labeling accompanying the prescription hearing aid.

(ix) A description of commonly occurring, avoidable events that could adversely affect or damage the prescription hearing aid, including but not limited to ear wax buildup, drops, immersion in water, or exposure to excessive heat.

(x) If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.

(xi) If the manufacturer provides a repair service or licenses or certifies third-party repair services, information on how and where to obtain repair service, including at least one specific address where the user can go or send the prescription hearing aid to obtain such repair service.

(xii) If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the prescription hearing aid, a summary of all such studies.

(3) *Labeling on the device.* The labeling on a prescription hearing aid itself shall bear all of the following clearly and permanently, except as provided in paragraph (c)(3)(iii) of this section:

(i) The serial number.

(ii) If the battery is removable, a ''+'' symbol to indicate the positive terminal for battery insertion unless the battery's physical design prevents inserting the battery in the reversed position.

(iii) If the prescription hearing aid is used or rebuilt, the manufacturer shall physically attach a removable tag to the hearing aid declaring that fact.

(4) *Technical specifications.* Technical specifications useful in selecting, fitting, and checking the performance of the prescription hearing aid shall appear in the user instructional brochure or in separate labeling that accompanies the device. You must determine the technical specification values for the prescription hearing aid labeling in accordance with the test procedures of the American National Standard, ''Specification of Hearing Aid Characteristics,'' ANSI/ASA S3.22–2014. As a minimum, the user instructional brochure or such other labeling shall include the appropriate values or information for the following technical specification elements as these elements are defined or used in such standard:

(i) Saturation output curve (SSPL 90 curve).

(ii) Frequency response curve.

(iii) Average saturation output (HF-Average SSPL 90).

(iv) Average full-on gain (HF-Average full-on gain).

(v) Reference test gain.

(vi) Frequency range.

(vii) Total harmonic distortion.

(viii) Equivalent input noise.

(ix) Battery current drain.

(x) Induction coil sensitivity (telephone coil aids only).

(xi) Input-output curve (only for hearing aids with automatic gain control).

(xii) Attack and release times (only for hearing aids with automatic gain control).

(5) *Misbranding.* A prescription hearing aid that is not labeled as required under this section and § 801.109 of this chapter shall be misbranded under sections 201(n), 502(a), and/or 502(f) of the Federal Food, Drug, and Cosmetic Act.

(d) *Incorporation by reference.* (1) The standard required in this section is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available from the sources indicated below. It is also available for inspection 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/code_of_federal_regulations/ibr_locations.html.:*

(2) *ANSI.* The American National Standards Institute, 1889 L Street NW, 11th Floor, Washington, DC 20036, *storemanager@ansi.org, https://www.ansi.org,* 202–293–8020.

(i) ANSI/ASA S3.22–2014, ''Specification of Hearing Aid Characteristics,'' dated November 2014.

(ii) [Reserved]

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

■ 7. The authority citation for part 808 is revised to read as follows:

Authority: 21 U.S.C. 360j, 360k, 371. Section 808.1 also issued under Sec. 709, Pub. L. 115–52, 131 Stat. 1065–67.

PART 808—[AMENDED]

■ 8. In part 808, remove the words ''the act'' and add in their place ''the Federal Food, Drug, and Cosmetic Act''.

■ 9. In § 808.1, add headings to paragraphs (a) through (f) and add paragraph (g) to read as follows:

§ 808.1 Scope.

(a) *Introduction.* * * *

(b) *General rule for State and local requirements respecting devices.* * * *

(c) *Exempting from preemption certain State or local requirements respecting devices.* * * *

(d) *Meaning of ''requirements applicable to a device.''* * * *

(e) *Determination of equivalence or difference of requirements applicable to a device.* * * *

(f) *Applicability of Federal requirements respecting devices.* * * *

(g) *Exemptions not applicable to certain State or local government requirements specifically related to hearing products.* An exemption under this part shall not apply to any State or local government law, regulation, order, or other requirement specifically related to hearing products, including any requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids, that:

(1) Would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of

over-the-counter hearing aids, as defined under section 520(q) of the Federal Food, Drug, and Cosmetic Act, through in-person transactions, by mail, or online; and

(2) Is different from, in addition to, or otherwise not identical to, the regulations issued under section 709(b) of the FDA Reauthorization Act of 2017.

■ 10. Revise § 808.3 to read as follows:

§ 808.3 Definitions.

Compelling local conditions includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

More stringent refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the Federal Food, Drug, and Cosmetic Act.

