FEDERAL REGISTER

Vol. 86 Thursday

No. 229 December 2, 2021

Pages 68389–68532

OFFICE OF THE FEDERAL REGISTER

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DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[EERE–2016–BT–TP–0029]

RIN 1904–AD71

Energy Conservation Program: Test Procedures for Central Air Conditioners and Heat Pumps; Correction

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule; correcting amendments.

SUMMARY: On January 5, 2017, the U.S. Department of Energy (''DOE'') published a final rule that made two sets of amendments to the test procedure for central air conditioners and heat pumps (''CAC/HPs''): amendments to the existing test procedure required for determining compliance with the current energy conservation standards; and establishment of a new test procedure that would be the basis for making efficiency representations as of the compliance date for any amended energy conservation standards. This document corrects typographical errors, omissions, and incorrect cross-references in the Code of Federal Regulations that resulted from the January 2017 final rule. Neither the errors nor the corrections in this document affect the substance of the rulemaking or any conclusions reached in support of the final rule.

DATES: Effective December 2, 2021.

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SUPPLEMENTARY INFORMATION:

I. Background

On January 5, 2017, DOE published a final rule regarding the Federal test procedure for central air conditioner and heat pumps. 82 FR 1426 (''January 2017 final rule''). The January 2017 final rule amended the test procedure for central air conditioners and heat pumps at title 10 of the Code of Federal Regulations (''CFR'') part 430 subpart B appendix M (''Appendix M'') and established a new test procedure at 10 CFR part 430 subpart B appendix M1 (''Appendix M1''). 82 FR 1426. Appendix M provides for the measurement of the cooling and heating performance of central air conditioners and heat pumps using the seasonal energy efficiency ratio (''SEER'') metric and heating seasonal performance factor (''HSPF'') metric, respectively. Appendix M1 specifies a revised SEER metric (''SEER2'') and a revised HSPF metric (''HSPF2''). The test procedures as amended and established in the January 2107 final rule for central air conditioners and heat pumps include a number of typographical errors, omissions, and incorrect cross-references, which may result in confusion in executing the test procedures. The errors and corrections are summarized in the Table I.1.

TABLE 1.1—SUMMARY OF ERRORS AND CORRECTIONS

CFR section(s)	Description of error and correction	Rationale
10 CFR 429.16(a)(1)	Corrects cross-references regarding represented values related to multi-split systems, multi-circuit systems, and multi-head mini-split systems by: (1) Replacing ''(c)(3)(ii)'' with ''(c)(3)(iii)''. (2) Replacing ''Additional representations are allowed, as described in paragraph (c)(3)(i) of this section.'' with ''Additional representations are allowed, as described in paragraphs (c)(3)(i) and (c)(3)(ii) of this section.''.	Cross-references did not get updated when the January 2017 final rule added 10 CFR 429.16(c)(3)(i).
10 CFR 429.16(f)(1)(i)(B), 10 CFR 429.16(f)(2)(ii)(A), and 10 CFR 429.16(f)(4)(i)(B).	Removes the language ''(b)(3)(i)(C)'' and ''(b)(3)(i)(B) and replaces with ''(b)(3)(iii)'' and ''(b)(3)(ii)'', respectively.	Transcription error—cross-references not properly updated.
Paragraph a of Section 3.6.4 of Appendix M and Paragraph a of Section 3.6.4 of appendix M1.	Corrects the instruction regarding compressor speed for the $H1_N$ heating mode test.	Instructions for compressor speed limitations for $H1_N$ test incorrectly incorporated.
Paragraphs b and c of Section 3.6.6 of appendix M.	Corrects incorrect references to HSPF2 in appendix M. HSPF2 is associated with appendix M1. The revision corrects the reference to ''HSPF''.	Reference inadvertently made to HSPF2 rather than HSPF.
Section 4.1.3.2 and Section 4.1.4.2 of appendix M.	Inserts missing inequalities in the titles, revising ''$\dot{Q}_c^{k=1}(T_j)$ $BL(T_j)$ $\dot{Q}_c^{k=2}(T_j)$,'' to read ''$\dot{Q}_c^{k=1}(T_j) < BL(T_j) < \dot{Q}_c^{k=2}(T_j)$.''.	Inequalities inadvertently omitted from the January 2017 final rule.

TABLE 1.1—SUMMARY OF ERRORS AND CORRECTIONS—Continued

CFR section(s)	Description of error and correction	Rationale
Sections 4.2.5.1, 4.2.5.2, and 4.2.5.3 of appendix M; Sections 4.2.5.1, 4.2.5.2, and 4.2.5.3 of appendix M1;.	Replaces cross-references to section ''3.1.9'' with ''3.1.10''.	Cross-references inadvertently not updated.
Section 4.2.5.1 of Appendix M; Section 4.2.5.1 of appendix M1.	Changes subscript on left side of equation for energy E from ''hp'' to ''h'' by replacing ''$\dot{E}_{hp}(T_j) = \dot{Q}_{hp}(T_j)$'' with ''$\dot{E}_{h}(T_j) = \dot{E}_{hp}(T_j)$''.	Transcription error.
Sections 4.2.5.1 of Appendix M; Section 4.2.5.1 of appendix M1.	Changes inequality for Case 2 of Section 4.2.5.1 to reflect intent consistent with Sections 4.2.5.2 and 4.2.5.3 by changing ''$T_o(T_j) > T_{cc}$'' to ''$T_o(T_j) < T_{cc}$''.	Transcription error.
Section 4.2.6.c of appendix M; Section 4.2.6.c of Appendix M1.	Changes designation of booster stage capacity to use the correct superscript ''k=3'' by replacing ''$\dot{Q}_{;h}^{k=2}(5)$'' with ''$\dot{Q}_{h}^{k=3}(5)$'' where the text describes what test is used to obtain the booster stage 5 °F capacity.	Transcription error. Booster capacity denoted as k=3 in all other locations throughout test procedure.
Section 4.2.6.2 of appendix M; Section 4.2.6.2 of appendix M1.	Changes the inequality in the equation of the title of Section 4.2.6.2 to be consistent with the text, ''Capacity Is Greater Than or Equal to the Building Heating Load.'' Replaces ''<'' with ''≤''.	Incorrect inequality.
Section 4.2.6.3 of appendix M; Section 4.2.6.3 of appendix M1.	Changes the title to specify the correct compressor stage for the case, revising ''High'' to ''Booster,'' which is the k=3 compressor stage.	Transcription error. Booster capacity denoted as k=3 in all other locations throughout test procedure.
Section 1.2 of appendix M1	Inserts the word ''minimum'' missing in the definition for ''minimum-speed-limiting variable-speed heat pump'' to indicate which speed is higher than its value for operation in a 47 °F ambient temperature.	Transcription error—missing word ''minimum.''
Section 3.1.4.7 of appendix M1	Replaces incorrect cross-reference to Section ''3.14.6'' with ''3.1.4.6''.	Transcription error.
Paragraph d to section 3.6.4 Table 14 of appendix M1.	Adds explicit description of the compressor speed to be used for the $H4_2$ 5 °F full-capacity heating mode test, consistent with the intent as described in the July 2016 SNOPR and January 2017 Final Rule preamble discussions.	Inadvertent omission of footnote.
Section 4.1.4.2 of appendix M1	Replaces the single instance of ''EER2'' in the section with ''EER''.	Transcription error.
Section 4.1.3.2 of appendix M1	Removes extraneous ''('' in the title line of the section.	Transcription error.

This document identifies and corrects these errors. Neither the errors nor the corrections in this document affect the substance of the rulemaking or any conclusions reached in support of the final rule.

II. Need for Correction

As published, the regulatory text in the January 2017 final rule may result in confusion due to incorrect symbols in the test procedure equations, typographical errors, incorrect cross-references, and missing footnotes. The following sections provide the rationale for each correction. Because this final rule would correct errors in the text and provide additional detail without making substantive changes in the January 2017 final rule, the changes addressed in this document are technical in nature.

A. Cross-References at 10 CFR 429.16(a)(1)

The January 2017 Final Rule added provisions for determining represented values for split systems in 10 CFR 429.16(c)(3)(i) but did not make corresponding edits to the cross-references contained within 10 CFR 429.16(a)(1), which describes the additional representations that are allowed for such systems (*i.e.,* in addition to the required representations). This document corrects this error by updating these cross-references.

B. Transcription Errors at 10 CFR 429.16(f)

In the January 2017 Final Rule, DOE established provisions for represented values required by the Federal Trade Commission—among them the annual operating cost in cooling mode. These sections rely on the calculated quantities for cooling capacity and SEER in order to determine operating costs but contain incorrect cross-references to the sections where these quantities are calculated. This document corrects the cross-references to refer to the correct sections for represented values of cooling capacity and SEER as adopted by the January 2017 Final Rule.

C. Reference to $H1_N$ Test in Section 3.6.4 of Appendix M and Appendix M1

In the January 2017 Final rule, DOE revised the requirement regarding compressor speed for the $H1_N$ heating mode test to ''allow the compressor speed used for the $H1_N$ test to be lower than used for the A2 test, provided that the $H1_N$ capacity is no lower than the A2 cooling capacity.'' 82 FR 1426, 1445. However, in codifying this revision in section 3.6.4 of appendix M and section 3.6.4 of appendix M1, DOE did not properly incorporate the changes. In appendix M, DOE inadvertently referred to the $H1_2$ capacity instead of the $H1_N$

capacity when making the comparison to the A2 cooling capacity. In appendix M1, DOE omitted the language entirely that allowed the $H1_N$ compressor speed to be lower than the speed used for the A2 test provided that the $H1_N$ capacity is no lower than the A2 cooling capacity. This document corrects these errors to reflect the appropriate compressor speed limitations for the $H1_N$ test that were adopted in the January 2017 Final Rule in both appendix M and appendix M1.

D. Reference to HSPF in Section 3.6.6 of Appendix M

The January 2017 Final Rule established the HSPF2 metric as measured per the newly created appendix M1. The HSPF2 metric is not defined for appendix M and does not apply in any section of that appendix. Rather, the applicable heating metric for appendix M is Heating Seasonal Performance Factor (''HSPF''). This document replaces two erroneous instances of HSPF2 with HSPF in paragraphs b and c of section 3.6.6 of appendix M.

E. Inequality Symbols in Sections 4.1.3.2 and 4.1.4.2 of Appendix M

The January 2017 Final Rule retained testing provisions in appendix M to calculate the electrical power consumption of CAC/HPs when building load is between minimum and maximum capacity in order to satisfy the building cooling demand. For two-stage CAC/HPs, section 4.1.3.2 details the case where the system operates *between* low (k=1) compressor stage and high (k=2) compressor stage in order to satisfy demand. For variable-speed CAC/HPs, section 4.1.4.2 details the case where the system operates at an intermediate compressor speed ''i'' that is *between* the low and high compressor speeds. In both cases, the title text for these sections reflects the intent of establishing a range of operation. However, in the following inequalities (which restate the title text), the inequality symbols were inadvertently omitted. This document adds the missing inequalities to reflect what was intended in the January 2017 Final Rule.

F. Cross-References in Sections 4.2.5.1, 4.2.5.2, and 4.2.5.3 of Appendix M and Appendix M1

The January 2017 Final Rule retained provisions in sections 4.2.5.1, 4.2.5.2, and 4.2.5.3 of appendices M and M1 for additional steps to calculate HSPF (or HSPF2 in the case of appendix M1) for heat pumps having heat comfort controllers. These sections each contain a case where outdoor bin temperatures are greater than the maximum supply temperature, T_{CC}, and reference section 3.1.9 of the respective appendix for calculating T_{CC}. However, section 3.1.10 is the correct cross-reference for calculating T_{CC}. This document corrects the cross-reference from 3.1.9 to 3.1.10 in accordance with the January 2017 Final Rule.

G. Symbol Subscripts in Section 4.2.5.1 of Appendix M and Appendix M1

Section 4.2.5.1 of both appendix M and appendix M1 specify calculating the space heating capacity and electrical power of the heat pump, and to denote these capacities and electrical power by using the subscript ''hp'' instead of ''h''. Case 1 of section 4.2.5.1 of both appendices specifies determining total electrical power consumption $E_h(T_j)$ as specified in section 4.2.1 of the same appendix, and provides an *id est* (''*i.e.*'') statement to illustrate the replacement of subscript ''h'' with ''hp''. Rather than state $E_h(T_j) = E_{hp}(T_j)$ as intended, the subscript ''h'' was inadvertently replaced with ''hp'' on both sides of the equation. This document corrects the errors in these sections.

H. Inequality Symbol in Section 4.2.5.1 of Appendix M and Appendix M1

In sections 4.2.5.1, 4.2.5.2, and 4.2.5.3 of both appendix M and appendix M1, Case 1 of each section covers instances where supply air temperature is greater than or equal to the comfort controller maximum supply temperature (*i.e.,* $T_o(T_j) \geq T_{cc}$). Case 2 covers the complimentary scenario where supply air temperature is less than the comfort controller maximum supply temperature (*i.e.,* $T_o(T_j) < T_{cc}$), such that collectively the two Cases cover the full range of possible supply air temperatures in comparison to the comfort controller maximum supply temperature. In section 4.2.5.1 of both appendices, the ''less than'' symbol in Case 2 was inadvertently codified as a ''greater than'' symbol. This document corrects this symbol to ''less than.''.

I. Symbol Superscript in Section 4.2.6.c of Appendix M and Appendix M1

The January 2017 Final Rule established provisions for testing of triple-capacity northern heat pumps, which utilize a third distinct stage of heating capacity—denoted as ''boost'' or ''booster''—that is higher than both the ''high'' and ''low'' stages. Section 4.2.6 of both appendix M and appendix M1 describes additional steps for HSPF calculation for triple-capacity northern heat pumps, referring to boost capacity with the superscript notation ''k=3'' in all but one instance: In section 4.2.6.c, the boost capacity is erroneously referred using the superscript notation ''k=2''. (Elsewhere in the test procedure, the notation ''k=2'' is used to refer to the ''high'' stage.) This document corrects that error by updating the superscript to ''k=3'' to be consistent with the intent established by the January 2017 final rule.

J. Inequality Symbol in Section 4.2.6.2 of Appendix M and Appendix M1

The January 2017 Final rule amended provisions for HSPF calculation of triple-capacity northern heat pumps in section 4.2.6. The title of section 4.2.6.2 describes cases where the heat pump operates at high (k=2) compressor capacity at temperature T_j and its capacity is greater than *or equal to* the building load (*i.e.,* building load is less than or equal to the compressor capacity). In the inequality immediately following, the building load is listed first, and a ''less than'' symbol ''<'' is erroneously used rather than a ''less than or equal to'' symbol (''≤''). This document corrects the symbol using ''≤'' to indicate a building load less than or equal to capacity, to be consistent with the intent of the section title as established by the January 2017 Final Rule.

K. Reference To Booster Capacity in Section 4.2.6.3 of Appendix M and Appendix M1

As discussed in paragraph I, the January 2017 Final rule established provisions for HSPF calculation of triple-capacity northern heat pumps in section 4.2.6. Section 4.2.6.3 describes cases where the heat pump operates at the (k=3) compressor capacity (*i.e.,* boost capacity) at temperature T_j and its capacity is greater than or equal to the building load. The title of this section erroneously refers to the (k=3) compressor capacity as ''high.'' Instead, the (k=3) compressor capacity should be referred to as the ''booster'' capacity (the ''high'' (k=2) capacity is covered by section 4.2.6.2). This document corrects the title of section 4.2.6.3 to be consistent with the intent established by the January 2017 Final Rule.

L. Missing Word ''Minimum'' in Section 1.2 of Appendix M1

In the January 2017 Final rule, DOE proposed a definition for ''minimum-speed-limiting variable-speed heat pump'' to refer to heat pumps that vary the minimum compressor speed when operating in outdoor temperatures that are in the range for which the minimum speed performance factors into the HSPF calculation (*i.e.,* between 35 °F and 62 °F). 82 FR 1426, 1458. However,

in codifying this definition in section 1.2 of appendix M1, DOE inadvertently omitted the word ''minimum'' when referring to compressor speed at 47 °F. This document adds the word ''minimum'' to the definition of minimum-speed-limiting variable-speed heat pump to reflect the intent established by the January 2017 Final Rule.

M. Cross-Reference in Section 3.1.4.7 of Appendix M1

The January 2017 Final Rule established provisions in section 3.1.4.7 of appendix M1 for determining the heating nominal air volume rate to be used in HSPF2 testing. This section omitted a period and erroneously cross-references section 3.14.6 for adjusting airflow—section 3.1.4.6 is the proper cross-reference. This document corrects these errors.

N. Missing Footnote in Table 14 of Appendix M1

Compressor speeds for variable-speed compressor systems are specified in Table 14 in section 3.6.4 of appendices M and M1. These sections are supposed to include footnotes that specify the ''Heating Full'' compressor speed at different outdoor temperature test conditions for systems containing a variable-speed compressor. However, at the optional $H4_2$ heating test condition (5 °F outdoor temperature) in appendix M1, the footnote is missing. (There is no $H4_2$ test condition for variable-speed heat pumps in appendix M so no footnote is required.) For all other test conditions that utilize a ''full'' compressor speed, Table 14 to appendix M1 includes footnotes describing the meaning of ''full'' compressor speed in the context of each test condition. To specify the $H4_2$ compressor speed for variable-speed heat pumps, a footnote is being added to Table 14 in appendix M1 to specify that the ''Heating Full'' speed refers to the maximum speed that the system's controls would operate the compressor in normal operation at 5 °F ambient temperature.

This correction is consistent with the discussion provided in the August 24, 2016 supplemental notice of proposed rulemaking (''SNOPR''), in which DOE stated that the full-speed compressor operation for variable-speed heat pumps could be very different at 5 °F than it is at 17 °F, thus an extrapolation of performance below 5 °F using the [17 °F compressor speed] trend between 17 °F and 5 °F is not appropriate. 81 FR 58164, 58193 (''August 2016 SNOPR''). The regulatory text in the August 2016 SNOPR provided instructional footnotes as to the appropriate ''Heating Full'' compressor speed for the heating test conditions except for the optional $H4_2$ heating test condition. 82 FR 58164, 58238. Comment was not received on the appropriate compressor speed at the 5 °F condition, and the erroneous omission of the footnote was carried over into the final rule, which adopted the proposal in the August 2016 SNOPR. 82 FR 1426, 1459, 1560. This correction also aligns with current industry test procedures for CAC/HPs (AHRI 210/240 2023) which includes a footnote in the test conditions table for variable-speed heat pumps specifying that the full compressor speed to be used at the 5 °F heating test condition is the maximum speed the system controls would operate the compressor at 5 °F ambient temperature.

O. Reference to EER in Section 4.1.4.2 of Appendix M1

Section 4.1.4.2 of appendix M1 specifies several equations in which variations of the EER metric are used. One of these equations contains the term $EER^{k=2}$. In the ''where'' statement following the equation, which defines each symbol used in the equation, $EER^{k=2}$ is erroneously referred to as $EER2^{k=2}$. This document corrects this error by referring instead to $EER^{k=2}$.

P. Extraneous Symbols in Section 4.1.3.2 of Appendix M1

The title of section 4.1.3.2 of appendix M1 contains extraneous ''('' symbols preceding the terms $BL(T_j)$ and $\dot{Q}_c^{k=2}(T_j)$. This document removes these extraneous symbols, consistent with the analogous terms in section 4.1.3.2 of appendix M.

III. Procedural Issues and Regulatory Review

Pursuant to the Administrative Procedure Act, 5 U.S.C. 553(b), DOE has determined there is good cause to find that prior notice and opportunity for public comment on the changes contained in this document are impracticable, unnecessary, or contrary to the public interest. Neither the errors nor the corrections in this document affect the substance of the January 2017 Final Rule or any of the conclusions reached in support of the final rule. Providing prior notice and an opportunity for public comment on correcting objective, typographical errors and omissions that do not change the substance of the test procedure serves no useful purpose. As such, this rule is similarly not subject to the 30-day delay in effective date requirement of 5 U.S.C. 553(d) otherwise applicable to rules that make substantive changes.