Political subdivision or *locality* means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

State means any State or Territory of the United States, including but not limited to, the District of Columbia and the Commonwealth of Puerto Rico.

Substantially identical to refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

§ 808.53 [Removed and Reserved]

■ 11. Remove and reserve § 808.53.

■ 12. Revise § 808.55 to read as follows:

§ 808.55 California.

The following California medical device requirements are preempted under section 521(a) of the Federal Food, Drug, and Cosmetic Act, and FDA has denied them exemption from preemption:

(a) *Medical devices; general provisions.* Sherman Food, Drug, and Cosmetic Law, Division 21 of the California Health and Safety Code, sections 26207, 26607, 26614, 26615, 26618, 26631, 26640, and 26441, to the extent that they apply to devices; and

(b) *Ophthalmic devices; quality standards.* California Business and Professions Code, section 2541.3 to the extent that it requires adoption of the American National Standards Institute standards Z–80.1 and Z–80.2.

§§ 808.57 through 808.101 [Removed and Reserved]

■ 13. Remove and reserve §§ 808.57 through 808.101.

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 14. The authority citation for part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 15. Redesignate § 874.3300 as § 874.3301 and revise to read as follows:

§ 874.3301 Bone-conduction hearing aid.

(a) *Identification.* A bone-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing and that transmits sound to the inner ear through the skull. A bone-conduction hearing aid is subject to the requirements in § 801.422 of this chapter.

(b) *Classification.* Class II.

■ 16. Revise § 874.3305 to read as follows:

§ 874.3305 Air-conduction hearing aid.

(a) *Identification.* An air-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing that conducts sound to the ear through the air. An air-conduction hearing aid may be wireless, self-fitting, or both. An air-conduction hearing aid is subject to the requirements in § 800.30 or § 801.422 of this chapter, as applicable. Air-conduction hearing aid generic types exclude the group hearing aid or group auditory trainer, master hearing aid, and the tinnitus masker, regulated under §§ 874.3320, 874.3330, and 874.3400, respectively.

(b) *Classification.* (1) *Legacy hearing aid.* Class I for an air-conduction hearing aid that is not a wireless or self-fitting device. This hearing aid is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

(2) *Wireless hearing aid.* Class II (special controls) for an air-conduction hearing aid that incorporates wireless technology in its programming or use. A wireless hearing aid may also be a self-fitting hearing aid. A wireless hearing aid that is not a self-fitting hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. The special controls for a wireless hearing aid are:

(i) Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device;

(ii) Performance testing must validate safety of exposure to non-ionizing radiation; and

(iii) Performance data must validate wireless technology functions.

(3) *Self-fitting hearing aid.* Class II (special controls) for a wireless air-conduction hearing aid that incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fittings and settings. A self-fitting hearing aid is not exempt from premarket notification procedures, notwithstanding the exemption in paragraph (b)(2) of this section. The special controls for a self-fitting hearing aid, in addition to the special controls for a wireless hearing aid if the device incorporates wireless technology, are:

(i) Clinical data must evaluate the effectiveness of the self-fitting strategy;

(ii) Electroacoustic parameters, including maximum output limits, distortion levels, self-generated noise levels, latency, and frequency response, must be specified and tested;

(iii) Software verification, validation, and hazard analysis must be performed; and

(iv) Usability testing must demonstrate that users can correctly use the device as intended under anticipated conditions of use.

■ 17. In § 874.3315, revise paragraph (a) to read as follows:

§ 874.3315 Tympanic membrane contact hearing aid.

(a) *Identification.* A tympanic membrane contact hearing aid is a prescription wearable device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane. A tympanic membrane contact hearing aid is subject to the requirements in § 801.422 of this chapter.

* * * * *

§ 874.3325 [Removed]

■ 18. Remove § 874.3325.

■ 19. In § 874.3950, add a sentence at the end of paragraph (a) to read as follows:

§ 874.3950 Transcutaneous air conduction hearing aid system.

(a) * * * A transcutaneous air conduction hearing aid system is subject to the requirements in § 801.422 of this chapter.