DOE has also concluded that the determinations made pursuant to the various regulatory review requirements applicable to the January 2017 final rule remain unchanged for this final rule technical correction. These determinations are set forth in the January 2017 final rule. 84 FR 1426, 1463–1468.

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Reporting and recordkeeping requirements.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Signing Authority

This document of the Department of Energy was signed on November 17, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 18, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons stated in the preamble, DOE corrects parts 429 and 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations by making the following correcting amendments:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 2. Section 429.16 is amended:
■ a. By revising the table in paragraph (a)(1);
■ b. In paragraph (f)(1)(i)(B) by removing ''(b)(3)(i)(C)'' and ''(b)(3)(i)(B)'' and adding in their place ''(b)(3)(iii)'' and ''(b)(3)(ii)'', respectively;
■ c. In paragraph (f)(2)(ii)(A) by removing ''(b)(3)(i)(C)'' and ''(b)(3)(i)(B)'' and adding in their place ''(b)(3)(iii)'' and ''(b)(3)(ii)'', respectively;
■ d. In paragraph (f)(4)(i)(B) by removing ''(b)(3)(i)(C)'' and ''(b)(3)(i)(B)'' and adding in their place ''(b)(3)(iii)'' and ''(b)(3)(ii)'', respectively.

The revision reads as follows:

§ 429.16 Central air conditioners and central air conditioning heat pumps

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Category	Equipment subcategory	Required represented values
Single-Package Unit	Single-Package AC (including Space-Constrained) Single-Package HP (including Space-Constrained).	Every individual model distributed in commerce.
Outdoor Unit and Indoor Unit (Distributed in Commerce by OUM).	Single-Split-System AC with Single-Stage or Two-Stage Compressor (including Space-Constrained and Small-Duct, High Velocity Systems (SDHV)).	Every individual combination distributed in commerce must be rated as a coil-only combination. For each model of outdoor unit, this must include at least one coil-only value that is representative of the least efficient combination distributed in commerce with that particular model of outdoor unit. Additional blower-coil representations are allowed for any applicable individual combinations, if distributed in commerce.
	Single-Split-System AC with Other Than Single-Stage or Two-Stage Compressor (including Space-Constrained and SDHV).	Every individual combination distributed in commerce, including all coil-only and blower coil combinations.
	Single-Split-System HP (including Space-Constrained and SDHV).	Every individual combination distributed in commerce.
	Multi-Split, Multi-Circuit, or Multi-Head Mini-Split Split System—non-SDHV (including Space-Constrained).	For each model of outdoor unit, at a minimum, a non-ducted ''tested combination.'' For any model of outdoor unit also sold with models of ducted indoor units, a ducted ''tested combination.'' When determining represented values on or after January 1, 2023, the ducted ''tested combination'' must comprise the highest static variety of ducted indoor unit distributed in commerce (*i.e.,* conventional, mid-static, or low-static). Additional representations are allowed, as described in paragraphs (c)(3)(i) and (c)(3)(ii) of this section, respectively.
	Multi-Split, Multi-Circuit, or Multi-Head Mini-Split Split System—SDHV.	For each model of outdoor unit, an SDHV ''tested combination.'' Additional representations are allowed, as described in paragraph (c)(3)(iii) of this section.
Indoor Unit Only Distributed in Commerce by ICM).	Single-Split-System Air Conditioner (including Space-Constrained and SDHV). Single-Split-System Heat Pump (including Space-Constrained and SDHV).	Every individual combination distributed in commerce.
	Multi-Split, Multi-Circuit, or Multi-Head Mini-Split Split System—SDHV.	For a model of indoor unit within each basic model, an SDHV ''tested combination.'' Additional representations are allowed, as described in section (c)(3)(iii) of this section.
Outdoor Unit with no Match		Every model of outdoor unit distributed in commerce (tested with a model of coil-only indoor unit as specified in paragraph (b)(2)(i) of this section).

* * * * *

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 3. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 4. Appendix M to subpart B of part 430 is amended:
■ a. In paragraph a. of section 3.6.4, by revising the fifth sentence;
■ b. In the last sentence of paragraph b., section 3.6.6, by removing ''HSPF2'' and adding in its place ''HSPF'';
■ c. In paragraph c., section 3.6.6, footnote 5, Table 15, by removing ''HSPF2'' and adding in its place ''HSPF'';
■ d. By revising the heading for section 4.1.3.2;
■ e. By revising the heading for section 4.1.4.2;
■ f. In section 4.2.5.1, in the ''Case 1'' paragraph, by removing ''3.1.9'', ''$\dot{E}_{hp}(T_j) = \dot{E}_{hp}(T_j)$'' and adding in its place, ''3.1.10'', ''$\dot{E}_h(T_j) = \dot{E}_{hp}(T_j)$'', and in the ''Case 2'' paragraph, by removing ''where $T_o(T_j) > T_{CC}$,'' and adding in its place ''where $T_o(T_j) < T_{CC}$,'', respectively;
■ g. In section 4.2.5.2, in the ''Case 1'' paragraph, by removing ''3.1.9'' and adding in its place ''3.1.10'' and in the ''Case 2'' paragraph, by removing ''For outdoor bin temperatures where $T_o(Tj)$ T_{CC}, determine $\dot{Q}_h(Tj)$ and $\dot{E}_h(Tj)$ using'' and adding in its place '' For outdoor bin temperatures where $T_o(Tj) < T_{CC}$, determine $\dot{Q}_h(Tj)$ and $\dot{E}_h(Tj)$ using'';

■ h. In section 4.2.5.3, by removing ''3.1.9'' and adding in its place ''3.1.10'' and in the ''Case 2'' paragraph, by removing ''For outdoor bin temperatures where $T_o^{k=1}(T_j)$ T_{CC}, determine $\dot{Q}_h^{k=1}(T_j)$ and $\dot{E}_h^{k=1}(T_j)$ using'' and adding in its place ''For outdoor bin temperatures where $T_o^{k=1}(T_j) < T_{CC}$, determine $\dot{Q}_h^{k=1}(T_j)$ and $\dot{E}_h^{k=1}(T_j)$ using'';
■ i. In paragraph c. of section 4.2.6, by removing ''$\dot{Q}_h^{k=2}(5)$'' and adding in its place ''$\dot{Q}_h^{k=3}(5)$'';
■ j. In section 4.2.6.2, in the heading, by removing ''$BL(Tj) < Q_h^{k=2}(Tj)$'' and adding in its place ''$BL(Tj) \leq Q_h^{k=2}(Tj)$''; and
■ k. By revising the heading for section 4.2.6.3.

The revisions read as follows:

Appendix M to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Central Air Conditioners and Heat Pumps

* * * * *

3. * * *

3.6 * * *

3.6.4 * * *

a. * * * For a cooling/heating heat pump, the compressor shall operate for the $H1_N$ test at a speed, measured by RPM or power input frequency (Hz), no lower than the speed used in the A2 test if the tested $H1_N$ heating capacity is less than the tested A2 cooling capacity. * * *

* * * * *

4. * * *

4.1.3 * * *

4.1.3.2 Unit Alternates Between High (k=2) and Low (k=1) Compressor Capacity to Satisfy the Building Cooling Load at Temperature Tj, $\dot{Q}_c^{k=1}(T_j) < BL(T_j) < \dot{Q}_c^{k=2}(T_j)$

* * * * *

4.1.4.2 Unit Operates at an Intermediate Compressor Speed (k=i) In Order To Match the Building Cooling Load at Temperature $\dot{Q}_c^{k=1}(T_j) < BL(T_j) < \dot{Q}_c^{k=2}(T_j)$

* * * * *

4.2 * * *

4.2.6 * * *

4.2.6.3 Heat Pump Only Operates at Booster (k=3) Compressor Capacity at Temperature T_j, and its Capacity Is Greater Than or Equal to the Building Heating Load, $BL(T_j) \leq Q_h^{k=3}(T_j)$.

* * * * *

■ 5. Appendix M1 to subpart B of part 430 is amended:
■ a. In section 1.2, by revising the definition of ''Minimum-speed-limiting variable-speed heat pump'';
■ b. In section 3.1.4.7, by removing ''3.14.6'' and adding in its place ''3.1.4.6'';
■ c. By revising paragraph a. of section 3.6.4;
■ d. In paragraph d., section 3.6.4, by revising Table 14;
■ e. In section 4.1.3.2, in the heading, by removing ''T_j, $Q_c^{k=1}(T_j) < (BL(T_j) < (Q_c^{k=2}(T_j)$'', and adding in its place ''T_j, $\dot{Q}_c^{k=1}(T_j) < BL(T_j) < \dot{Q}_c^{k=2}(T_j)$'';
■ f. In section 4.1.4.2, by removing ''$EER2^{k=2}(T_j)$'' and adding in its place ''$EER^{k=2}(T_j)$'';
■ g. In section 4.2.5.1, in the ''Case 1'' paragraph by removing ''3.1.9'' and adding in its place ''3.1.10'' and removing ''$\dot{E}_{hp}(T_j) = \dot{E}_{hp}(T_j)$'' and adding in its place ''$\dot{E}_h(T_j) = \dot{E}_{hp}(T_j)$'', and in the ''Case 2'' paragraph by removing ''$T_o(T_j) > T_{CC}$,'' and adding in its place '' $T_o(T_j) < T_{CC}$,'';
■ h. In section 4.2.5.2, in the ''Case 1'' paragraph, by removing ''3.1.9'' and adding in its place ''3.1.10'';
■ i. In section 4.2.5.3, in the ''Case 1'' paragraph, by removing ''3.1.9'' and adding in its place ''3.1.10'' and in the ''Case 2'' paragraph by removing ''For outdoor bin temperatures where $T_o^{k=1}(T_j)$ T_{CC}, determine $\dot{Q}_h^{k=1}(T_j)$ and $\dot{E}_h^{k=1}(T_j)$ using'' and adding in its place and ''For outdoor bin temperatures where $T_o^{k=1}(T_j) < T_{CC}$, determine $\dot{Q}_h^{k=1}(T_j)$ and $\dot{E}_h^{k=1}(T_j)$ using'';
■ j. In paragraph c. of section 4.2.6, by removing ''$\dot{Q}_h^{k=2}(5)$'' and adding in its place ''$\dot{Q}_h^{k=3}(5)$'';
■ k. In section 4.2.6.2, in the heading, by removing ''$BL(Tj) < \dot{Q}_h^{k=2}(Tj)$'' and adding in its place ''$BL(T_j) \leq \dot{Q}_h^{k=2}(T_j)$'';
and
■ l. In section 4.2.6.3, in the heading, by removing ''Heat Pump Only Operates at High (k=3)'' and adding in its place ''Heat Pump Only Operates at Booster (k=3)''.

The revisions read as follows:

Appendix M1 to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Central Air Conditioners and Heat Pumps

* * * * *

1. * * *

1.2 * * *

Minimum-speed-limiting variable-speed heat pump means a heat pump for which the compressor minimum speed (represented by revolutions per minute or motor power input frequency) is higher than its minimum value for operation in a 47 °F ambient temperature for any bin temperature T_j for which the calculated heating load is less than the calculated intermediate-speed capacity.

* * * * *

3. * * *

3.6 * * *

3.6.4 *Tests for a Heat Pump Having a Variable-Speed Compressor*

a. Conduct one maximum temperature test ($H0_1$), two high temperature tests ($H1_N$ and $H1_1$), one frost accumulation test ($H2_V$), and one low temperature test ($H3_2$). Conducting one or more of the following tests is optional: An additional high temperature test ($H1_2$), an additional frost accumulation test ($H2_2$), and a very low temperature test ($H4_2$). Conduct the optional high temperature cyclic ($H1C_1$) test to determine the heating mode cyclic-degradation coefficient, C_D^h. If this optional test is conducted but yields a tested C_D^h that exceeds the default C_D^h or if the optional test is not conducted, assign C_D^h the default value of 0.25. Test conditions for the nine tests are specified in Table 14. The compressor shall operate at the same heating full speed, measured by RPM or power input frequency (Hz), as the maximum speed at which the system controls would operate the compressor in normal operation in 17 °F ambient temperature, for the $H1_2$, $H2_2$ and $H3_2$ Tests. The compressor shall operate for the $H1_N$ test at the maximum speed at which the system controls would operate the compressor in normal operation in 47 °F ambient temperature. Additionally, for a cooling/heating heat pump, the compressor shall operate for the $H1_N$ test at a speed, measured by RPM or power input frequency (Hz), no lower than the speed used in the A2 test if the tested $H1_N$ heating capacity is less than the tested A2 cooling capacity.

* * * * *

d. * * *

TABLE 14—HEATING MODE TEST CONDITIONS FOR UNITS HAVING A VARIABLE-SPEED COMPRESSOR

Test description	Air entering indoor unit temperature (°F)		Air entering outdoor unit temperature (°F)		Compressor speed	Heating air volume rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb		
$H0_1$ test (required, steady).	70	60(max)	62	56.5	Heating Minimum	Heating Minimum.[1]
$H1_2$ test (optional, steady).	70	60(max)	47	43	Heating Full[4]	Heating Full-Load.[3]
$H1_1$ test (required, steady).	70	60(max)	47	43	Heating Minimum	Heating Minimum.[1]

TABLE 14—HEATING MODE TEST CONDITIONS FOR UNITS HAVING A VARIABLE-SPEED COMPRESSOR—Continued

Test description	Air entering indoor unit temperature (°F)		Air entering outdoor unit temperature (°F)		Compressor speed	Heating air volume rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb		
$H1_N$ test (required, steady).	70	60(max)	47	43	Heating Full[5]	Heating Full-Load.[3]
$H1C_1$ test (optional, cyclic).	70	60(max)	47	43	Heating Minimum	([2]).
$H2_2$ test (optional)	70	60(max)	35	33	Heating Full[4]	Heating Full-Load.[3]
$H2_V$ test (required)	70	60(max)	35	33	Heating Intermediate	Heating Intermediate.[6]
$H3_2$ test (required, steady).	70	60(max)	17	15	Heating Full[4]	Heating Full-Load.[3]
$H4_2$ test (optional, steady).	70	60(max)	5	3(max)	Heating Full[7]	Heating Full-Load.[3]

[1] Defined in section 3.1.4.5 of this appendix.
[2] Maintain the airflow nozzle(s) static pressure difference or velocity pressure during an ON period at the same pressure or velocity as measured during the $H1_1$ test.
[3] Defined in section 3.1.4.4 of this appendix.
[4] Maximum speed that the system controls would operate the compressor in normal operation in 17 °F ambient temperature. The $H1_2$ test is not needed if the $H1_N$ test uses this same compressor speed.
[5] Maximum speed that the system controls would operate the compressor in normal operation in 47 °F ambient temperature.
[6] Defined in section 3.1.4.6 of this appendix.
[7] Maximum speed that the system controls would operate the compressor in normal operation at 5 °F ambient temperature.

* * * * *

[FR Doc. 2021–25539 Filed 12–1–21; 8:45 am]
BILLING CODE 6450–01–P

FARM CREDIT ADMINISTRATION

12 CFR Parts 614, 615, 620 and 628

RIN 3052–AD27

Regulatory Capital Rules: Tier 1/Tier 2 Framework

AGENCY: Farm Credit Administration.

ACTION: Notification of effective date.

SUMMARY: The Farm Credit Administration (FCA) issued a final rule to amend the regulatory capital requirements for Farm Credit System (System or FCS) institutions. The amendments clarified certain provisions in the Tier 1/Tier 2 Capital Framework and codified the guidance provided in an FCA bookletter.

DATES: *Effective date:* The final rule amending 12 CFR parts 614, 615, 620 and 628 published on October 1, 2021 (86 FR 54347), is effective on January 1, 2022.

FOR FURTHER INFORMATION CONTACT:

Technical information: Jeremy R. Edelstein, *EdelsteinJ@fca.gov,* Associate Director or Clayton D. Milburn, *MilburnC@fca.gov,* Senior Financial Analyst, 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:* Rebecca S. Orlich, *Orlichr@fca.gov,* Senior Counsel, or Jennifer A. Cohn, *Cohnj@fca.gov,* Assistant General Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: On October 1, 2021, FCA issued a final rule to amend the regulatory capital requirements for System institutions. The amendments clarified provisions in the Tier 1/Tier 2 Capital Framework, codified the guidance provided in FCA Bookletter BL–068, reduced administrative burden, and amended definitions pertaining to qualified financial contracts. In accordance with 12 U.S.C. 2252(c)(1), the final rule provided an effective date of the later to occur of January 1, 2022 or 30 days after the date of rule's publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulation is January 1, 2022.

Dated: November 29, 2021.

Ashley Waldron,

Secretary, Farm Credit Administration.

[FR Doc. 2021–26173 Filed 12–1–21; 8:45 am]
BILLING CODE 6705–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0674; Airspace Docket No. 21–ASW–14]

RIN 2120–AA66

Amendment Class D and Class E Airspace; Ardmore, OK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects typographic errors in the final rule published in the **Federal Register** on October 26, 2021, amending the Class D and Class E airspace at Ardmore, OK.

DATES: Effective date 0901 UTC, January 27, 2022. The Director of the Federal Register approves this incorporation by reference action under Title 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** (86 FR 59015; October 26, 2021) for FR Doc. 2021–23008 amending the Class D and Class E

airspace at Ardmore, OK. Subsequent to publication, the FAA identified typographic errors that occurred when the notice to proposed rulemaking was transposed to the final rule in the Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area and Class E airspace extending upward from 700 feet above the surface airspace legal descriptions. This action corrects those errors.

Class D and Class E airspace designations are published in paragraph 5000, 6002, and 6005, respectively, of FAA Order JO 7400.11F dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be subsequently published in FAA Order JO 7400.11.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, Amendment Class D and Class E Airspace; Ardmore, OK, published in the **Federal Register** of October 26, 2021 (86 FR 59015), FR Doc. 2021–23008, is corrected as follows:

71.1 [Amended]

■ On page 59016, column 2, line 41, amend to read, ''Airport extending from the 4.3-mile radius of''.

■ On page 59016, column 2, line 60, amend to read, ''That airspace extending upward from''.

Issued in Fort Worth, Texas, on November 29, 2021.

Martin A. Skinner,

Acting Manager, Operations Support Group ATO Central Service Center.

[FR Doc. 2021–26187 Filed 12–1–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. FDA–2021–N–0622]

Medical Devices; Anesthesiology Devices; Classification of the Isocapnic Ventilation Device

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the isocapnic ventilation device into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the isocapnic ventilation device's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 2, 2021. The classification was applicable on March 14, 2019.

FOR FURTHER INFORMATION CONTACT: Todd Courtney, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1216, Silver Spring, MD 20993–0002, 301–796–6371, *Todd.Courtney@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the isocapnic ventilation device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On August 18, 2017, Thornhill Research, Inc. submitted a request for De Novo classification of the ClearMate. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in

combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 14, 2019, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 868.5480.[1] We have named the generic type of device isocapnic ventilation device, and it is identified as a prescription device used to administer a blend of carbon dioxide and oxygen gases to a patient to induce hyperventilation. This device may be labeled for use with breathing circuits made of reservoir bags (21 CFR 868.5320), oxygen cannulas (21 CFR 868.5340), masks (21 CFR 868.5550), valves (21 CFR 868.5870), resuscitation bags (21 CFR 868.5915), and/or tubing (21 CFR 868.5925).

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—ISOCAPNIC VENTILATION DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Hypocapnia (lacking CO_2).	Nonclinical performance testing, and Labeling.
Hypercapnia (excess CO_2).	Nonclinical performance testing, and Labeling.
Hypoxemia (lacking O_2).	Nonclinical performance testing, and Labeling.
High airway pressure (*e.g.,* barotrauma).	Nonclinical performance testing, and Labeling.
Adverse tissue reaction.	Biocompatibility evaluation.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

At the time of classification, isocapnic ventilation devices are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

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

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 868

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 868.5480 to subpart F to read as follows:

§ 868.5480 Isocapnic ventilation device.

(a) *Identification.* An isocapnic ventilation device is a prescription device used to administer a blend of carbon dioxide and oxygen gases to a patient to induce hyperventilation. This device may be labeled for use with breathing circuits made of reservoir bags (§ 868.5320), oxygen cannulas (§ 868.5340), masks (§ 868.5550), valves (§ 868.5870), resuscitation bags (§ 868.5915), and/or tubing (§ 868.5925).

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Nonclinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use, including the following performance characteristics:

(i) Gas concentration accuracy testing for the range of intended concentrations;

(ii) Airway pressure delivery accuracy testing;

(iii) Supplemental O_2 flowrate accuracy testing;

(iv) Alarm testing; and

(v) Use life testing.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Labeling must include the following:

(i) Instructions for use;

(ii) A precaution that monitoring of capnography is necessary during treatment with non-spontaneously breathing patients; and

(iii) Use life specification.

Dated: November 29, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26201 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2021–N–0285]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Esophageal Tissue Characterization System

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the esophageal tissue characterization system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the esophageal tissue characterization system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 2, 2021. The classification was applicable on December 23, 2019.

FOR FURTHER INFORMATION CONTACT: Pramodh Kariyawasam, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2536, Silver Spring, MD 20993–0002, 301–348–1911, *Pramodh.Kariyawasam@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the esophageal tissue characterization system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act. Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 17, 2018, Diversatek Healthcare Inc. submitted a request for De Novo classification of the Mucosal Integrity Conductivity Test System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 23, 2019, FDA issued an order to the requester classifying the device into class II. In this final order,[1] FDA is codifying the classification of the device by adding 21 CFR 876.1450. We have named the generic type of device esophageal tissue characterization system, and it is identified as a device intended for obtaining measurements of electrical properties within esophageal tissue.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—ESOPHAGEAL TISSUE CHARACTERIZATION SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Device malfunction related to: • Breaking • Fractures • Unintentional separation of components • Inaccurate reading • Failure to sense • Endoscope incompatibility	Nonclinical performance testing; Shelf life testing; Software verification, validation, and hazard analysis; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Electrical shock and electrical interference from other devices	Electrical safety testing, Electromagnetic compatibility (EMC) testing, and Labeling.
Procedural risks (which may include procedures of endoscopy with sedation).	Labeling.
Infection/cross-contamination	Reprocessing validation, Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

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

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2.Add § 876.1450 to subpart B to read as follows:

§ 876.1450 Esophageal tissue characterization system.

(a) *Identification.* An esophageal tissue characterization system is a device intended for obtaining measurements of electrical properties within esophageal tissue.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) All patient contacting components of the device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate the device can accurately measure the designated electrical characteristics.

(3) Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Electromagnetic compatibility and electrical safety, mechanical safety, and thermal safety of the device must be performed.

(6) Performance data must validate the reprocessing instructions for any reusable components of the device.

(7) Labeling must include:

(i) Specific instructions regarding the proper placement and use of the device;

(ii) Instructions for reprocessing of any reusable components; and

(iii) An expiration date for single use components.

Dated: November 26, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26200 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2021–N–0261]

Medical Devices; Neurological Devices; Classification of the Trunk and Limb Electrical Stimulator To Treat Headache

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the trunk and limb electrical stimulator to treat headache into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the trunk and limb electrical stimulator to treat headache's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and

effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 2, 2021. The classification was applicable on May 20, 2019.

FOR FURTHER INFORMATION CONTACT: Erin Keegan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 1649, Silver Spring, MD 20993–0002, 240–402–6534, *Erin.Keegan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the trunk and limb electrical stimulator to treat headache as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On November 6, 2018, Theranica Bioelectronics Ltd submitted a request for De Novo classification of the Nerivio Migra. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 20, 2019, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 882.5899.[1] We have named the generic type of device trunk and limb electrical stimulator to treat headache, and it is identified as a device intended to treat headache through the application of electrical stimulation anywhere on the body of the patient apart from the patient's head or neck through electrodes placed on the skin. The stimulation may be provided transcutaneously or percutaneously.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—TRUNK AND LIMB ELECTRICAL STIMULATOR TO TREAT HEADACHE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Electrical, mechanical, or thermal hazards that may result in user discomfort or injury (*e.g.,* electrical shock or burn)..	Non-clinical performance testing; Electrical, mechanical, and thermal safety testing; Electromagnetic compatibility (EMC) testing; Software verification, validation, and hazard analysis; and Labeling.
Interference with other devices	EMC testing, and Labeling.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—TRUNK AND LIMB ELECTRICAL STIMULATOR TO TREAT HEADACHE RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
Software malfunction leading to injury or discomfort (*e.g.,* tissue damage due to over-stimulation).	Software verification, validation, and hazard analysis.
Hardware malfunction leading to injury or discomfort	Non-clinical performance testing, Shelf life testing, and Labeling.
Use error that may result in user discomfort, injury, or delay treatment for headaches.	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

III. Analysis of Environmental Impact

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

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 882.5899 to subpart F to read as follows:

§ 882.5899 Trunk and limb electrical stimulator to treat headache.

(a) *Identification.* A trunk and limb electrical stimulator to treat headache is a device intended to treat headache through the application of electrical stimulation anywhere on the body of the patient apart from the patient's head or neck through electrodes placed on the skin. The stimulation may be provided transcutaneously or percutaneously.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. This testing must include:

(i) Characterization of the electrical stimulation, including the following: Waveforms; output modes; maximum output voltage and maximum output current (at 500Ω, 2kΩ, and 10kΩ loads); pulse duration; frequency; net charge per pulse; and maximum phase charge, maximum current density, maximum average current, and maximum average power density (at 500Ω);

(ii) Characterization of the impedance monitoring system; and

(iii) Characterization of the electrode performance including the electrical performance, adhesive integrity, shelf-life, reusability, and current distribution of the electrode surface area.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance testing must demonstrate electromagnetic compatibility and electrical, mechanical, and thermal safety in the intended use environment.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Labeling must include the following:

(i) Instructions for use, including the typical sensations experienced during treatment;

(ii) A detailed summary of the electrical stimulation output, and the device technical parameters, including any wireless specifications;

(iii) A shelf life for the electrodes and reuse information; and

(iv) Instructions on care and cleaning of the device.

Dated: November 26, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26175 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2021–N–0290]

Medical Devices; Neurological Devices; Classification of the Conditioning Tool for Eating Disorders

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the conditioning tool for eating disorders into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the conditioning tool for eating disorders' classification. We are taking this action because we

have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 2, 2021. The classification was applicable on March 31, 2011.

FOR FURTHER INFORMATION CONTACT: Michael Hoffmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 4110, Silver Spring, MD 20993–0002, 301–796–6476, *Michael.Hoffmann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the conditioning tool for eating disorders as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on May 24, 2007, finding the Mandometer not substantially equivalent to a predicate not subject to premarket approval. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

AB Mando submitted a request for De Novo classification of the Mandometer, dated June 19, 2007. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 31, 2011, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 882.5060.[1] We have named the generic type of device conditioning tool for eating disorders, and it is identified as a prescription device that non-invasively measures the mass of food eaten during a meal and provides feedback in the form of eating rate, patient satiety, and eating pattern information to the patient.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—CONDITIONING TOOL FOR EATING DISORDERS RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Ineffective treatment leading to worsening condition of the patient, progression of disease, and/or delay of alternative treatments.	Nonclinical performance testing; Software validation, verification and hazard analysis; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Electrical shock or burns	Electrical safety testing, Electromagnetic compatibility (EMC) testing, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

At the time of classification, conditioning tools for eating disorders are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. Analysis of Environmental Impact

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

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 882.5060 to subpart F to read as follows:

§ 882.5060 Conditioning tool for eating disorders.

(a) *Identification.* A conditioning tool for eating disorders is a prescription device that non-invasively measures the mass of food eaten during a meal and provides feedback in the form of eating rate, patient satiety, and eating pattern information to the patient.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Nonclinical performance testing must demonstrate:

(i) Device measurement accuracy and repeatability; and

(ii) Device feedback accuracy.

(2) Software verification, validation, and hazard analysis must be performed.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance testing must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(5) Labeling and patient labeling must be provided which includes the following:

(i) Information identifying and explaining how to use the device and its components; and

(ii) Information on how the device operates and the typical course of treatment.

Dated: November 26, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26176 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2021–N–0648]

Medical Devices; Orthopedic Devices; Classification of the Intraoperative Orthopedic Strain Sensor

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the intraoperative orthopedic strain sensor into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the intraoperative orthopedic strain sensor's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 2, 2021. The classification was applicable on March 28, 2019.

FOR FURTHER INFORMATION CONTACT: Colin O'Neill, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4458, Silver Spring, MD 20993–0002, 301–796–6428, *Colin.ONeill@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the intraoperative orthopedic strain sensor as class II (special controls), which we have determined will provide a

reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On July 19, 2018, Intellirod Spine, Inc. submitted a request for De Novo classification of the LOADPRO™ Intraoperative Rod Strain Sensor. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 28, 2019, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 888.3090.[1] We have named the generic type of device intraoperative orthopedic strain sensor, and it is identified as an adjunct tool intended to measure strain on an orthopedic implant in the intraoperative setting only. The device is not intended to provide diagnostic information or influence clinical decision making.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—INTRAOPERATIVE ORTHOPEDIC STRAIN SENSOR RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Prolonged operative time due to device error or use error.	Usability testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; and Labeling.
Electrical shock or device failure due to interference from other devices.	Electromagnetic compatibility testing, and Electrical safety testing.
Infection	Sterilization validation, Reprocessing validation, Shelf life testing, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

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

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 888.3090 to subpart D to read as follows:

§ 888.3090 Intraoperative orthopedic strain sensor.

(a) *Identification.* A strain sensor device is an adjunct tool intended to measure strain on an orthopedic implant in the intraoperative setting only. The device is not intended to provide diagnostic information or influence clinical decision making.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be conducted:

(i) Mechanical testing to evaluate the effect of the device on the mechanical performance of the implant and to characterize the mechanical limits of the components used with the implant; and

(ii) Accuracy and repeatability testing of strain measurements.

(2) Usability testing must evaluate the effect of the device on the performance of the surgical procedure.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance testing must support the sterility and shelf life of the patient-contacting components of the device.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Performance data must validate the reprocessing instructions for reusable components of the device.

(7) Performance data must be provided to demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(8) Labeling must include the following:

(i) A shelf life;

(ii) Instructions for use;

(iii) Reprocessing instructions for any reusable components; and

(iv) A statement that the device is not intended to provide diagnostic information or influence clinical decision making.

Dated: November 29, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26183 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2021–0879]

Special Local Regulations; Charleston Parade of Boats, Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation for the Charleston Parade of Boats on December 11, 2021. This action is necessary to ensure safety of life on navigable waters of the United States during the Charleston Parade of Boats. During the enforcement period, no person or vessel may enter, transit through, anchor in, or remain within the designated area unless authorized by the Captain of the Port Charleston (COTP) or a designated representative.

DATES: The regulations in 33 CFR 100.704, Table 1 to § 100.704, Item No. 10, will be enforced from 4:00 p.m. until 8:30 p.m. on December 11, 2021.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email LCDR Chad Ray, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740–3184, email *Chad.L.Ray@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.704, Item No. 10, for the Charleston Parade of Boats from 4:00 p.m. through 8:30 p.m. on December 11, 2021. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Seventh Coast Guard District § 100.704, Item No. 10, specifies the location of the regulated area for the Charleston Parade of Boats, which encompasses a portion of the waterways during the parade transit from Charleston Harbor Anchorage A through Shutes Folly, Bennis Reach, Horse Reach, Hog Island Reach, Town Creek Lower Reach, Ashley River, and finishing at City Marina. During the enforcement period, if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period

via the Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

Dated: November 23, 2021.

J.D. Cole,

Captain, U.S. Coast Guard, Captain of the Port Charleston.

[FR Doc. 2021–26202 Filed 12–1–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0875]

RIN 1625–AAOO

Safety Zone; Fireworks Display, Columbia River, Richland, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters within a 600-foot radius of a fireworks display on the Columbia River for the City of Richland Christmas Fireworks Display in Richland, WA. This action is necessary to provide for the safety of life on these navigable waters during the fireworks display. Entry of vessels or persons, transiting though, mooring, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Sector Columbia River or a designated representative.

DATES: This rule is effective from 7:30 p.m. through 9 p.m. on December 3, 2021, and from 7:30 p.m. through 9 p.m. on December 4, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0875 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Sean Morrison, Waterways Management Division, Marine Safety Unit Portland, Coast Guard; telephone 503–240–9319, email *D13-SMB-MSUPortlandWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The City of Richland did not alert the Coast Guard of the fireworks display and the associated safety hazards until November 9, 2021. We must establish this safety zone on December 3, 2021 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because an urgent action is needed to respond to the safety hazards associated with the planned fireworks display on December 3 and 4, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Columbia River has determined that potential hazards associated with the fireworks display on December 3, 2021 and December 4, 2021, will be a safety concern for anyone within a 600-foot radius of the fireworks display. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the fireworks display is taking place.

IV. Discussion of the Rule

This rule establishes a safety zone for the City of Richland Christmas Fireworks Display from 07:30 p.m. through 09 p.m. on December 3, 2021 and from 07:30 p.m. through 09 p.m. on December 4, 2021. The Safety Zone will cover all navigable waters within 600-feet of the pier located on the Columbia River near Howard Amon Park Waterfront on 80 Lee Boulevard, Richland, WA 99352 at approximate location 46°16′29″ N; 119°16′10″ W. W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the fireworks display is taking place. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of the U.S. Coast Guard Sector Columbia River.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safetly transit around this safety zone which would impact a small designated area on the Columbia River for 1.5 hours during two consecutive evenings, when vessel traffic is normally low. Moreover the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety

zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only 1.5 hours that will prohibit entry within 600 feet of a fireworks display. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is amending 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1, Revision No. 01.2.

■ 2. Add § 165.T13–0875 to read as follows:

§ 165.T13–0875 Safety Zone; Fireworks Display, Columbia River, Richland, WA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Columbia River, surface to bottom, 600 feet from the fireworks display site at approximately 46°16′29″ N; 119°16′10″ W. These coordinates are based on the pier located on the Columbia River near Howard Amon Park Waterfront on 80 Lee Boulevard, Richland, WA 99352.

(b) *Definitions.* As used in this section, a designated representative means a designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of the U.S. Coast Guard Sector Columbia River.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Columbia River (COTP) or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by calling (503) 209–2468 or the Sector Columbia River Command Center on Channel 16 VHF–FM. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 7:30 p.m. through 9 p.m. on December 3, 2021, and from 7:30 p.m. through 9 p.m. on December 4, 2021.

Dated: November 23, 2021.

M.S. Jackson,

Captain, U.S. Coast Guard, Captain of the Port Sector Columbia River.

[FR Doc. 2021–26158 Filed 12–1–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0891]

RIN 1625–AA00

Safety Zone; Haro Strait, San Juan County, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving safety zone for navigable waters within a 500-yard radius around the ZIM KINGSTON. The safety zone is needed to protect personnel, vessels, and the marine environment from the potential hazards associated with the vessel transit. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Puget Sound.

DATES: This rule is effective without actual notice from December 2, 2021 through 9 a.m. on December 6, 2021. For purposes of enforcement, actual notice will be used from 10 a.m. on November 24, 2021 until December 2, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0891 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Peter McAndrew, Sector Puget Sound Waterways Management Division, U.S. Coast Guard; telephone 206–217–6045, email *SectorPugetSoundWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule, as the Coast Guard received initial notification on October 31, 2021 of an anticipated vessel transit from Victoria, BC to Vancouver, BC through US Waters by the ZIM KINGSTON. On or around October 21, 2021, the ZIM KINGSTON lost containers overboard and two containers subsequently caught on fire and may contain toxic flammable gas or other hazardous materials. Immediate action is needed to respond to the potential safety hazards associated with the ZIM KINGSTON's transit. It is impracticable to publish an NPRM for this temporary rule because the safety zone must be established by November 24, 2021 to protect waterway users.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to protect personnel, vessels, and the marine environment from the potential hazards associated with the vessel transit of the ZIM KINGSTON.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port (COTP) Puget Sound has determined that potential hazards associated with the transit of the ZIM KINGSTON will be a safety concern for anyone within a 500-yard radius of the vessel. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the transit.

IV. Discussion of the Rule

This rule establishes a safety zone from 10 a.m. November 24, 2021 through 9 a.m. December 6, 2021. The safety zone will cover all navigable waters within 500 yards of the ZIM KINGSTON. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the vessel is in transit. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the fact that the safety zone created by this rule is limited in size and duration. Vessel traffic would be able to safely transit around this safety zone. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain

about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone for navigable waters within a 500-yard radius around the ZIM KINGSTON between 10 a.m. November 24, 2021 through 9 a.m. December 6, 2021. The safety zone is needed to protect personnel, vessels, and the marine environment from the potential hazards associated with the vessel transit. It is categorically excluded from further review under paragraph L[60] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–0891 to read as follows:

§ 165.T13–0891 Safety Zone; Haro Strait, San Juan County, WA.

(a) *Location.* The following area is a moving safety zone: All navigable waters within a 500-yard radius around the ZIM KINGSTON.

(b) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Puget Sound (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF Channel 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This rule will be enforced from 10 a.m. November 24, 2021, through 9 a.m. December 6, 2021.

Dated: November 24, 2021.

C.R. Cederholm,

Captain, U.S. Coast Guard, Acting, Captain of the Port Puget Sound.

[FR Doc. 2021–26157 Filed 12–1–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AR40

Awards Under the Nehmer Court Orders for Disability or Death Caused by a Condition Presumptively Associated With Herbicide Exposure; Implementing Court Order.

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is issuing this final rule to amend its regulation regarding the process for identifying and paying appropriate payees entitled to retroactive benefits. This amendment is necessary to implement a federal district court order directing the VA to remove certain regulatory text concerning subsequent release of compensation to a payee when the full amount of unpaid benefits has previously been released.

DATES:

Effective date: This final rule is effective December 2, 2021.

Applicability date: The provisions of this final rule shall apply to circumstances in which VA has received information about a newly identified and eligible payee (hereafter ''new payee'') who has yet to receive the *Nehmer*-related benefits to which the new payee is entitled.

FOR FURTHER INFORMATION CONTACT: Christopher O. Adeloye, Staff Attorney, Benefits Law Group, Office of General Counsel (022), 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–7662. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION:

I. Background and Basis for Revision of Regulation

In 1991, as part of the *Nehmer* litigation (*Nehmer* v. *U.S. Department of Veterans Affairs,* 712 F.Supp. 1404 (N.D. Cal. May 3, 1989)) before the U.S. District Court for the Northern District of California, the parties entered into a

consent decree that required VA to readjudicate claims filed by a specific class of veterans who served in the Republic of Vietnam. In the event that VA's readjudication of a veteran's claim was favorable, VA would make payment of any past-due benefits to the veteran. However, as clarified by a subsequent court order, if VA's readjudication of a veteran's claim was favorable but the veteran was deceased, VA would pay the full amount of any past-due benefits to the first individual or entity listed, in this order: (1) The veteran's spouse; (2) the veteran's children in equal shares; (3) the veteran's parents in equal shares; and (4) the veteran's estate.

On September 17, 2021, the plaintiffs in *Nehmer* filed a motion with the district court in which they sought to enforce the consent decree. As part of their motion, the plaintiffs requested that the court issue an order requiring VA to rescind the last sentence in section 3.816(f)(3): ''If, following such efforts, VA releases the full amount of unpaid benefits to a payee, VA may not thereafter pay any portion of such benefits to any other individual, unless VA is able to recover the payment previously released.''

On November 10, 2021, the court issued an order (*Nehmer* v. *U.S. Department of Veterans Affairs,* No. C86–06160 WHA, USDC N. District California, November 10, 2021) vacating the final sentence of section 3.816(f)(3), directing VA to issue a rule rescinding that sentence, and requiring VA to publish that rule in the **Federal Register**. Consistent with that order, VA is issuing this rulemaking to remove the final sentence from section 3.816(f)(3).