* * * * *

Dated: October 8, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2021–22473 Filed 10–19–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1380]

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.'' The FDA Reauthorization Act of 2017 (FDARA) directed FDA to update and finalize the draft guidance entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,'' issued on November 7, 2013. Therefore, FDA is issuing this updated draft guidance, which supersedes the November 7, 2013, draft guidance. This updated draft guidance is intended to describe hearing aids, personal sound amplification products (PSAPs), their respective intended uses, and the regulatory requirements that apply to these products. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by January 18, 2022 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–2020–D–1380 for ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Shu-Chen Peng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1224, Silver Spring, MD 20993–0002, 301–796–6481.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) directs FDA to establish a category of over-the-counter (OTC) hearing aids through rulemaking, and mandates that FDA establish various requirements for this category of devices. FDA has issued a proposed rule to establish the OTC category of hearing aids and to implement the requirements of FDARA (''Proposed Rule'') as published elsewhere in this edition of the **Federal Register**. In the proposed rule, FDA has also proposed multiple related changes to the overall regulatory framework for hearing aids to harmonize existing regulations with the proposed OTC category while continuing to provide a reasonable assurance of safety and effectiveness.

FDARA also directed FDA to update and finalize the draft guidance entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,'' issued on November 7, 2013. To fulfill this requirement of FDARA, FDA is issuing this updated draft guidance, which supersedes the November 7, 2013, draft guidance. This updated draft guidance reflects the current regulatory framework for hearing aids and summarizes the new regulatory framework for hearing aids in the proposed rule. After the proposed rule is finalized, this guidance will be updated accordingly so that it only reflects the final regulatory framework for hearing aids.

This guidance identifies current applicable legal requirements under the Federal Food, Drug, and Cosmetic Act for hearing aids and for PSAPs. This guidance is intended to describe hearing aids, PSAPs, their respective intended uses, and the regulatory requirements that apply to both types of products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.'' 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1832 and complete title to identify the guidance you are requesting.

III. 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 the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part(s)	Topic	OMB control No.
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
807, subpart E	Premarket notification	0910–0120
814	Premarket Approval Application	0910–0231
1000 through 1050	Electronic Products	0910–0025

This draft guidance also refers to proposed collections of information described in FDA's proposed rule on ''Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids.'' The proposed collections of information in the proposed rule are subject to review by OMB under the PRA (44 U.S.C. 3501–3521). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule as published elsewhere in this edition of the **Federal Register** and has submitted it for OMB approval.

Dated: October 12, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–22612 Filed 10–19–21; 8:45 am]

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FEDERAL REGISTER

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Part III

The President

Federal Register
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Wednesday, October 20, 2021

Presidential Documents

Title 3—

The President

Proclamation 10289 of October 15, 2021

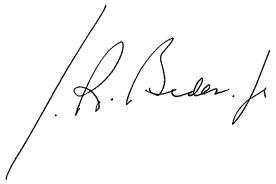
National Peace Officers' Memorial Service

By the President of the United States of America

A Proclamation

In honor of the National Peace Officers' Memorial Service being held in Washington, D.C., to remember and pay respect to law enforcement officers who died in the line of duty and their families, by the authority vested in me as President of the United States by the Constitution and the laws of the United States of America, I hereby order that the flag of the United States shall be flown at half-staff at the White House and upon all public buildings and grounds, at all military posts and naval stations, and on all naval vessels of the Federal Government in the District of Columbia and throughout the United States and its Territories and possessions on Saturday, October 16, 2021. I also direct that the flag shall be flown at half-staff for the same length of time at all United States embassies, legations, consular offices, and other facilities abroad, including all military facilities and naval vessels and stations.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of October, 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. 2021–23049
Filed 10–19–21; 11:15 am]
Billing code 3395–F2–P

Presidential Documents

Proclamation 10290 of October 15, 2021

National Character Counts Week, 2021

By the President of the United States of America

A Proclamation

Every day, each of us makes countless decisions that ultimately define our character and who we are as people. Life's daily choices may not always seem consequential, but they have tremendous potential to transform our communities, our country, and our world. Our words have the power to lift up or tear down, to inspire or discourage, and to comfort or torment. Our actions have the power to create or destroy, to heal or to hurt, and to unify or divide.

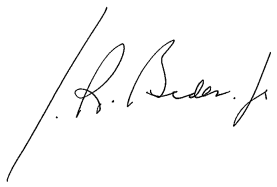
As Americans, our individual character—the sum of qualities that defines who we are and how we treat one another—shapes the character of our Nation and shapes the world we leave for our children. Our character is defined and revealed by the choices we make over a lifetime and, in the case of our Nation, from generation to generation. As we celebrate National Character Counts Week, I encourage all Americans to examine and embody the highest ideals that define our Nation and that have helped us overcome our greatest challenges.