Administrative Procedure Act

The Secretary of Veterans Affairs finds that there is good cause under the provisions of 5 U.S.C. 553(b)(B) and (d)(3) to publish this rule without prior opportunity for public comment and with an immediate effective date. The good cause exception allows an agency to forego public notice and comment where it would be ''impracticable, unnecessary, or contrary to the public interest.'' *See* 5 U.S.C. 553(b)(B). Similarly, under 5 U.S.C. 553(d)(3), an agency may forego the requirement for a delayed effective date ''for good cause found and published with the rule.'' This amendment to section 3.816(f)(3) is ministerial in that it simply implements the court's November 10, 2021, order. Furthermore, delay in publication of this notice could lead to confusion among the public, particularly among new payees who may otherwise lack notice that the final sentence in section 3.816(f)(3) has been vacated. As the court noted in its order, this presents a ''serious risk'' to certain payees who may otherwise believe they are not entitled to their share of a *Nehmer* award. For these reasons, notice and comment and a delayed effective date are unnecessary, impracticable, and contrary to the public interest, and, consequently, VA has good cause under the Administrative Procedure Act to publish this rule without prior opportunity for public comment and with an immediate effective date.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the 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 effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov*.

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, is not applicable to this rulemaking because notice of proposed rulemaking is not required. 5 U.S.C. 601(2), 603(a), 604(a).

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Assistance Listing

The Assistance Listing program numbers and titles for this rule are 64.104 Pension for Non-Service-Connected Disability for Veterans; 64.105 Pension to Veterans Surviving Spouses, and Children; 64.109 Veterans Compensation for Service-Connected Disability; 64.110 Veterans Dependency and Indemnity Compensation for Service-Connected Death.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on November 24, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 3 is amended as follows:

PART 3—ADJUDICATION

Subpart A—Special Benefits

■ 1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501.

§ 3.816 [Amended]

■ 2. Amend § 3.816 by removing the last sentence in paragraph (f)(3).

[FR Doc. 2021–26084 Filed 12–1–21; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0354; FRL–8958–02–R4]

Air Plan Approval; North Carolina; Mecklenburg Air Quality Permit Rules Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision to the Mecklenburg County portion of the North Carolina SIP, hereinafter referred to as the Mecklenburg Local Implementation Plan (LIP). The revision was submitted by the State of North Carolina, through the North Carolina Division of Air Quality (NCDAQ), on behalf of Mecklenburg County Air Quality (MCAQ) via a letter dated April 24, 2020, and was received by EPA on June 19, 2020. The revision updates several Mecklenburg County Air Pollution Control Ordinance (MCAPCO) rules incorporated into the LIP and adds several rules. EPA is approving these changes pursuant to the Clean Air Act (CAA or Act).

DATES: This rule is effective January 3, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2021–0354. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Evan Adams, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9009. Mr. Adams can also be reached via electronic mail at *adams.evan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Overview

In a notice of proposed rulemaking (NPRM) published on September 17, 2021 (86 FR 51848), EPA proposed to approve changes to several rules in the Mecklenburg County LIP. The April 24, 2020, submittal includes changes and updates to the following rules to more closely align them with their analog SIP-approved North Carolina regulations.[1] The January 21, 2016, changes from MCAQ include updates to MCAPCO Rule 1.5214—*Commencement of Operation;* and the January 14, 2019, changes from MCAQ include updates to MCAPCO Rules 1.5212—*Applications;* 1.5213—*Action on Application; Issuance of Permit;* 1.5215—*Application Processing Schedule;* 1.5219—*Retention of Permit at Permitted Facility;* 1.5221—*Permitting of Numerous Similar Facilities;* 1.5222—*Permitting of Facilities at Multiple Temporary Sites;* and 1.5232—*Issuance, Revocation, and Enforcement of Permits.*[2] Additionally, the January 14, 2019, portion of the revision requests approval of MCAPCO Rules 1.5217—*Confidential Information;* 1.5218—*Compliance Schedule for Previously Exempted Activities;* and 1.5220—*Applicability Determinations.*[3] The submittal also asks EPA to reincorporate the following rules into the LIP with a new effective date: MCAPCO Rules 1.5301, *Special Enforcement Procedures;* 1.5302, *Criminal Penalties;* 1.5303, *Civil Injunction;* 1.5304, *Civil Penalties;* 1.5306, *Hearings;* 1.5307, *Judicial Review;* 2.0301, *Purpose;* and 2.0305, *Emission Reduction Plant: Alert Level.* The text of these rules has not changed.

The September 17, 2021, NPRM provides detail regarding the background and rationale for EPA's action. Comments were due on or before October 18, 2021, and EPA received three comment submittals. Two submittals are from one individual (hereinafter the ''Commenter''), are similar in nature, and are addressed below. The third submittal simply thanked EPA. These comments are available in the docket for this action.

Comment: The Commenter is disappointed that the majority of the MCAPCO rules have not been updated by EPA, NCDAQ, or MCAQ since 2003 and notes that recent discoveries have been made regarding the detrimental effects of air pollution in urban areas such as Mecklenburg County. The Commenter is pleased that changes are being made to the MCAPCO rules and states that continuously reviewing and updating air pollution regulations in Mecklenburg County is vital to the public health and wellbeing of local residents.

Response: EPA does not have the authority to modify Mecklenburg County's air quality rules. However, the County has updated a number of its MCAPCO rules since 2003 and submitted many of these updates to EPA for incorporation into the LIP through the State's April 24, 2020 SIP revision. In this rulemaking, EPA is acting solely to incorporate the rules identified earlier in this section and discussed in the NPRM. The Agency will address the remainder of the rules contained in the SIP revision in separate actions.

The CAA establishes a system of cooperative federalism that sets specific roles for EPA and the states. In this system, EPA provides national leadership and sets national standards for environmental protection such as the National Ambient Air Quality Standards (NAAQS).[4] Pursuant to CAA sections 108 and 109, EPA must thoroughly review each NAAQS every five years to account for the latest scientific knowledge regarding the effects of the air pollutant on public health and welfare.[5] EPA solicits public comment as part of each five-year review and invites the Commenter to share recent scientific discoveries regarding air pollution during those comment periods.

While EPA sets the NAAQS, states play a primary role in implementation. Under CAA section 110, states have broad discretion to choose the mix of emission limitations and other control measures, means, or techniques that they will implement (or update) through

[1] EPA notes that the April 24, 2020, submittal was received by EPA on June 19, 2020.

[2] The April 24, 2020, revision contains changes to other Mecklenburg LIP-approved rules that are not addressed in this notice. EPA will be acting on those rules in separate actions.

[3] MCAPCO Rules 1.5217—*Confidential Information;* 1.5218—*Compliance Schedule for Previously Exempted Activities;* and 1.5220—*Applicability Determinations* were erroneously included in the table at 40 CFR 52.1770(c).

[4] *See https://www.epa.gov/criteria-air-pollutants/naaqs-table* for information regarding the current NAAQS.

[5] *See https://www.epa.gov/criteria-air-pollutants/process-reviewing-national-ambient-air-quality-standards* for information regarding EPA's five-year NAAQS review process.

a SIP to provide for attainment and maintenance of the NAAQS. EPA's role, with respect to a SIP revision, is focused on reviewing the submission to determine whether it meets the minimum criteria of the CAA. Where it does, EPA must approve the submission. When approving a SIP revision, the Agency is not establishing its own requirements for the state to implement. If, at any time, EPA finds that a SIP is inadequate to attain or maintain the relevant NAAQS or otherwise does not comply with the CAA, EPA has the authority under CAA section 110(k)(5) to require the state to revise its SIP to correct such inadequacies.

EPA agrees that air pollution is detrimental to human health and welfare and appreciates the Commenter's support for this action.

II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of MCAPCO Rule 1.5214—*Commencement of Operation,* which has an effective date of December 15, 2015; and Rules 1.5212—*Applications;* 1.5213—*Action on Application; Issuance of Permit;* 1.5215—*Application Processing Schedule;* 1.5217—*Confidential Information;* 1.5218—*Compliance Schedule for Previously Exempted Activities;* 1.5219—*Retention of Permit at Permitted Facility;* 1.5220—*Applicability Determinations;* 1.5221—*Permitting of Numerous Similar Facilities;* 1.5222—*Permitting of Facilities at Multiple Temporary Sites;* and 1.5232—*Issuance, Revocation, and Enforcement of Permits,* all of which have an effective date of December 18, 2018, into the Mecklenburg County portion of the North Carolina SIP.

EPA has made and will continue to make these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[6]

[6] *See* 62 FR 27968 (May 22, 1997).

III. Final Action

EPA is finalizing approval of changes to LIP-approved MCAPCO Rules 1.5212—*Applications;* 1.5213—*Action on Application; Issuance of Permit;* 1.5214—*Commencement of Operation;* 1.5215—*Application Processing Schedule;* 1.5219—*Retention of Permit at Permitted Facility;* 1.5221—*Permitting of Numerous Similar Facilities;* 1.5222—*Permitting of Facilities at Multiple Temporary Sites;* and 1.5232—*Issuance, Revocation, and Enforcement of Permits.* Additionally, EPA is proposing to approve MCAPCO Rules 1.5217—*Confidential Information;* 1.5218—*Compliance Schedule for Previously Exempted Activities;* and 1.5220—*Applicability Determinations* into the LIP. EPA is taking final action to approve these changes to the LIP because they are consistent with the CAA.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided they meet the criteria of the CAA. This action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 31, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead,

Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: November 26, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart II—North Carolina

■ 2. In § 52.1770(c)(3), the table is amended by removing the entries for ''Section 1.5212,'' ''Section 1.5213,'' ''Section 1.5214,'' ''Section 1.5215,'' ''Section 1.5217,'' ''Section 1.5218,'' ''Section 1.5219,'' ''Section 1.5220,'' ''Section 1.5221,'' ''Section 1.5222,'' and ''Section 1.5232'' and adding in their place entries for ''Rule 1.5212,'' ''Rule 1.5213,'' ''Rule 1.5214,'' ''Rule 1.5215,'' ''Rule 1.5217,'' ''Rule 1.5218,'' ''Rule 1.5219,'' ''Rule 1.5220,'' ''Rule 1.5221,'' ''Rule 1.5222,'' and ''Rule 1.5232'' to read as follows:

§ 52.1770 Identification of plan.

* * * * *

(c) * * *

(3) EPA Approved Mecklenburg County Regulations

State citation	Title/subject	State effective date	EPA approval date	Explanation
Article 1.0000	**Permitting Provisions for Air Pollution Sources, Rules and Operating Regulations for Acid Rain Sources, Title V and Toxic Air Pollutants**			
*	*	*	*	*
Section 1.5200	**Air Quality Permits**			
*	*	*	*	*
Rule 1.5212	Applications	12/18/2018	12/2/2021, [Insert citation of publication]	
Rule 1.5213	Action on Application; Issuance of Permit	12/18/2018	12/2/2021, [Insert citation of publication]	
Rule 1.5214	Commencement of Operation	12/15/2015	12/2/2021, [Insert citation of publication]	
Rule 1.5215	Application Processing Schedule	12/18/2018	12/2/2021, [Insert citation of publication]	
Rule 1.5217	Confidential Information	12/18/2018	12/2/2021, [Insert citation of publication]	
Rule 1.5218	Compliance Schedule for Previously Exempted Activities.	12/18/2018	12/2/2021, [Insert citation of publication]	
Rule 1.5219	Retention of Permit at Permitted Facility	12/18/2018	12/2/2021, [Insert citation of publication]	
Rule 1.5220	Applicability Determination	12/18/2018	12/2/2021, [Insert citation of publication]	
Rule 1.5221	Permitting of Numerous Similar Facilities	12/18/2018	12/2/2021, [Insert citation of publication]	
Rule 1.5222	Permitting of Facilities at Multiple Temporary Sites.	12/18/2018	12/2/2021, [Insert citation of publication]	
*	*	*	*	*
Rule 1.5232	Issuance, Revocation, and Enforcement of Permits.	12/18/2018	12/2/2021, [Insert citation of publication]	

* * * * *

[FR Doc. 2021–26141 Filed 12–1–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2019–0156; FRL–8697–02–R4]

Air Plan Approval; FL, GA, NC, SC; Interstate Transport (Prongs 1 and 2) for the 2015 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is approving State Implementation Plan (SIP) submissions from Florida, Georgia, North Carolina, and South Carolina, addressing the Clean Air Act (CAA or Act) Good Neighbor interstate transport infrastructure SIP requirements for the 2015 8-hour ozone National Ambient Air Quality Standard (NAAQS or standards). EPA has determined that each state's SIP contains adequate provisions to prohibit emissions that will significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state. This action is being taken in accordance with the CAA.

DATES: This rule is effective January 3, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2019–0156. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's

official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Evan Adams of the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Mr. Adams can be reached by telephone at (404) 562–9009, or via electronic mail at *adams.evan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 30, 2019, EPA proposed to approve SIP submissions from Alabama, Florida, Georgia, North Carolina, South Carolina, and Tennessee [1] as meeting the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I), or the Good Neighbor provision, for the 2015 8-hour ozone NAAQS. *See* 84 FR 71854. Specifically, the 2019 notice of proposed rulemaking (NPRM) originally proposed to find that emissions from sources in these states will not significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other state based on information for the analytic year 2023, consistent with the 2024 Moderate area attainment date. Refer to the December 30, 2019 NPRM for an explanation of the CAA requirements, the four-step framework that EPA applies under the Good Neighbor provision for ozone NAAQS, a detailed summary of the state submissions, and EPA's proposed rationale for approval. *See* 84 FR 71854. The public comment period for the December 30, 2019, NPRM closed on January 29, 2020.[2]

Subsequent to the publication of the NPRM on December 30, 2019, two events caused EPA to adjust its analysis of the aforementioned SIP submissions. First, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) issued its ruling in *Maryland* v. *EPA,* 958 F.3d 1185 (D.C. Cir. 2020) (*Maryland*), which held that EPA must address Good Neighbor obligations consistent with the 2021 attainment date for downwind areas classified as being in Marginal nonattainment under the 2015 8-hour ozone NAAQS, ''not at some later date.'' 958 F.3d at 1203–04 (citing *Wisconsin* v. *EPA,* 938 F.3d 303, 314 (D.C. Cir. 2019) (*Wisconsin*)).[3] Second, on October 30, 2020, EPA released and accepted public comment on updated 2023 modeling that used the 2016 emissions platform developed under the EPA/Multi-Jurisdictional Organization (MJO)/state collaborative project as the primary source for the base year and future year emissions data. On April 30, 2021, EPA published the final Revised Cross-State Air Pollution Rule (CSAPR) Update for the 2008 ozone NAAQS (Revised CSAPR Update) using the same modeling that was made publicly available in the proposed rulemaking for the Revised CSAPR Update.[4] Although that modeling focused on the year 2023, EPA conducted an interpolation analysis of these modeling results to generate air quality and contribution values for the 2021 analytic year, consistent with the *Maryland* holding, as the relevant analytic year for the 2015 8-hour ozone NAAQS.

As a result, EPA issued a supplemental notice of proposed rulemaking (SNPRM) on July 19, 2021, which relied on the new modeling and analysis to supplement EPA's proposed finding in the December 30, 2019 NPRM that emissions from sources in Florida, Georgia, North Carolina, and South Carolina will not significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other state.[5] *See* 86 FR 37942. The new modeling and analysis indicated that Florida, Georgia, North Carolina, and South Carolina, individually, will not contribute greater than one percent of the 2015 8-hour ozone NAAQS to any potential nonattainment or maintenance receptors in 2021. In addition, EPA analyzed past and projected emissions of ozone precursors (nitrogen oxides (NO_X) and volatile organic compounds (VOCs)), finding a downward trend in emissions to support the modeling analysis and indicate that the contributions from emissions from sources in Florida, Georgia, North Carolina, and South Carolina to ozone receptors in downwind states will continue to decline and remain below one percent of the 2015 8-hour ozone NAAQS. Thus, the July 19, 2021 SNPRM provided that ''EPA continues to propose to approve the interstate transport portions of the infrastructure SIP submissions from Florida, Georgia, North Carolina, and South Carolina as meeting CAA section 110(a)(2)(D)(i)(I) requirements for the 2015 8-hour ozone NAAQS.'' *See* 86 FR 37942.

The technical rationale for EPA's proposed action is given in the July 19, 2021 SNPRM and in supportive materials contained in the docket for this action. The comment period for the July 19, 2021 SNPRM closed on August 18, 2021, and EPA received no additional comments. However, EPA did receive comments on the original December 30, 2019 NPRM, and relevant responses are provided in section II. EPA is finalizing the approval of this action based on the technical rationale

[1] The submittals from these six southeastern states were submitted separately under the following cover letters: Alabama Department of Environmental Management dated August 20, 2018 (received by EPA on August 27, 2018); Florida Department of Environmental Protection dated September 18, 2018 (received by EPA on September 26, 2018); Georgia Environmental Protection Division dated September 19, 2018 (received by EPA on September 24, 2018); North Carolina Department of Environmental Quality dated September 27, 2018 (received by EPA October 10, 2018); South Carolina Department of Health and Environmental Control dated and received by EPA on September 7, 2018; and Tennessee Department of Environment and Conservation dated September 13, 2018 (received by EPA on September 17, 2018).

[2] On March 24, 2020, former EPA Region 4 Administrator Mary Walker signed a document (hereinafter referred to as the March 24, 2020 document) that EPA had intended to become a final rule upon publication in the **Federal Register**. However, the March 24, 2020 document was never published in the **Federal Register**. Further, on January 19, 2021, former EPA Region 4 Administrator Mary Walker signed a second document (hereinafter referred to as the January 19, 2021 document) that EPA had intended to become a final rule, which EPA posted to its website at *https://www.epa.gov/air-quality-implementation-plans/epas-approval-2015-8-hour-ozone-interstate-transport-requirements.* EPA noted in that posting ''Notwithstanding the fact that the EPA is posting a pre-publication version, the final rule will not be promulgated until published in the **Federal Register**.'' EPA will not publish either the March 24, 2020 document or the January 19, 2021 document in the **Federal Register**, and now intends that this notice constitutes final action with respect to the 2019 proposal, superseding all versions of previous draft final action documents.

[3] *Maryland* involved EPA's denial of administrative petitions filed by the states of Maryland and Delaware under CAA section 126(b), seeking to have EPA impose emissions limits on sources in upwind states alleged to be emitting in violation of the Good Neighbor Provision. The court disagreed with EPA that use of a 2023 analytic year, consistent with the 2024 attainment date for areas classified as being in Moderate nonattainment, was a proper reading of the court's earlier decision in *Wisconsin. Id.* at 1204.

[4] *Revised Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS,* 86 FR 23054; *see also* Emissions Modeling TSD titled ''Preparation of Emissions Inventories for the 2016v1 North American Emissions Modeling Platform.'' This TSD is available in the docket for this action and at *https://www.epa.gov/air-emissionsmodeling/2016v1-platform.* The underlying modeling files are available on data drives in the Docket office for public review. *See* the docket for the Revised CSAPR Update (EPA–HQ–OAR–2020–0272). *See also Air Quality Modeling Data Drives_Final RCU.pdf,* available in the docket for this action for a file inventory and instructions on how to access the modeling files.

[5] EPA previously proposed to approve infrastructure SIP elements submitted to fulfill the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I) for the states of Alabama and Tennessee for the 2015 8-hour ozone NAAQS in the December 30, 2019, NPRM referenced previously in this rule. However, the July 19, 2021 SNPRM did not address these submissions, and EPA is deferring action on the referenced SIP submissions from Alabama and Tennessee at this time.

presented in the July 19, 2021 SNPRM and in accordance with the CAA.

II. Response to Comments

EPA received four sets of adverse comments and one set of supportive comments on the December 30, 2019, NPRM. The comments were submitted by the Midwest Ozone Group, Sierra Club, New Jersey Department of Environmental Protection, New York State Department of Environmental Conservation, and one anonymous commenter. The full set of comments is provided in the docket for this final rule. This section contains summaries of the comments and EPA's responses.