I have long said that the story of America is the story of ordinary people doing extraordinary things. It is a story of strength and resilience, courage and character. Today, our Nation faces tests like very few before—from fighting the COVID–19 pandemic and addressing longstanding inequities and injustices, to confronting the ravages of climate change, and responding to threats to our very democracy. Despite these trials, it is the character of the American people—courageous, selfless, and community-minded—that is pulling us through. As we see in our first responders on the frontlines of the pandemic helping their communities with selfless compassion, in our service members bravely serving around the globe, in our scientists pursuing knowledge with integrity, in our firefighters combating wildfires, and in our teachers and parents and students adapting to new learning environments with patience and determination—Americans are meeting the moment by working to see that we overcome our challenges together.

Character is also revealed by our choices. We must choose to uphold the dignity of all Americans by protecting their health and security, investing in their education and development, helping the needy and the vulnerable, and erasing the stain of hate and discrimination from our society. On this and so many other tasks, I firmly believe that the American people are up to the challenge.

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 17 through October 23, 2021, as National Character Counts Week. I encourage all Americans to set aside differences and join in efforts of service that contribute to their communities.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of October, 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. 2021–23051
Filed 10–19–21; 11:15 am]
Billing code 3395–F2–P

Presidential Documents

Proclamation 10291 of October 15, 2021

National Forest Products Week, 2021

By the President of the United States of America

A Proclamation

For thousands of years, humans have relied on forests for food, fuel, shelter, and medicine among other important uses. Today, forests support the livelihoods of people across the globe, providing jobs and an economic base for families and communities. In the United States, our forests are vital to our Nation, our people, and our economy. They provide wildlife habitat, clean air and water, and renewable materials and energy for the benefit of Americans. Forests also provide Americans countless opportunities for recreation and relaxation, and they remain vital for ceremonies and cultural practices long held by Tribal Nations. During National Forest Products Week, we celebrate the wealth of products and benefits our forests provide, and we recommit ourselves to wisely and sustainably stewarding them to meet our Nation's needs today and long into the future.

While celebrating our forests, we must also acknowledge they are under duress. Climate change threatens our forests by increasing the severity and frequency of wildfires, droughts, floods, and extreme temperatures. My Administration is committed to confronting the climate crisis and the associated challenges facing our forests, including those stemming from biodiversity loss, extreme weather, and insect and disease outbreaks. That is why my Administration launched the ''America the Beautiful'' initiative with the goal of bringing Americans together to conserve at least 30 percent of our lands and waters by 2030. This initiative elevates forest restoration as a way to create jobs while also reducing the threat of catastrophic wildfires, restoring ecosystem function, and fighting the climate crisis. This ambitious goal will drive us forward to meet the urgent challenges we face in maintaining the health, diversity, and productivity of our forests.

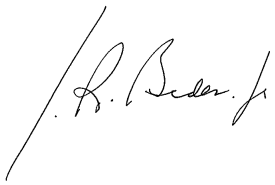
Our forests and the many ecosystem services and wood products they provide are key elements in securing an environmentally sustainable economy. My Administration will continue to advance community-driven conservation and restoration initiatives that will create good jobs—especially in low-income and rural communities—and generate economic growth. My Administration is also supporting business opportunities that advance forest conservation and create jobs by expanding markets for innovative forest products through Federal programs such as the United States Department of Agriculture Forest Service Wood Innovations and Community Wood grant programs. We are proposing investments in sustainable and innovative uses for wood waste materials to produce advanced biofuels, biochar, heat, and power—including through sustainable aviation fuels and other sustainable biofuels. These programs have the potential to support increased connections between the health of our forests, economic opportunity, and the production of valuable renewable energy.

To recognize the importance of the many products generated from our Nation's forests, the Congress, by Public Law 86–753 (36 U.S.C. 123), as amended, has designated the week beginning on the third Sunday in October of each year as ''National Forest Products Week'' and has authorized and requested the President to issue a proclamation in observance of this week. As part of National Forest Products Week, let us rededicate ourselves to

working together across public, Tribal, and private lands to sustain the ability of America's forests to continue to provide the multitude of benefits that will enhance our lives for generations to come.

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 17 through October 23, 2021, as National Forest Products Week. I call upon the people of the United States to join me in this observance and in recognizing all Americans who are responsible for the stewardship of our Nation's beautiful, forested landscapes.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of October, 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. 2021–23052
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Reader Aids

Federal Register

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Wednesday, October 20, 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.

H.R. 4981/P.L. 117–51
To amend the Fentanyl Sanctions Act, to modify certain deadlines relating to the Commission on Combating Synthetic Opioid Trafficking. (Oct. 19, 2021; 135 Stat. 408)

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