Comment 1: Several commenters asserted that EPA's December 30, 2019 NPRM improperly focused on the analytic year of 2023, which the commenters argue ignores the August 2021 attainment date faced by Marginal 2015 ozone nonattainment areas. These commenters asserted that EPA's decision focused on 2023 (consistent with the August 2024 attainment date for Moderate nonattainment areas under the 2015 8-hour ozone NAAQS, rather than the August 2021 attainment date for Marginal nonattainment areas), which contravenes the statutory text and the *Wisconsin* decision, and is arbitrary and capricious. The commenters specifically mention that the distinction EPA has drawn between Marginal and Moderate areas is misleading, that it is unreasonable for EPA to expect downwind areas to voluntarily request reclassifications to Moderate, and that EPA has not provided adequate support for its assumption that Marginal areas will achieve attainment by 2021. A commenter also contended that the CSAPR Update is insufficient to bring all downwind states into attainment with the 2015 8-hour ozone NAAQS, citing a conclusion made in the December 30, 2019, NPRM in support of a 2023 analytic year and monitoring data from the 2017 ozone season indicating certain 8-hour daily maximum concentrations at air quality monitors in Delaware were above the level of the NAAQS. In addition, a commenter asserted that recent monitoring data at other monitoring sites suggests that these areas will continue to have difficulty attaining the NAAQS in 2021.

Response 1: The comments related to the 2023 analytic year refer to a D.C. Circuit court decision addressing, in part, the issue of the relevant analytic year for the purposes of evaluating interstate ozone transport under the Good Neighbor provision. On September 13, 2019, the D.C. Circuit issued the *Wisconsin* decision, remanding the CSAPR Update (81 FR 74504, October 26, 2016) to the extent that it failed to require upwind states to eliminate their significant contribution no later than the next applicable attainment date by which downwind states must come into compliance with the NAAQS, as established under CAA section 181(a). *See* 938 F.3d 303, 313. In the December 30, 2019 NPRM, EPA had interpreted that holding as limited to the attainment dates for Moderate nonattainment area or higher classifications under CAA section 181 on the basis that Marginal nonattainment areas have reduced planning requirements and other considerations. *See* 84 FR 71854, 71856–58.

On May 19, 2020, however, the D.C. Circuit issued the *Maryland* decision that cited the *Wisconsin* decision in holding that EPA must assess the impact of interstate transport on air quality at the next downwind attainment date, including Marginal area attainment dates, in evaluating the basis for EPA's denial of a petition under CAA section 126(b). *See* 958 F.3d 1185, 1203–04. The court noted that ''section 126(b) incorporates the Good Neighbor Provision,'' and therefore ''the EPA must find a violation [of section 126] if an upwind source will significantly contribute to downwind nonattainment at the next downwind attainment deadline. Therefore, the EPA must evaluate downwind air quality at that deadline, not at some later date.'' *Id.* at 1204 (emphasis added). EPA interprets the court's holding in *Maryland* as requiring the Agency, under the Good Neighbor provision, to address Good Neighbor obligations by no later than the next applicable attainment date for downwind areas, including a Marginal area attainment date under section 181 for ozone nonattainment.[6]

The December 30, 2019 NPRM proposing approval of the 2015 8-hour ozone Good Neighbor SIPs for Florida, Georgia, North Carolina, and South Carolina on the basis of a 2023 analytic year analysis predates the D.C. Circuit's decisions in *Wisconsin* and *Maryland.* In the July 19, 2021 SNPRM, EPA explained why it now considers 2021 to be the relevant analytic year for the purposes of determining whether sources in Florida, Georgia, North Carolina, and South Carolina will significantly contribute to downwind nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other state. *See* 86 FR 37944. Also in the July 19, 2021 SNPRM, EPA conducted an additional analysis for the year 2021, and provided additional notice and opportunity for public comment. *Id.* Thus, comments regarding the improper use of 2023 as a model year are now moot.[7]

Multiple commenters stated that the approach for identifying nonattainment and maintenance receptors in the original December 30, 2019 NPRM failed to identify all of the potential receptors relevant in a 2021 analytic year. In addition to their objections to EPA's selection of the 2023 analytic year, these commenters argued that measured design values at certain monitoring sites made clear that certain areas would not be able to attain the 2015 8-hour ozone NAAQS by the 2021 Marginal area attainment date. The shift in the July 19, 2021 SNPRM and this final action to a 2021 analytic year partially addresses the concerns raised by these commenters. To the extent commenters are arguing that EPA's method of defining nonattainment and maintenance receptors for Good Neighbor purposes ignores certain areas that may have air quality problems in 2021 based solely on historical measured data, EPA disagrees with these comments. EPA's method of defining these receptors, as described in section II of the SNPRM takes into account both measured data and reasonable projections based on modeling analysis.[8]

[6] EPA notes that the court in *Maryland* did not have occasion to evaluate circumstances in which EPA may determine that an upwind linkage to a downwind air quality problem exists at steps 1 and 2 of the four-step interstate transport framework by a particular attainment date, but for reasons of impossibility or profound uncertainty the Agency is unable to mandate upwind pollution controls by that date. *See Wisconsin,* 938 F.3d at 320. The D.C. Circuit noted in *Wisconsin* that upon a sufficient showing, these circumstances may warrant a certain degree of flexibility in effectuating the implementation of the Good Neighbor provision. Such circumstances are not at issue in the present action.

[7] EPA recognizes that this action is now being finalized after the Marginal area attainment date has passed and after the close of the 2021 ozone season. However, this does not change EPA's analysis or its conclusion. The modeling information available in the record and included in the supplemental proposal also indicates that these four states will not be linked to any downwind nonattainment or maintenance receptors in 2023 and 2028, confirming that no new linkages to downwind receptors are projected in later years.

[8] Further, as recognized by the court in *Wisconsin,* 938 F.3d at 320, nonattainment areas that measure clean data in a given year, even if not sufficient to be redesignated to attainment based on the three-year design value, may qualify for up to two one-year extensions of their attainment dates, as provided at CAA section 181(a)(5). Thus, simply providing the value that would be needed in 2020 in order for an area to be designated to attainment using the three-year average, as some commenters did, does not present a complete picture of the likelihood that an area will be ''reclassified'' or ''bumped-up.''

Regarding the contention that the CSAPR Update, which covered the 2008 8-hour ozone NAAQS, will not be sufficient to bring areas into attainment of the 2008 or 2015 8-hour ozone NAAQS, this is not relevant to the analysis in support of this action. Whether downwind states may or may not reach attainment of the 2015 8-hour ozone NAAQS with the assistance of the upwind state emissions reductions resulting from the CSAPR Update is not determinative of whether Florida, Georgia, North Carolina, and South Carolina have Good Neighbor obligations for the 2015 8-hour ozone NAAQS pursuant to the CAA. At issue is whether Florida, Georgia, North Carolina, and South Carolina will significantly contribute to downwind nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other state. The updated information presented in the SNPRM made clear that they will not, and no party commented on that updated information.

Comment 2: Several commenters call into question certain assumptions used in EPA's 2023 air quality modeling described in the March 2018 memorandum. A number of commenters contend that EPA's modeling was flawed because it relied on ''unenforceable emissions limitations,'' including assumptions that power plants equipped with selective catalytic reduction (SCR) controls would emit at or below 0.10 pounds per one million British Thermal Units (lb/mmBtu) beginning in 2017. One commenter contended that many plants emit above that rate. Another commenter asserts that EPA should not approve any prong 1 and 2 SIPs [9] that reflect ''EPA's flawed data showing attainment by 2023.''

Response 2: As discussed previously and in the SNPRM, EPA is relying on updated modeling and analysis based on the 2021 analytic year and not the 2023 air quality modeling described in the March 2018 memorandum. However, EPA disagrees that its assessment of air quality and contributions at step 1 and 2 of the four-step interstate transport framework is flawed because it relies on unenforceable emission assumptions for electric generating units (EGUs) or that those assumptions are otherwise unrealistic. As an initial matter, in this context it is appropriate for EPA to focus on actual EGU emission projections, rather than modeling only enforceable limits (sometimes referred to as ''allowable'' emissions). EPA has previously explained that its analysis at steps 1 and 2 of the four-step interstate transport framework is appropriately focused on a projection of *actual* air quality concentrations and upwind-state contributions. As EPA explained in the final CSAPR Close-out, this approach to conducting future-year modeling in the Good Neighbor analysis to identify downwind air quality problems and linked states is consistent with the use of current measured data in the designations process under section 107 of the CAA. *See* 83 FR 65878, 65887–88 (December 21, 2018).[10] In both cases, the purpose is to determine whether there is an actual air quality problem that needs to be further addressed (in the designations context, whether an area is in nonattainment of a NAAQS; in the Good Neighbor context, whether there are expected future air quality problems (*i.e.,* downwind nonattainment or maintenance receptors) and upwind state contribution to these downwind nonattainment or maintenance receptors that require further analysis at steps 3 and 4). EPA's future-year air quality projections reflect a variety of factors, including current emissions data, on-the-books control measures, economic market influences, and meteorology. Like the factors that affect measured ozone concentrations used in the designations process, not all of the factors influencing EPA's modeling projections are or can be subject to enforceable limitations on emissions or ozone concentrations. However, EPA believes that consideration of these factors contributes to a reasonable estimate of anticipated future ozone concentrations and contributions at steps 1 and 2 of the four-step interstate transport framework. In short, EPA's consideration of these factors—even when not based on or amendable to enforceable limits or controls—in its future-year modeling projections used at steps 1 and 2 of the Good Neighbor analysis is reasonable. *See* 83 FR at 65888 (December 21, 2018). Only where such analysis indicates an upwind-state linkage under projected conditions does further analysis proceed at steps 3 and 4 of the four-step interstate transport framework to determine what enforceable emissions limits should be required in the linked upwind state. EPA's air quality modeling and analysis is designed to reflect what downwind air quality problems will exist in the relevant analytic year, and the assumptions used are based on realistic projections of source emissions.

In response to the commenters' contention that EPA should not model using the 0.1 lb/mmBtu emission rate assumption for EGUs because it is not enforceable and some units emit higher than this rate, this concern is addressed by the updates contained in the updated 2023 modeling used to derive EPA's 2021 air quality analysis for this final action. Specifically, as noted in the SNPRM, EPA is relying on updated Integrated Planning Model (IPM) modeling for its EGU projection in the updated analysis for this final action. Additionally, EPA has modeled a range of scenarios reflecting alternative EGU assumptions—each resulting in the same finding made in this action.[11]

Although EPA disagrees with these comments regarding the modeling approach it took at the original proposal with respect to projecting EGU emissions,[12] the Agency made updates to incorporate the latest modeling and data, which address the concerns expressed by the commenters. The December 30, 2019 NPRM rule relied on air quality modeling analysis and data released in 2018 that showed results from analytic work completed in 2017 (prior to the completion of the first year of CSAPR Update compliance).[13] As explained in the modeling TSD referenced in the July 19, 2021 SNPRM, EPA started with the latest historical data at that time (2016) and assumed that, on average, SCR-controlled coal units would operate at 0.1 lb/mmBtu if not already doing so (reflecting the fleet's response (on average) to the CSAPR Update that would begin in 2017).[14] In this final action, EPA's future year air quality projections are informed by actual compliance data from 2019, which allows EPA to rely less on compliance assumptions and more on actual data from the past three years in evaluating likely EGU emissions in 2021. EPA estimated future

[9] Section 110(a)(2)(D)(i)(I) requires SIPs to contain adequate provisions that prohibit any source or other types of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state (prong 1) and from interfering with maintenance of the NAAQS in another state (prong 2).

[10] The CSAPR Close-out was vacated on grounds unrelated to this issue. *See New York* v. *EPA,* 781 F. App'x. 4 (D.C. Cir. 2019).

[11] *See* the Ozone Air Quality Assessment Tool (AQAT) spreadsheet and the Ozone Policy Analysis TSD located in the docket for this action for details about these scenarios, emissions, and air quality estimates.

[12] As explained further in this rule, the analysis supporting the December 30, 2019 proposal over-estimated EGU emissions.

[13] *See* March 2018 memorandum, located in the docket for this action.

[14] Technical Support Document (TSD) Additional Updates to Emissions Inventories for the Version 6.3, 2011 Emissions Modeling Platform for the Year 2023, available at *https://www.epa.gov/sites/production/files/2017-11/documents/2011v6.3_2023en_update_emismod_tsd_oct2017.pdf.*

year emissions using the January 2020 IPM Reference Case, which was informed by actual 2018 compliance rates rather than anticipated compliance rates (*i.e.,* 2018 reported emission rates (not a 0.1 lb/mmBtu assumption)). This largely obviates the commenters' concern regarding the 0.1 lb/mmBtu assumption at proposal. Moreover, the IPM modeling explicitly includes the CSAPR Update enforceable limits (*i.e.,* the states' trading allowance budgets) at both the regional and state level. With these enforceable limits included, the model allowed covered sources to emit up to those limits if it would be economically advantageous to do so, but this did not occur in the modeling.

EPA projected future 2021 and 2023 baseline EGU emissions using the version 6—January 2020 reference case of the IPM.[15] [16] IPM, developed by ICF Consulting, is a state-of-the-art, peer-reviewed, multi-regional, dynamic, deterministic linear programming model of the contiguous U.S. electric power sector. It provides forecasts of least cost capacity expansion, electricity dispatch, and emission control strategies while meeting energy demand and environmental, transmission, dispatch, and reliability constraints. EPA has used IPM for over two decades to better understand power sector behavior under future business-as-usual conditions and to evaluate the economic and emission impacts of prospective environmental policies. The model is designed to reflect electricity markets as accurately as possible. EPA uses the best available information from utilities, industry experts, gas and coal market experts, financial institutions, and government statistics as the basis for the detailed power sector modeling in IPM. The model documentation provides additional information on the assumptions discussed here as well as all other model assumptions and inputs. The IPM version 6—January 2020 reference base case accounts for updated federal and state environmental regulations, committed EGU retirements and new builds, and technology cost and performance assumptions as of late 2019. This projected base case accounts for the effects of the finalized Mercury and Air Toxics Standards rule, the CSAPR and the CSAPR Update, New Source Review settlements, final actions EPA has taken to implement the Regional Haze Rule, and other on-the-books federal and state rules through 2019 impacting sulfur dioxide, NO_X, directly emitted particulate matter, and CO_2. For the new 2023 air quality modeling used to interpolate air quality projections in 2021, EPA relied on these 2023 EGU emissions to inform the broader emissions inventory.

The EGU emissions data—both historical and projected—are shown in Table 1, and compared with the CSAPR Update enforceable budget, demonstrate: (1) The reasonableness of EPA's practice of not solely using enforceable levels in deriving projections of actual conditions and contribution at steps 1 and 2 of the interstate-transport framework for ozone, and (2) the robustness of its examination.

TABLE 1—REPORTED OZONE SEASON NO_X EMISSIONS FROM EGUS IN THE CSAPR UPDATE REGION [17]

Reported ozone season NO_X emissions (tons)						IPM projection (tons) [18]	CSAPR Update budget (enforceable tons)
2015	2016	2017	2018	2019	2020	2021	2021
398,831	371,994	294,483	289,988	251,763	227,325	222,900	313,626

In sum, EPA's EGUs assumptions show that its projected ozone-season EGU emissions levels from proposal of 283,164 tons in 2023 was, if anything, conservative—that is, it is likely that emissions levels from EGUs will be lower than what was projected in the proposal, not higher as suggested by the commenter. The 2019 ozone-season data reflected emissions that were already 20 percent below the CSAPR Update budgets, reflecting a 13 percent drop from the prior year, and at a pace of reduction that strongly suggests actual emissions from EGUs in 2021 will be well below the CSAPR Update budget levels. In other words, the emissions levels that the commenter claimed were not reasonable to expect in 2023 have already been achieved—four years ahead of that analytic year. The EGU projections EPA used in its analysis for 2021, as discussed previously, are reasonable and properly inform its analysis of ozone levels and contribution in that analytic year. In order for emissions in 2021 to rise to total budget levels (*e.g.,* 313,626 tons, representing the aggregate budgets for the covered states), a decade-long decline in ozone-season NO_X emissions would have to not only cease but reverse sharply.

Supported by the most recent reported emissions data, EPA concludes that its EGU projections used in the most recent modeling and in the interpolation of that modeling to 2021 are reasonable and conservative. Thus, EPA believes it is reasonable and appropriate to rely on these emissions projections in its air quality analysis for 2021 to approve the 2015 8-hour ozone transport SIP submissions for Florida, Georgia, North Carolina, and South Carolina.

Comment 3: A commenter states that EPA's 2023 modeling described in the March 2018 memorandum is also flawed given the modeling's reliance on certain federal emissions reduction programs, which the commenter argues EPA is ''actively working to undermine.'' For example, the commenter points to EPA's proposed repeal of its rule regulating emissions from glider vehicles, glider engines, and glider kits, 82 FR 53442 (November 16, 2017) (Proposed Repeal of the Glider Rule), noting that EPA has estimated unregulated glider vehicles would increase emissions by approximately 300,000 tons annually in 2025. The

[15] *See https://www.epa.gov/airmarkets/analysis-revised-cross-state-air-pollution-rule-update* (last accessed November 8, 2021).

[16] The January 2020 IPM reference case is a later version than what was released with 2016v1.

[17] This data analysis relies on 40 CFR part 75 emissions reporting data as available in EPA Air Markets Program Data available at *http://ampd.epa.gov/ampd/.*

[18] These values are available in the Air Quality Modeling Base Case State Emissions file (fossil >25 MW worksheet) available at *https://www.epa.gov/airmarkets/analysis-revised-cross-state-air-pollution-rule-update.* Additionally, as noted in the Revised CSAPR proposal, EPA's earlier engineering analytics used a more conservative 283,164 tons for 2023. As a sensitivity analysis for the proposed Revised CSAPR Update Modeling using IPM, EPA also used an updated engineering analytics EGU estimate (relying on 2019 data) that resulted in a 2021 estimate of 238,798 tons.

commenter notes that even though EPA never finalized the Proposed Repeal of the Glider Rule, EPA's enforcement office issued a memorandum on July 6, 2018, stating that it would not enforce the Glider Rule. The commenter states that although this ''no action assurance'' is being challenged in court and has been temporarily stayed, ''EPA's non-enforcement efforts underline the unreasonableness of relying on the emissions reductions from this rule as a basis for concluding that Marginal nonattainment areas will attain the 2015 NAAQS by 2021.'' The commenter also asserts that EPA's recent actions ''weakening'' the Corporate Average Fuel Economy (CAFE) standards for light-duty vehicles and EPA's recent proposal to withdraw the Control Techniques Guidelines (CTGs) for the Oil and Natural Gas Industry call into question the accuracy of EPA's 2023 modeling, and that ''each deregulatory action . . . demonstrates the arbitrariness of EPA's assumption that Marginal nonattainment areas will comply with the 2015 NAAQS by 2021 without additional ozone-precursor pollution reductions from southeastern upwind states.''

Response 3: As an initial matter, the updated 2023 modeling used to interpolate 2021 contributions that was relied on did not make different regulatory assumptions than the previous 2023 modeling released with the March 2018 memorandum regarding the Glider Rule and the light-duty CAFE standards, so the comment is relevant to the updated modeling as presented in the SNPRM. However, EPA disagrees that EPA's updated air quality modeling did not properly account for expected changes in projected emissions that would result from changes to federal programs. The mobile source and non-EGU emissions inventories in both the previous and updated modeling do not reflect changes in emissions resulting from rulemakings finalized in calendar year 2016 or later, nor do they reflect any rules proposed but not yet finalized since 2016, as only finalized rules are reflected in modeling inventories. This reflects EPA's normal practice to only include changes in emissions from final regulatory actions in its modeling because, until such rules are finalized, any potential changes in NO_X or VOC emissions are speculative.

EPA did not finalize the Proposed Repeal of the Glider Rule. EPA announced in the U.S. Office of Management and Budget's Spring 2020 Unified Agenda and Regulatory Plan that ''EPA is no longer pursuing this action, and the emission standards and other requirements for heavy-duty glider vehicles, glider engines, and glider kits will remain in place as published in the 'Greenhouse Gas Emissions and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles Phase 2' final rule on October 26, 2016 (81 FR 73478).'' [19] Additionally, EPA withdrew the conditional no action assurance for small manufacturers of glider vehicles in a memorandum dated July 26, 2018.[20]

EPA did not finalize the proposed withdrawal of the CTGs for oil and natural gas sources. On March 9, 2018, for reasons explained in the **Federal Register** (83 FR 10478), EPA proposed to withdraw the 2016 CTG for the oil and natural gas industry. However, EPA did not finalize the proposal to withdraw the CTG. EPA announced in the U.S. Office of Management and Budget's Spring 2020 Unified Agenda and Regulatory Plan that ''the CTG will remain in place as published on October 27, 2016 (81 FR 74798).'' [21]

EPA and the National Highway Traffic Safety Administration have finalized the revisions to the greenhouse gas (GHG) and CAFE standards for light duty vehicles.[22] However, that final action is not expected to have a meaningful impact on 2021 ozone-precursor emissions. Because the vehicles affected by the 2017–2025 GHG standards would still need to meet applicable criteria pollutant emissions standards (*e.g.,* the Tier 3 emissions standards; *see* 79 FR 23414), the SAFE Vehicles Rule anticipated that any impacts of the SAFE Vehicles Rule on ozone precursor emissions ''would most likely be far too small to observe.'' *See* 85 FR 25041.

Comment 4: Two commenters disagree with EPA guidance that a 1 ppb contribution threshold is acceptable to determine whether an upwind contribution is significant, stating it is arbitrary and capricious. One commenter also asserts that allowing different states contributing to a collective problem to use different air quality threshold rates to avoid regulation is inequitable. The commenters refer to EPA's August 31, 2018 memorandum from Peter Tsirigotis, titled ''Analysis of Contribution Thresholds for Use in Clean Air At Section 110(a)(2)(D)(i)(I) Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards'' (''August 2018 memorandum''),[23] and generally contend that the August 2018 memorandum provides an insufficient evaluation regarding the result of such approach on downwind states' ability to attain and maintain the relevant NAAQS and shifts the responsibility for upwind pollution from upwind to downwind states.

Response 4: As the commenters correctly note, the August 2018 memorandum suggested that states could potentially justify the use of an alternative contribution threshold of 1 ppb with respect to the 2015 8-hour ozone NAAQS in step 2 of EPA's four-step interstate framework under the Good Neighbor provision. However, EPA is not making a determination in this final action to approve a state's use of an alternative 1 ppb threshold. Neither EPA's NPRM, SNRPM, nor this final action rely on a 1 ppb threshold and are instead based on a finding that Florida, Georgia, North Carolina, and South Carolina will not contribute at or above one percent of the level of the NAAQS at any projected nonattainment or maintenance receptor based on EPA modeling. The use of the one percent threshold is consistent with all of EPA's ozone transport actions since the promulgation of the original CSAPR in 2011. For the 2015 8-hour ozone NAAQS, where the impacts of a state's emissions on all out of state receptors are below a one percent of the NAAQS threshold, no further analysis is required to determine that that state is not contributing to an out of state air quality problem under the Good Neighbor provision. Therefore, there is no need to evaluate any potential higher contribution threshold, as discussed in the August 2018 memorandum, in the present final action.

Comment 5: A commenter states that ozone exposure has significant health impacts, particularly for the respiratory system. The commenter cites the 2013 EPA Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Final Report) and several other health studies in order to describe numerous health impacts associated with ozone exposure in detail.

Response 5: EPA agrees that ozone has a number of adverse health impacts.

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[19] *See also https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202004&RIN=2060-AT79* (last accessed October 10, 2021).

[20] *See https://www.epa.gov/sites/production/files/2018-07/documents/memo_re_withdrawal_of_conditional_naa_regarding_small_manufacturers_of_glider_vehicles_07-26-2018.pdf* (last accessed October 10, 2021).

[21] *See https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202004&RIN=2060-AT76* (last accessed October 10, 2021).

[22] ''The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks,'' 85 FR 24174 (April 30, 2020) (SAFE Vehicles Rule).

[23] Available at *https://www.epa.gov/sites/production/files/2018-09/documents/contrib_thresholds_transport_sip_subm_2015_ozone_memo_08_31_18.pdf.*

See National Ambient Air Quality Standards for Ozone, Final Rule, 80 FR 65292 (October 26, 2015).[24] EPA evaluates air quality criteria and impacts to public health and welfare as part of the comprehensive standard setting process. *Id.* EPA's final rule revising the primary and secondary ozone NAAQS includes a thorough explanation of human exposure and health risk assessments conducted in support of the Agency's review of evidence of ambient ozone exposures on human health effects, as well as detailed rationales for the Administrator's decisions on both standards. *See* 80 FR 65292.

The commenter does not explain how the information they provided regarding health impacts from ambient ozone exposure should influence EPA's action on the Florida, Georgia, North Carolina, and South Carolina Good Neighbor SIP submissions for the 2015 8-hour ozone NAAQS, and EPA considers such comments to be outside of the scope of this action. As stated previously, EPA's evaluation of air quality criteria and impacts to public health and welfare are part of the standard setting process, rather than a step completed through actions on individual SIP submissions that address Good Neighbor interstate transport infrastructure SIP requirements pursuant to CAA section 110(a)(2)(D)(i)(I). EPA's evaluation of individual SIP revisions is limited to determining whether the statutory criteria for implementation and attainment of the NAAQS and other CAA requirements, as applicable, have been satisfied. *See* CAA section 110(k)(2), (3).

Comment 6: EPA received one supportive set of comments on the December 30, 2019, NPRM. The comments support EPA's application of the 4-step process, and state that EPA correctly concluded that none of the states in EPA's December 30, 2019, NPRM contributed above 1 percent to downwind receptors. Commenters also expressed support for flexibility in addressing the Good Neighbor SIPs.

Response 6: EPA agrees with commenter that it appropriately applied steps 1 and 2 of the four-step interstate transport framework (which the commenter refers to as the 4-step process), and that, according to EPA's analysis, neither Florida, Georgia, North Carolina nor South Carolina contribute above one percent of the 2015 8-hour ozone NAAQS to any downwind state. With respect to the portion of the comment regarding retaining the ability for states to take different approaches to analyzing and addressing their Good Neighbor obligations, EPA's use of certain analytic methods in this action (such as the use of a one percent of NAAQS contribution threshold or the definition of nonattainment and maintenance receptors) does not in itself necessarily preclude different approaches to Good Neighbor analysis in other contexts, where EPA determines to be appropriate and consistent with legal requirements and governing case law.

III. Final Action

EPA is finalizing approval of revisions to the Florida, Georgia, North Carolina, and South Carolina SIPs. EPA finds that emissions from sources in Florida, Georgia, North Carolina, and South Carolina will not significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in any other state. Thus, EPA is approving the interstate transport portions of the infrastructure SIP submissions from Florida, Georgia, North Carolina, and South Carolina, separately, as meeting CAA section 110(a)(2)(D)(i)(I) requirements for the 2015 8-hour ozone NAAQS.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. These actions merely approve state law as meeting Federal requirements and do not impose additional requirements beyond those imposed by state law. For that reason, these actions:

- Are not significant regulatory actions subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, for Florida, Georgia, and North Carolina, the Good Neighbor SIPs are not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

For South Carolina, because this final action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law, this action for the state of South Carolina does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). Therefore, this final action will not impose substantial direct costs on Tribal governments or preempt Tribal law. The Catawba Indian Nation Reservation is located within the boundary of York County, South Carolina. Pursuant to the Catawba Indian Claims Settlement Act, S.C. Code Ann. 27–16–120 (Settlement Act), ''[a]ll state and local environmental laws and regulations apply to the [Catawba Indian Nation and] Reservation and are fully enforceable by all relevant state and local agencies and authorities.'' The Catawba Indian Nation also retains authority to impose regulations applying higher environmental standards to the Reservation than those imposed by state law or local governing bodies, in accordance with the Settlement Act.

[24] *See also National Ambient Air Quality Standards for Ozone, Final Rule* for the 2008 NAAQS, 73 FR 16436 (March 27, 2008), 16440, 16450–51, 16470–71 & n.20.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 31, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* CAA section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 26, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart K—Florida

■ 2. In § 52.520(e), amend the table by adding a new entry for ''110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS'' at the end of the table to read as follows:

§ 52.520 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED FLORIDA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	**Federal Register** notice	Explanation
*	*	*	*	*
110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS.	9/18/2018	12/2/2021	[Insert citation of publication]	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

Subpart L—Georgia

■ 3. In § 52.570(e) amend the table by adding a new entry for ''110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS'' at the end of the table to read as follows:

§ 52.570 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED GEORGIA NON-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
*	*	*	*	*
110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS.	Georgia	9/24/2018	12/2/2021, [Insert citation of publication]	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

Subpart II—North Carolina

■ 4. In § 52.1770(e), amend the table by adding a new entry for ''110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS'' at the end of the table to read as follows:

§ 52.1770 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED NORTH CAROLINA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	**Federal Register** citation	Explanation
*	*	*	*	*
110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS.	9/27/2018	12/2/2021	[Insert citation of publication]	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

Subpart PP—South Carolina

■ 5. In § 52.2120(e), amend the table by adding a new entry for ''110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS'' at the end of the table to read as follows:

§ 52.2120 Identification of plan.

* * * * *

(e) * * *

Provision	State effective date	EPA approval date	Explanation
* *	*	* *	* *
110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS.	9/7/2018	12/2/2021, [Insert citation of publication]	..... Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

[FR Doc. 2021–26144 Filed 12–1–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

EPA–R04–OAR–2020–0428; FRL–8911–02–R4]

Air Plan Approval; TN; Montgomery County Limited Maintenance Plan for the 1997 8-Hour Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a state implementation plan (SIP) revision submitted by the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC), Air Pollution Control Division, on June 23, 2020. The SIP revision includes the 1997 8-hour ozone national ambient air quality standards (NAAQS) Limited Maintenance Plan (LMP) for the Montgomery County, Tennessee portion of the Clarksville-Hopkinsville Area (hereinafter referred to as the ''Montgomery County Area'' or ''Area''). The Clarksville-Hopkinsville Area is comprised of Montgomery County, Tennessee, and Christian County, Kentucky. EPA is approving Tennessee's LMP for the Montgomery County Area because it provides for the maintenance of the 1997 8-hour ozone NAAQS within the Montgomery County Area through the end of the second 10-year portion of the maintenance period. The effect of this action would be to make certain commitments related to maintenance of the 1997 8-hour ozone NAAQS in the Montgomery County Area federally enforceable as part of the Tennessee SIP.

DATES: This rule is effective January 3, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R04–OAR–2020–0428. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials can either be retrieved electronically via *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Sarah LaRocca, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8994. Ms. LaRocca can also be reached via electronic mail at *larocca.sara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1979, under section 109 of the Clean Air Act (CAA or Act), EPA established primary and secondary NAAQS for ozone at 0.12 parts per million (ppm), averaged over a 1-hour period. *See* 44 FR 8202 (February 8, 1979). On July 18, 1997, EPA revised the primary and secondary NAAQS for ozone to set the acceptable level of ozone in the ambient air at 0.08 ppm, averaged over an 8-hour period. *See* 62 FR 38856 (July 18, 1997).[1] EPA set the 8-hour ozone NAAQS based on scientific evidence demonstrating that ozone causes adverse health effects at lower concentrations and over longer periods of time than was understood when the pre-existing 1-hour ozone NAAQS was set. EPA determined that the 8-hour ozone NAAQS would be more protective of human health, especially children and adults who are active outdoors, and individuals with a pre-existing respiratory disease, such as asthma.

Following promulgation of a new or revised NAAQS, EPA is required by the CAA to designate areas throughout the nation as attaining or not attaining the NAAQS. On April 15, 2004, EPA designated the Clarksville-Hopkinsville Area, which included Montgomery County, Tennessee, and Christian County, Kentucky, as nonattainment for the 1997 8-hour ozone NAAQS, and the designation became effective on June 15, 2004. *See* 69 FR 23858 (April 30, 2004). Similarly, on May 21, 2012, EPA designated areas as unclassifiable/attainment or nonattainment for the 2008 8-hour ozone NAAQS. EPA designated Montgomery County as unclassifiable/attainment for the 2008 8-hour ozone NAAQS. This designation became effective on July 20, 2012. *See* 77 FR 30088 (May 21, 2012). In addition, on November 16, 2017, areas were designated for the 2015 8-hour ozone NAAQS. The Montgomery County Area was designated attainment/unclassifiable for the 2015 8-hour ozone NAAQS, with an effective date of January 16, 2018. *See* 82 FR 54232 (November 16, 2017).

A state may submit a request to redesignate a nonattainment area that is attaining a NAAQS to attainment, and, if the area has met other required criteria described in section 107(d)(3)(E) of the CAA, EPA may approve the

[1] In March 2008, EPA completed another review of the primary and secondary ozone NAAQS and tightened them further by lowering the level for both to 0.075 ppm. *See* 73 FR 16436 (March 27, 2008). Additionally, in October 2015, EPA completed a review of the primary and secondary ozone NAAQS and tightened them by lowering the level for both to 0.070 ppm. *See* 80 FR 65292 (October 26, 2015).

redesignation request.[2] One of the criteria for redesignation is to have an approved maintenance plan under CAA section 175A. The maintenance plan must demonstrate that the area will continue to maintain the NAAQS for the period extending ten years after redesignation, and it must contain such additional measures as necessary to ensure maintenance and such contingency provisions as necessary to assure that violations of the NAAQS will be promptly corrected. Eight years after the effective date of redesignation, the state must also submit a second maintenance plan to ensure ongoing maintenance of the NAAQS for an additional ten years pursuant to CAA section 175A(b) (*i.e.,* ensuring maintenance for 20 years after redesignation).

EPA has published long-standing guidance for states on developing maintenance plans.[3] The Calcagni memo provides that states may generally demonstrate maintenance by either performing air quality modeling to show that the future mix of sources and emission rates will not cause a violation of the NAAQS or by showing that projected future emissions of a pollutant and its precursors will not exceed the level of emissions during a year when the area was attaining the NAAQS (*i.e.,* attainment year inventory). *See* Calcagni memo at page 9. EPA clarified in three subsequent guidance memos that certain areas could meet the CAA section 175A requirement to provide for maintenance by showing that the area was unlikely to violate the NAAQS in the future, using information such as the area's design value [4] being significantly below the standard and the area having a historically stable design value.[5] EPA refers to a maintenance plan containing this streamlined demonstration as an LMP.

EPA has interpreted CAA section 175A as permitting the LMP option because section 175A of the Act does not define how areas may demonstrate maintenance, and in EPA's experience implementing the various NAAQS, areas that qualify for an LMP and have approved LMPs have rarely, if ever, experienced subsequent violations of the NAAQS. As noted in the LMP guidance memoranda, states seeking an LMP must still submit the other maintenance plan elements outlined in the Calcagni memo, including: An attainment emissions inventory, provisions for the continued operation of the ambient air quality monitoring network, verification of continued attainment, and a contingency plan in the event of a future violation of the NAAQS. Moreover, a state seeking an LMP must still submit its section 175A maintenance plan as a revision to its SIP, with all attendant notice and comment procedures. While the LMP guidance memoranda were originally written with respect to certain NAAQS,[6] EPA has extended the LMP interpretation of section 175A to other NAAQS and pollutants not specifically covered by the previous guidance memos.[7]

In a notice of proposed rulemaking (NPRM), published on September 23, 2021 (86 FR 52864), EPA proposed to approve Tennessee's LMP because the State made a showing, consistent with EPA's prior LMP guidance, that the Area's ozone concentrations are well below the 1997 8-hour ozone NAAQS and have been historically stable and that it met the other maintenance plan requirements. The details of Tennessee's submission and the rationale for EPA's action are explained in the NPRM. Comments on the September 23, 2021, NPRM were due on or before October 25, 2021. EPA did not receive any comments on the September 23, 2021, NPRM.

II. Final Action

EPA is taking final action to approve the Montgomery County Area LMP for the 1997 8-hour ozone NAAQS, submitted by TDEC on June 23, 2020, as a revision to the Tennessee SIP. EPA is approving the Montgomery County Area LMP because it includes a sufficient update of the various elements of the 1997 8-hour ozone NAAQS Maintenance Plan approved by EPA for the first 10-year portion of the maintenance period (including emissions inventory, assurance of adequate monitoring and verification of continued attainment, and contingency provisions) and retains the relevant provisions of the SIP under sections 110(k) and 175A of the CAA.

EPA also finds that the Montgomery County Area qualifies for the LMP option and that the Montgomery County Area LMP is sufficient to provide for maintenance of the 1997 8-hour ozone NAAQS in the Clarksville-Hopkinsville Area over the second 10-year maintenance period (*i.e.,* through 2025).

III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

[2] Section 107(d)(3)(E) of the CAA sets out the requirements for redesignating a nonattainment area to attainment. They include attainment of the NAAQS, full approval of the applicable SIP pursuant to CAA section 110(k), determination that improvement in air quality is a result of permanent and enforceable reductions in emissions, demonstration that the state has met all applicable section 110 and part D requirements, and a fully approved maintenance plan under CAA section 175A.

[3] John Calcagni, Director, Air Quality Management Division, EPA Office of Air Quality Planning and Standards (OAQPS), ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' September 4, 1992 (Calcagni memo).

[4] The ozone design value for a monitoring site is the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations. The design value for an ozone area is the highest design value of any monitoring site in the area.

[5] See ''Limited Maintenance Plan Option for Nonclassifiable Ozone Nonattainment Areas,'' from Sally L. Shaver, OAQPS, November 16, 1994; ''Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas,'' from Joseph Paisie, OAQPS, October 6, 1995; and ''Limited Maintenance Plan Option for Moderate PM_{10} Nonattainment Areas,'' from Lydia Wegman, OAQPS, August 9, 2001. Copies of these guidance memoranda can be found in the docket for this rulemaking.

[6] The prior memos addressed: Unclassifiable areas under the 1-hour ozone NAAQS, nonattainment areas for the PM_{10} (particulate matter with an aerodynamic diameter less than 10 microns) NAAQS, and nonattainment for the carbon monoxide (CO) NAAQS.

[7] *See, e.g.,* 79 FR 41900 (July 18, 2014) (approval of the second ten-year LMP for the Grant County 1971 SO_2 maintenance area).

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
• Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 31, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental Protection, Air Pollution Control, Incorporation by Reference, Intergovernmental Relations, Nitrogen Oxides, Ozone, Reporting and Recordkeeping Requirements, Volatile Organic Compounds.

Dated: November 26, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 52.2220 amend the table in paragraph (e) by adding, at the end of the table, the entry ''1997 8-Hour Ozone Second 10-Year Limited Maintenance Plan for the Montgomery County, Tennessee Area'' to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED TENNESSEE NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State effective date	EPA approval date	Explanation
*	*	*	*	*
1997 8-Hour Ozone Second 10-Year Limited Maintenance Plan for the Montgomery County, Tennessee Area.	Montgomery County	6/10/2020	12/2/2021, [Insert citation of publication].	

* * * * *

[FR Doc. 2021–26143 Filed 12–1–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB27

National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: On April 4, 2018, the Secretary of Health and Human Services (the Secretary) published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend the National Vaccine Injury Compensation Program (VICP or Program) Vaccine Injury Table (Table), consistent with the statutory requirement to include vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in pregnant women. Specifically, the Secretary sought public comment regarding how the addition of this new category should be formatted on the Table. Through this final rule, the Secretary amends the Table to add ''and/or pregnant women'' after ''children'' to the existing language in Item XVII as proposed in the NPRM. This change will apply only to petitions for compensation under the VICP filed after the effective date of this final rule.

DATES: This rule is effective January 3, 2022.

FOR FURTHER INFORMATION CONTACT: Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8N146B, Rockville, MD 20857, or by telephone (855) 266–2427. This is a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa-10 *et seq.*), established the VICP, a Federal compensation program for individuals thought to be injured by certain vaccines. The statute governing the VICP has been amended several times since 1986 and will be hereinafter

referred to as ''the Vaccine Act.'' Petitions for compensation under the VICP are filed in the United States Court of Federal Claims (Court), with a copy served on the Secretary, who is the ''Respondent.'' The Court, acting through judicial officers called Special Masters, makes findings as to eligibility for, and the amount of, compensation.

To gain entitlement to compensation under this Program, a petitioner must establish that a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating the occurrence of what is referred to as a ''Table injury.'' That is, a petitioner may show that the vaccine recipient suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the ''Vaccine Injury Table''—corresponding to the vaccination in question and that the onset of such injury took place within the period also specified in the Table. If so, the injury is presumed to have been caused by the vaccination, and the petitioner is entitled to compensation (assuming that other Vaccine Act requirements are satisfied) unless the respondent affirmatively shows that the injury was caused by some factor other than the vaccination (see 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B), and 300aa–14(a)).

Revisions to the Table are authorized under 42 U.S.C. 300aa–14(c) and (e). Prior to the 21st Century Cures Act (Cures Act) (Pub. L. 114–255), the only vaccines covered under the VICP were those recommended by the CDC for routine administration to children (for example, vaccines that protect against seasonal influenza), are subject to an excise tax by Federal law, and added to the Table by the Secretary. The Table currently includes 17 vaccine categories, with 16 categories for specific vaccines, as well as their corresponding illness, disability, injury, or condition covered, and the requisite time within which the first symptom or manifestation of onset or significant aggravation must begin after the vaccine administration to receive the Table's legal presumption of causation. One category of the Table, ''Item XVII,'' includes, ''Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.'' Two injuries—Shoulder Injury Related to Vaccine Administration (SIRVA) and vasovagal syncope—are listed as associated injuries for this category. Through this general category, new vaccines recommended by the CDC for routine administration to children and subject to an excise tax are covered under the VICP prior to being added to the Table as a separate vaccine category.

The Cures Act amended 42 U.S.C. 300aa–14(e) to expand the types of vaccines covered under the VICP. *See* section 3093(c)(1) of the Cures Act. The amended statute requires that the Secretary revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). *See* 42 U.S.C. 300aa–14(e)(3). This action does not alter the current status quo because the CDC has not recommended any categories of vaccines for routine administration to pregnant women that are not also recommended for routine administration to children.

Summary of the Final Rule

As discussed in the NPRM (83 FR 14391), Congress enacted a mechanism for modification of the Table, through the promulgation of regulatory changes by the Secretary after consultation with the Advisory Commission on Childhood Vaccines (ACCV). The Secretary is revising the Table to include new vaccines recommended by the CDC for routine administration in pregnant women in Item XVII of the Table. On September 8, 2017, the Program consulted the ACCV regarding options for adding this new category of vaccines to the Table. The ACCV voted unanimously to amend the existing language in Item XVII of the Table to add ''and/or pregnant women'' after ''children'' authorizing coverage under the VICP of any new vaccine recommended by CDC for routine administration in pregnant women (and subject to an excise tax) after the publication of a notice of coverage. The ACCV viewed this option as a simple approach to revising the Table, rather than adding a new general Item XVIII to the Table for vaccines recommended for routine administration in pregnant women. Therefore, following the ACCV's recommendation, the Secretary has amended the existing language in Item XVII of the Table to add ''and/or pregnant women'' after ''children.'' This amendment allows any new vaccine recommended by the CDC for routine administration in pregnant women (and subject to an excise tax) to be added to this general category of the Table after the Secretary publishes a notice of coverage. The publication of a notice of coverage reflects the Secretary's approval of CDC's recommendation and the determination that the statutory requirements for coverage under the VICP have been met.

The Secretary also has retained the two injuries currently associated with Item XVII of the Table, SIRVA and vasovagal syncope, as Table injuries for vaccines recommended by the CDC for routine administration in pregnant women. In its 2012 Report, ''Adverse Effects of Vaccines: Evidence and Causality,'' the Institute of Medicine considered SIRVA and vasovagal syncope as mechanistic injuries resulting from the injection of a vaccine and not from the contents of a particular formulation of a vaccine. Thus, these conditions are listed as Table injuries for any new vaccine recommended by the CDC for routine administration to children (after the imposition of an excise tax and publication by the Secretary of a notice of coverage) to account for any new injected vaccines that potentially may lead to SIRVA or vasovagal syncope. Therefore, the Secretary also has included these injuries on the Table for new vaccines recommended by the CDC for routine administration in pregnant women.

VICP petitions must be filed within the applicable statutes of limitations. With the Table change, the general statutes of limitations applicable to petitions filed with the VICP, set forth in 42 U.S.C. 300aa–16(a), continue to apply. The alternate statute of limitations afforded by 42 U.S.C. 300aa–16(b) does not apply to this Table change. This is because, at present, there are no vaccines added to the Table under the revised general category, since the only vaccines the CDC currently recommends for routine administration in pregnant women are already covered on the Table. In the future, when any new vaccine, not already covered under the VICP, is recommended by the CDC for routine administration in pregnant women, subject to an excise tax, and added to the Table, the alternate statute of limitations afforded by 42 U.S.C. 300aa–16(b) would apply if certain requirements are met.[1]

II. Responses to Public Comments

The NPRM provided a 180-day comment period (April 4, 2018–October 1, 2018), and HRSA received 51 comments during that time, including during a public hearing. There were 48 written comments submitted. The

[1] Under 42 U.S.C. 300aa–16(b), the alternate statute of limitations applies where the effect of the revision would make an individual, who was not eligible before the revision, eligible to seek compensation under the Program or to significantly increase the individual's likelihood of obtaining compensation.

number and sources of the comments are as follows: 44 from individuals, two from pharmaceutical companies, and two from organizations, with one stating it represents 12 other entities. In addition, HRSA held a public hearing on the NPRM on September 17, 2018, and a national organization and two individuals presented oral comments.

While the Secretary only sought public comment on how best to implement the statutory amendment to add vaccines recommended by the CDC for routine administration in pregnant women to the Table, many commenters offered comments beyond the scope of the request. Nevertheless, the Secretary carefully considered all 51 comments received in the development of this final rule. Below is a summary of the comments and the Secretary's response to them.

Comment: Several comments supported the addition of vaccines recommended for routine administration in pregnant women to the Table, stating that maternal immunization will improve the health of the mother, her unborn child, newborns, and the overall health of the nation.

Response: Based on existing evidence and data trends, the Secretary agrees that the eradication and reduction of vaccine-preventable diseases through immunization has directly increased life expectancy by reducing mortality. Pregnant women are at risk for vaccine-preventable disease–related morbidity and mortality and adverse pregnancy outcomes, including congenital anomalies, spontaneous abortion, preterm birth, and low birth weight. In addition to providing direct maternal benefit, vaccination during pregnancy likely provides direct fetal and infant benefit through passive immunity (transplacental transfer of maternal vaccine-induced antibodies). Among the vaccines recommended by the CDC for adults, currently, two are specifically recommended for routine administration during pregnancy, and hepatitis A, hepatitis B, meningococcal (ACWY), and meningococcal (B) are recommended in pregnancy based on additional risk factors.

Comment: A comment supporting the proposed changes in the NPRM suggests that the recommendations of the CDC should be included as additional language on the Table, supporting the safe administration of vaccines in pregnant women.

Response: The Table does not include language about the safe administration of vaccines, as the purpose of the Table is to list and explain injuries and/or conditions that are presumed to be caused by covered vaccines, unless another cause is proven, for potential compensation under the VICP. However, CDC develops best practice guidance for the safe administration of vaccines that can be found at *https://www.cdc.gov/vaccines/hcp/acip-recs/index.html.*

Comment: Comments supporting the proposed changes in the NPRM indicated that the CDC recommendations for the administration of routine vaccination to pregnant women would result in increased communication and knowledge around vaccines recommended for pregnant women, leading to increased informed consent and facilitate decision-making regarding immunizations. In addition, this may result in the development of new vaccines for pregnant women.

Response: Recommendations for the routine use of vaccines in pregnant women are issued by the CDC and are harmonized to the greatest extent possible with recommendations made by the American College of Gynecologists and Obstetricians, the American Academy of Family Physicians, and the American College of Physicians. The Advisory Committee on Immunization Practices, established in 1964 by the Surgeon General of the United States, is chartered as a Federal advisory committee to provide expert external advice and guidance to the Director of the CDC on the use of vaccines in the civilian population. The Advisory Committee on Immunization Practices makes recommendations to the Director of the CDC for vaccines authorized or licensed by the Food and Drug Administration for the prevention of diseases. Providing information regarding whether these recommendations increase communication and knowledge around vaccines recommended for pregnant women, and facilitating decision-making regarding immunizations, is beyond the scope of this final rule.

Comment: Some comments supporting the proposed changes in the NPRM suggested that adding the category of pregnant women to the Table would allow the VICP to function more efficiently and pregnant women would have recourse should an alleged injury occur.

Response: The Secretary agrees that the addition of the category of vaccines recommended for routine administration in pregnant women to the Table will make the VICP function more efficiently. The addition of such vaccines to Item XVII of the Table will allow any new vaccines that in the future are recommended by the CDC for routine administration in pregnant women (and subject to an excise tax) to be covered under the VICP after the Secretary issues a notice of coverage, without requiring further rulemaking.

In addition, the Table lists covered vaccines and associated injuries, making it easier for some people to get compensation. The Table lists and explains injuries and/or conditions that are presumed to be caused by vaccines unless another cause is proven. The Table's Qualification and Aids to Interpretation define some of the injuries and/or conditions listed on the Table. The Table also lists periods in which the first symptom of these injuries and/or conditions must occur after receiving the vaccine to receive the Table's presumption of causation. If the first symptom of an injury and/or condition listed on the Table occurs within the listed time, and any associated definition(s) included in the Qualification and Aids to Interpretation are satisfied, it is presumed that the vaccine was the cause of the injury or condition unless another cause is proven.

Comment: Several comments opposed the proposed changes in the NPRM because they stated that the administration of vaccines to pregnant women and their unborn children causes injuries, such as miscarriages, pre-eclampsia, cancer, autism, neurodevelopmental disorders of infants, and learning disabilities. Some opposed the addition of the category of pregnant women to the Table because they believe that there is a lack of vaccine safety testing and studies, especially regarding the administration of vaccines in pregnant women. Some comments suggested there is no scientific evidence that vaccinating pregnant women is safe or advantageous and that there are limited benefits and increased risks for vaccinating pregnant women. In addition, some adamantly opposed all vaccinations.

Response: As noted in the NPRM, a recent amendment to the Vaccine Act requires that the Secretary revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). See 42 U.S.C. 300aa–14(e)(3).

Moreover, the United States has a long-standing vaccine safety program that closely and constantly monitors the safety of vaccines. A critical part of the vaccine safety program is the CDC's Immunization Safety Office, which identifies possible vaccine side effects and conducts studies to determine whether health problems are caused by vaccines. Information regarding vaccine

safety and current research are available by conducting literature reviews.

Pregnant women are at risk for vaccine-preventable disease-related morbidity and mortality and adverse pregnancy outcomes, including congenital anomalies, spontaneous abortion, preterm birth, and low birth weight. In addition to providing direct maternal benefit, vaccination during pregnancy may provide direct fetal and infant benefit through passive immunity (transplacental transfer of maternal vaccine-induced antibodies).

Existing evidence and data trends indicate that the eradication and reduction of vaccine-preventable diseases through immunization has directly increased life expectancy by reducing mortality. In addition, numerous published and peer-reviewed scientific studies have found that neither vaccines nor vaccine ingredients cause the neurodevelopmental disorders of autism, Attention-Deficit/Hyperactivity Disorder, or speech or language delay.

Comment: Some comments opposing the proposed changes in the NPRM stated that pregnant women are often coerced or forced to be vaccinated without being given information about possible vaccine side effects to themselves and/or their unborn child/children.

Response: This final rule does not require vaccines for pregnant women. However, the CDC and the American Academy of Pediatrics, as well as other medical organizations, publish information regarding the safety of recommended vaccines. In addition, Vaccine Information Statements, which are information sheets produced by the CDC that explain both the benefits and risks of VICP-covered vaccines, are required to be provided to all individuals, or their legal representatives, before receiving such vaccines. However, the decision to ultimately be vaccinated rests with the individual or legal representative.

Comment: Some comments opposing the NPRM stated that by recommending vaccines to pregnant women, liability protection is conferred upon vaccine manufacturers and that this creates a disincentive to conduct safety research on vaccines. Some stated a belief that the addition of pregnant women will now eliminate the pregnant woman's right to sue for damages.

Response: The Vaccine Act created the VICP, a no-fault alternative to the traditional tort system. It provides compensation to people thought to be injured by vaccines recommended by the CDC for routine administration to children and now pregnant women. When a vaccine is added to the Vaccine Injury Table, it is covered under the VICP. To help ensure a stable vaccine supply, the VICP generally provides liability protection for vaccine manufacturers and health care providers for injuries caused by VICP-covered vaccines. Claims alleging injuries or death from certain vaccines generally must be filed with the VICP before a lawsuit can be filed in civil court.

Comment: Some comments opposed the addition of the category of vaccines recommended for routine administration in pregnant women to the Table, as this would provide vaccine manufacturers the ability to increase revenue by having a new population to target with their products.

Response: As noted previously, the Secretary is required by statute to revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). See 42 U.S.C. 300aa–14(e)(3).

Comment: Some comments opposing the change proposed in the NPRM suggested that the VICP be eliminated.

Response: The Vaccine Act established the VICP, and Congress would need to enact legislation to eliminate the VICP. Eliminating the Program is beyond the scope of this final rule.

Comment: Some comments supporting and opposing the changes proposed in the NPRM suggested additional changes to the Table, such as adding injuries to the Table. Commenters opposing changes proposed in the rule stated that vaccines cause miscarriages and other conditions, such as chorioamnionitis, encephalitis/encephalopathy, Guillain-Barré Syndrome, and neurodevelopmental disorders, and can negatively affect the offspring of pregnant women who have undiagnosed genetic disorders. Some commenters requested that the Table be revised or expanded to include all vaccines that could be recommended in pregnancy and their potential complications, and vaccines contraindicated during pregnancy, including statistics of complications.

Response: Consistent with the statutory requirement, the Secretary is revising the Table to include new vaccines recommended by the CDC for routine administration in pregnant women. The Secretary is implementing this change by amending the existing language in Item XVII of the Table to include ''and/or pregnant women'' after ''children.'' This will add to that general category of the Table, any new vaccine recommended by the CDC for routine administration in pregnant women, after imposition of an excise tax and publication of a notice of coverage by the Secretary.

As explained above, in its 2012 Report, ''Adverse Effects of Vaccines: Evidence and Causality,'' the Institute of Medicine considered SIRVA and vasovagal syncope as mechanistic injuries resulting from the injection of a vaccine and not from the contents of a particular formulation of a vaccine. Thus, these conditions are listed as Table injuries for any new vaccine recommended by the CDC for routine administration to children or pregnant women (after the imposition of an excise tax and publication by the Secretary of a notice of coverage) to account for any new injected vaccines that potentially may lead to SIRVA or vasovagal syncope. In the future, when specific vaccines recommended for routine administration in pregnant women are added to the Table, the Secretary will review the literature to determine if other injuries should be added to the Table for those new vaccines.

Comment: Comments supporting and opposing the proposed change in the NPRM speculated that there is the potential for increased compensation for adverse reactions resulting from increased injury claims, as both the mother and her unborn child are now eligible to file a claim for a vaccine related injury. Commenters expressed concern with possible abuse in reporting and compensation, compounded by the addition of SIRVA and vasovagal syncope as injuries to the Table.

Response: The Secretary is required by statute to revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). *See* 42 U.S.C. 300aa–14(e)(3). Additionally, with respect to vaccination of pregnant women, the Cures Act permits two VICP petitions to be filed: One on behalf of a woman who was pregnant when vaccinated and one on behalf of her live-born child whose injury(s) was allegedly sustained *in utero. See* 42 U.S.C. 300aa–11(b)(2).

Comment: A commenter questioned who would be the proper petitioner in the context of maternal immunization (*i.e.,* would the petitioner be the pregnant woman, the child born after his/her pregnant mother was vaccinated, or both?).

Response: The Cures Act amended the Vaccine Act to permit VICP claims filed on behalf of live-born children for injuries allegedly sustained *in utero* as a result of maternal immunizations with respect to covered vaccines. *See* 42

U.S.C. 300aa–11(f). In addition, the Cures Act modified the Vaccine Act's ''one petition'' requirement by allowing two VICP petitions: One on behalf of a woman who was pregnant when vaccinated and one on behalf of her child whose injury(s) was allegedly sustained *in utero. See* 42 U.S.C. 300aa–11(b)(2).

III. Regulatory Impact Analysis

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety, distributive, and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities, HHS must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

The Office of Information and Regulatory Affairs has determined that this rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866.

HHS has determined that no substantial additional administrative and compensation resources are required to implement the requirements in this rule. Compensation will be made in the same manner. As in all other VICP cases, to be found entitled to compensation, petitioners will need to prove by a preponderance of the evidence either that they meet the requirements of the Table or that their injury was caused by the vaccine unless the respondent affirmatively shows that the injury was caused by some factor other than the vaccination. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

The National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table Final Rule is ''not significant'' because no substantial resources are required to implement the requirements in this rule. This rule adds ''and/or pregnant women'' to the new vaccines category (Item XVII) on the Table. Currently, the only vaccines recommended for routine administration in pregnant women are already on the Table because they are recommended for routine administration to children and have an excise tax imposed on them. Therefore, this final rule does not have a significant impact on a substantial number of small entities. Additionally, this rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. We have determined that the final rule is not a ''major rule'' within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, it will not have effects on state, local, and tribal governments and on the private sector such as requiring consultation under the Unfunded Mandates Reform Act of 1995.

The provisions of this final rule do not, on the basis of family well-being, affect the following family elements: Family safety; family stability; marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning; disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

This final rule is not being treated as a ''significant regulatory action'' as defined under section 3(f) of Executive Order 12866. As stated above, this final rule will modify the Table based on legal authority.

Impact of the New Rule

This final rule will allow any vaccines that in the future are recommended by the CDC for routine administration to pregnant women and subject to an excise tax to be covered under the VICP after the Secretary issues a notice of coverage, without requiring further rulemaking. In addition, this final rule will have the effect of making it easier for future petitioners alleging injuries that meet the criteria in the Vaccine Injury Table to receive the Table's presumption of causation, which relieves them of having to prove that the vaccine actually caused or significantly aggravated their injury.

Paperwork Reduction Act of 1995

This final rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Accordingly, 42 CFR part 100 is amended as set forth below:

PART 100—VACCINE INJURY COMPENSATION

■ 1. The authority citation for 42 CFR part 100 continues to read as follows:

Authority: Secs. 312 and 313 of Public Law 99–660 (42 U.S.C. 300aa–1 note); 42 U.S.C. 300aa–10 to 300aa–34; 26 U.S.C. 4132(a); and sec. 13632(a)(3) of Public Law 103–66.

■ 2. In § 100.3, amend the Table in paragraph (a) by revising entry ''XVII'' to read as follows:

§ 100.3 Vaccine injury table.

(a) * * *

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury, or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
* * * *	* * *	
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children and/or pregnant women, after publication by the Secretary of a notice of coverage.	A. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	B. Vasovagal syncope	≤1 hour.

* * * * *

[FR Doc. 2021–26197 Filed 12–1–21; 8:45 am]

BILLING CODE 4150–28–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 63

[IB Docket No. 16–155; FCC 21–104]

Process Reform for Executive Branch Review of Certain FCC Applications and Petitions Involving Foreign Ownership

AGENCY: Federal Communications Commission.

ACTION: Final action.

SUMMARY: This document summarizes the Federal Communications Commission's (Commission) decision in the Second Report and Order in the *Process Reform for Executive Branch Review of Certain FCC Applications and Petitions Involving Foreign Ownership* proceeding, in which the Commission adopted Standard Questions that certain applicants with reportable foreign ownership will be required to answer as part of the Executive Branch review process of their applications.

DATES: The Commission adopted the Standard Questions on September 30, 2021.

FOR FURTHER INFORMATION CONTACT: Jocelyn Jezierny, International Bureau, Telecommunications and Analysis Division, at (202) 418–0887 or *Jocelyn.Jezierny@fcc.gov.* For information regarding the PRA information collection requirements contained in the PRA, contact Cathy Williams, Office of the Managing Director, at (202) 418–2918 or *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Report and Order, FCC 21–104, adopted on September 30, 2021, and released on October 1, 2021. The full text of this document is available on the Commission's website at *https://docs.fcc.gov/public/attachments/FCC-21-104A1.pdf.* To request materials in accessible formats for people with disabilities, send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Supplemental Final Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared a Supplemental Final Regulatory Flexibility Analysis (Supplemental FRFA) of the possible significant impact on small entities of the Standard Questions and procedures addressed in this Second Report and Order.

Congressional Review Act

The Commission will include a copy of this Second Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A).

Synopsis

I. Introduction

1. In this Second Report and Order, we adopt a set of standardized national security and law enforcement questions (Standard Questions) that certain applicants and petitioners (together, ''applicants'') with reportable foreign ownership will be required to answer as part of the Executive Branch review process of their applications and petitions (together, ''applications''). In the *Executive Branch Review Order,* the Commission adopted rules and procedures to facilitate a more streamlined and transparent review process for coordinating applications with the Executive Branch agencies (the Departments of Justice, Homeland Security, Defense, State, and Commerce, as well as the United States Trade Representative) for their views on any national security, law enforcement, foreign policy, or trade policy issues associated with the foreign ownership of the applicants. The *Executive Branch Review Order* also established firm time frames for the Executive Branch agencies to complete their review consistent with Executive Order 13913, which established the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (the Committee).[1] To expedite the national security and law enforcement review of such applications, applicants must provide their answers to the Standard Questions directly to the Committee prior to or at the same time they file their applications with the Commission. This process would replace the current practice of the Executive Branch seeking such threshold information directly from the applicants after the Commission refers the applications.

II. Background

2. For over 20 years, the Commission has referred certain applications that have reportable foreign ownership to the Executive Branch agencies for their review.[2] In the *Executive Branch Review Order,* the Commission formalized the review process and established firm time frames for the Executive Branch national security and law enforcement agencies to complete their review, consistent with Executive Order 13913 that established the Committee in 2020. The types of applications the Commission generally refers include applications for international section 214 authorizations and submarine cable landing licenses and applications to assign, transfer control or modify such authorizations and licenses where the applicant has reportable foreign ownership, and all petitions for section 310(b) foreign ownership rulings.[3]

[1] Executive Order No. 13913 of April 4, 2020, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, 85 FR 19643, 19643 through 44 (Apr. 8, 2020) (Executive Order 13913) (establishing the ''Committee,'' composed of the Secretary of Defense, the Secretary of Homeland Security, and the Attorney General of the Department of Justice, who serves as the Chair, and the head of another executive department or agency, or any Assistant to the President, as the President determines appropriate (Members), and also providing for Advisors, including the Secretary of State, the Secretary of Commerce, and the United States Trade Representative); *id.* (stating that, ''[t]he security, integrity, and availability of United States telecommunications networks are vital to United States national security and law enforcement interests'').

[2] In adopting rules for foreign carrier entry into the U.S. telecommunications market over two decades ago in its *Foreign Participation Order,* the Commission affirmed that it would consider national security, law enforcement, foreign policy, and trade policy concerns in its public interest review of applications for international section 214 authorizations and submarine cable landing licenses and petitions for declaratory ruling under section 310(b) of the Act. *Rules and Policies on Foreign Participation in the U.S. Telecommunications Market; Market Entry and Regulation of Foreign-Affiliated Entities,* IB Docket Nos. 97–142 and 95–22, Report and Order and Order on Reconsideration, 12 FCC Rcd 23891, 23919, paragraph 63 (1997) (*Foreign Participation Order*), recon. denied, 15 FCC Rcd 18158 (2000).

[3] *Process Reform for Executive Branch Review of Certain FCC Applications and Petitions Involving Foreign Ownership,* IB Docket No. 16–155, Report and Order, 85 FR 76360 (Nov. 27, 2020), 35 FCC Rcd 10927, 10935–38, paragraphs 24 through 28 (2020) (*Executive Branch Review Order*) (setting out which types of applications will generally be referred to the Executive Branch, but noting the Commission has the discretion to refer additional types of applications if we find that the specific circumstances of an application require the input of the Executive Branch); *see also Erratum* (Appendix B—Final Rules), DA 20–1404 (OMD/IB rel. Nov. 27, 2020), 47 CFR 1.40001(a)(1); *Numbering Policies for Modern Communications,* WC Docket No. 13–97; *Telephone Number Requirements for IP-Enabled Service Providers,* WC Docket No. 07–243; *Implementation of TRACED Act Section 6(a)—Knowledge of Customers by Entities with Access to Numbering Resources,* WC Docket No. 20–67; *Process Reform for Executive Branch Review of Certain FCC Applications and Petitions Involving Foreign Ownership,* IB Docket No. 16–155, Further Notice of Proposed Rulemaking, FCC 21 through 94, paragraphs 23 through 29 (2021) (seeking comment on referring certain numbering applications to the

3. Among other requirements of the Executive Order, for applications referred by the Commission, the Committee has 120 days for initial review, plus an additional 90 days for secondary assessment if the Committee determines that the risk to national security or law enforcement interests cannot be mitigated with standard mitigation measures.[4] The Executive Order states that the 120-day initial review period starts when the Chair of the Committee determines that an applicant has provided complete responses to the Standard Questions.

4. In the *Executive Branch Review Order,* the Commission required (1) international section 214 authorization and submarine cable landing license applicants with reportable foreign ownership and (2) petitioners for a foreign ownership ruling under section 310(b) whose applications are not excluded from routine referral, to provide specific information regarding ownership, network operations, and other matters when filing their applications. The Commission adopted the following five categories of information that will be required by rule from applicants, but did not adopt the specific questions: (1) Corporate structure and shareholder information; (2) relationships with foreign entities; (3) financial condition and circumstances; (4) compliance with applicable laws and regulations; and (5) business and operational information, including services to be provided and network infrastructure. The Commission directed the International Bureau (Bureau) to develop, solicit comment on, and make publicly available on the Commission's website the Standard Questions. The Commission also directed the Bureau to maintain and update the Standard Questions, as needed. The rules require applicants to submit responses to the Standard Questions directly to the Committee prior to, or at the same time as, the filing of certain applications with the Commission.[5] As explained in the Executive Branch Review Order, responses to the Standard Questions are only required to be submitted for applications that the Commission refers to the Committee. If an application is not subject to referral, or is subject to one of the exclusion categories in section 1.40001(a)(2), then the applicant need not submit responses to the Standard Questions to the Committee.[6]

5. Under the Commission's rules, the Committee has up to 30 days after the Commission refers an application to send further specifically tailored questions (Tailored Questions) to an applicant in the event that additional information is needed to conduct the national security and law enforcement review of the application. The initial 120-day review time frame begins when the Committee Chair notifies the Commission that it has determined that the responses to the national security and law enforcement questions are complete.[7]

6. *Standard Questions Public Notice.* On December 30, 2020, the Bureau released a public notice seeking comment on six separate sets of Standard Questions and a supplement for the provision of personally identifiable information (PII), all of which are based on questions that the Committee currently provides to applicants after our referral of an application.[8] Specifically, the Bureau invited comment on specific suggested changes to language in the questions contained in the following documents:

- Attachment A—Standard Questions for an International Section 214 Authorization Application.[9] Standard Questions for an international section 214 authorization application filed pursuant to 47 CFR 63.18, including a modification of an existing authorization;
- Attachment B—Standard Questions for an Application for Assignment or Transfer of Control of an International Section 214 Authorization.[10] Standard Questions for an assignment or transfer of control of an international section 214 authorization application filed pursuant to 47 CFR 63.24;
- Attachment C—Standard Questions for a Submarine Cable Landing License Application.[11] Standard Questions for a cable landing license application filed pursuant to 47 CFR 1.767 including a modification of an existing license;
- Attachment D—Standard Questions for an Application for Assignment or Transfer of Control of a Submarine Cable Landing License.[12] Standard

Executive Branch). Pursuant to the new rules, an applicant for an international section 214 authorization or submarine cable license is considered to have ''reportable foreign ownership'' when any foreign owner of the applicant must be disclosed in the application pursuant to section 63.18(h) of the Commission's rules. 47 CFR 63.18(h); *see Erratum,* 47 CFR 1.40001(d).

[4] *See* Executive Order No. 13913, 85 FR at 19645, § 5. During the initial review or secondary assessment of an application, ''if an applicant fails to respond to any additional requests for information after the Chair determines the responses are complete, the Committee may either extend the initial review or secondary assessment period or make a recommendation to the FCC to dismiss the application without prejudice.'' *Id.* at § 5(d).

[5] *Executive Branch Review Order,* 35 FCC Rcd at 10946, paragraphs 48 through 49; *see Erratum,* 47 CFR 1.40003(a), 47 CFR 1.767(i), 1.5001(m), 63.18(p) (effective date delayed indefinitely, *see* 85 FR 76360, Nov. 27, 2020). Currently, and consistent with the national security and law enforcement agencies' practice prior to release of the *Executive Branch Review Order,* the Committee generally initiates review of a referred application by sending the applicant a set of questions seeking further information (that is, after an application has been filed). The applicant provides answers to these questions and any follow-up questions directly to the Committee, without involvement of Commission staff. The Committee uses the information gathered through the questions to conduct its review and determine whether it needs to negotiate a mitigation agreement, which can take the form of a letter of assurances or national security agreement with the applicant to address potential national security or law enforcement issues. *See Executive Branch Review Order,* 35 FCC Rcd at 10929 through 30, paragraph 5.

[6] Since the *Executive Branch Review Order* specifically stated that applicants whose application comes within the categories of applications generally excluded from referral will not be required to submit responses to the Standard Questions, we see no need to make any changes to address MLB's suggestion that an applicant submitting an application that fits within the referral exclusion categories ''should only be required to complete a certification to that effect and be able to forgo responding to the Standard Questions.'' *See Executive Branch Review Order,* 35 FCC Rcd at 10942, paragraph 40, n.107.

[7] 47 CFR 1.40004(e)(1) (''In the event that the Executive Branch has not transmitted the tailored questions to an applicant within thirty (30) days of the Commission's referral of an application, petition, or other filing, the Executive Branch may request additional time by filing a request in the public record established in all applicable Commission file numbers and dockets associated with the application, petition, or other filing. The Commission, in its discretion, may allow an extension or start the Executive Branch's 120–day review clock immediately. If the Commission allows an extension and the Executive Branch does transmit the tailored questions to the applicant, petitioner, or other filer within the authorized extension period, the initial 120–day review period will begin on the date that Executive Branch determines the applicant's, petitioner's, or other filer's responses to be complete. If the Executive Branch does not transmit the tailored questions to the applicant, petitioner, or other filer within the authorized extension period, the Commission, in its discretion, may start the initial 120–day review period.'').

[8] *International Bureau Seeks Comment on Standard Questions for Applicants Whose Applications Will Be Referred to the Executive Branch for Review Due to Foreign Ownership,* IB Docket No. 16–155, Public Notice, 35 FCC Rcd 14906 (IB 2020), 86 FR 12312 (Mar. 3, 2021) (*Standard Questions Public Notice*).

[9] *Standard Questions Public Notice,* Attachment A—Standard Questions for an International Section 214 Authorization Application, 35 FCC Rcd at 14911 (Attachment A/International Section 214).

[10] *Standard Questions Public Notice,* Attachment B—Standard Questions for an Application for an Assignment or Transfer of Control of an International Section 214 Authorization, 35 FCC Rcd at 14924 (Attachment B/International Section 214 Assignment or Transfer).

[11] *Standard Questions Public Notice,* Attachment C—Standard Questions for Submarine Cable Landing License Application, 35 FCC Rcd at 14938 (Attachment C/Submarine Cable Application).

[12] *Standard Questions Public Notice,* Attachment D—Standard Questions for an Application for Assignment or Transfer of Control of a Submarine Cable Landing License, 35 FCC Rcd at 14951

Continued

Questions for an assignment or transfer of control of a cable landing license application filed pursuant to 47 CFR 1.767;

- Attachment E—Standard Questions for a Section 310(b) Petition for Declaratory Ruling Involving a Broadcast Licensee.[13] Standard Questions for a petition for declaratory ruling for foreign ownership in a broadcast licensee above the benchmarks in section 310(b) of the Communications Act (the Act) filed pursuant to 47 CFR 1.5000–1.5004;
- Attachment F—Standard Questions for a Section 310(b) Petition for Declaratory Ruling Involving a Common Carrier Wireless or Common Carrier Earth Station Licensee.[14] Standard Questions for a petition for declaratory ruling for foreign ownership in a common carrier wireless or common carrier earth station licensee above the benchmarks in section 310(b) of the Act filed pursuant to 47 CFR 1.5000–1.5004; and
- Attachment G—Personally Identifiable Information (PII) Supplement.[15] Each set of Standard Questions references a supplement to assist the Committee in identifying PII.

III. Discussion

7. Based on the comments in the record, we adopt the Standard Questions largely as proposed in the *Standard Questions Public Notice,* with some important changes to more narrowly tailor and clarify the instructions and certain questions that will decrease the burdens on applicants. We find that the Standard Questions—with these changes and clarified instructions—will ensure that the Committee has the information it needs to conduct its national security and law enforcement review, while also addressing concerns raised by commenters that certain questions were unclear or overly burdensome.

A. Terminology

8. *Clarification and Improvement of Definitions.* The instructions section in each questionnaire contains definitions of key terms. The term ''Corporate Officer'' is defined in all attachments to encompass ''Senior Officers,'' a separately defined term. As proposed, each set of Standard Questions included a definition of ''Senior Officer,'' but only Attachment E/Broadcast Section 310(b) PDR included the term ''Senior Vice President'' in the definition as an example of a ''Senior Officer.'' MLB states that ''the Standard Questions include separate definitions for 'corporate officer,' 'senior officer,' and 'director,' even though the questions themselves do not distinguish between these categories because they seek the same information from all individuals in these managerial roles.'' With respect to Attachment E/Broadcast Section 310(b) PDR, NAB states that by only including Senior Vice President in this attachment's definition of ''Senior Officer,'' it puts ''an undue and unjustified burden on broadcast petitioners'' because broadcasters assign the title of Senior Vice President to numerous employees, many of whom have no ability to make executive decisions at the company level. NAB recommends that the term ''Senior Officer'' should be limited to those officers who have authority to make executive decisions at the company level.

9. We agree that the definition of ''Senior Officer'' should be modified to be consistent across all the Standard Questions. Specifically, as suggested by NAB, we modify the definition of ''Senior Officer'' to capture any individual with authority to act on behalf of the entity, not by an individual's title. In the Standard Questions, the definition of ''Senior Officer'' is modified to include: ''any individual that has actual or apparent authority to act on behalf of the Entity. Depending upon the circumstances, such individuals could include the Chief Executive Officer, the President, Chief Financial Officer, Chief Information Officer, Senior Vice President, Chief Technical Officer, or Chief Operating Officer.''

10. We reject MLB's suggestion to eliminate separate definitions for ''Remote Access'' and ''Managed Services.'' MLB questions why the terms ''Remote Access'' and ''Managed Services'' are defined separately, ''even though these features are functionally identical for the underlying information sought by the questions.'' MLB suggests condensing definitions in order to ''lessen the likelihood of confusion over terms that can be used interchangeably. . . .'' The Standard Questions define ''Remote Access'' as ''access from a point that is not physically co-located with the Applicant's network facilities, or that is not at a point within the Applicant's network.'' The term ''Managed Services'' is also referred to as ''Enterprise Services'' both of which are defined as ''the provision of a complete, end-to-end communications solution to customers.'' While it is possible that there may be situations in which an applicant's ''Managed Services'' could include ''Remote Access,'' we do not view the terms as synonymous. We therefore retain the separate definitions of these two terms. For consistency with the questionnaires, we correct an omission and add the definitions of ''Remote Access'' and ''Managed Services'' to Attachment F/Common Carrier Wireless or Earth Station PDR.

11. MLB adds that the terms ''Controlling Interest'' and ''Immediate Owner'' are defined but not used in any questions. Contrary to MLB's claim, the term ''Controlling Interest'' is used in Attachment C/Submarine Cable Application, Question 3.[16] However, after review of the other questionnaires, we observed that versions of this question are used in all other attachments without using the term ''Controlling Interest.'' For clarity and consistency, we modify this question in all other attachments to add the term ''Controlling Interest.'' We remove ''Immediate Owner'' from the definitions section of all Standard Questions as that term is not used in any subsequent questions.

12. We also recognize that the Standard Questions used inconsistent terms, and correct these inadvertent errors in each set of Standard Questions. For example, we have revised all questionnaires so that they are consistent in the use of the defined terms ''Ultimate Owner'' and ''Ultimate Parent.'' In addition, questions in the proposed questionnaires inconsistently asked for information about Corporate Officers, Senior Officers, and Directors, or occasionally just Corporate Officers.[17] We modify the questions

(Attachment D/Submarine Cable Assignment or Transfer).

[13] *Standard Questions Public Notice,* Attachment E—Standard Questions for Section 310(b) Petition for Declaratory Ruling Involving a Broadcast Licensee, 35 FCC Rcd at 14965 (Attachment E/Broadcast Section 310(b) PDR).

[14] *Standard Questions Public Notice,* Attachment F—Standard Questions for Section 310(b) Petition for Declaratory Ruling Involving a Common Carrier Wireless or Common Carrier Earth Station Licensee, 35 FCC Rcd at 14979 (Attachment F/Common Carrier Wireless or Earth Station PDR).

[15] *Standard Questions Public Notice,* Attachment G—Personally Identifiable Information (PII) Supplement, 35 FCC Rcd at 14993 (Attachment G/PII).

[16] Attachment C/Submarine Cable Application, Question 3 states: ''Identify each Individual or Entity included as part of the submarine cable system Applicant, specifically identifying any foreign Entities or Foreign Government-controlled Entities, including the Ultimate Parent/Owner of the Applicant and any other Individuals/Entities holding an Ownership Interest in the chain of ownership, including a *Controlling Interest* in the Applicant.''

[17] For example, *compare* Attachment A/International Section 214, Question 13, 35 FCC Rcd at 14916 (''Has the Applicant, *any investor with an Ownership Interest in the Applicant, any of its Corporate Officers,* or any associated foreign entities . . . ''), *with* Attachment B/International Section 214 Assignment or Transfer, Question 13,

such that each time a question asks for Corporate Officer information, the question will include Senior Officers and Directors.

13. *Five Percent (5%) Ownership Interest.* We reject comments that request we modify the definition of ''Ownership Interest.'' Each set of Standard Questions defines an Owner as ''an Individual or Entity that holds an Ownership Interest in the Applicant/Licensee'' and an Ownership Interest in turn is defined as ''a 5% or greater equity (non-voting) and/or voting interest, whether directly or indirectly held, or a Controlling Interest in the Applicant, and includes the ownership in the Ultimate Parent/Owner of the Applicant and any other Entity(ies) in the chain of ownership. . . .'' Subsequent questions in each questionnaire seek information, including PII, about applicant owners and entities with ownership interests (*i.e.,* the 5% or greater interest holders).

14. MLB, NAB, and USTelecom argue that the Ownership Interest definition is too expansive and requires applicants to submit information for owners that have no influence or control over the applicant, including as insulated interest holders. MLB argues that ''[s]ome of the information, including PII, requested from intermediate or non-controlling investors should not be required if the applicant can certify that the intermediate investor is truly passive and has no ability to control or influence the operations of licensee, as is the case with limited partners in a private equity fund.'' MLB also believes that ''[c]ompiling and reviewing this information is a tedious endeavor that has negligible bearing on the fundamental questions of foreign ownership, control, and influence analyzed by the Committee.'' USTelecom urges the Commission to ''revise the Standard Questions to apply only to the Commission's standard 10% ownership interest because the 5% threshold would sweep in far too many owners, with little influence per owner, and lead to unnecessary complications, delays and burdens in responding to the standard questions,'' and adds that ''[l]arge, publicly traded companies may not have the level of visibility into entities owning 5% stakes that would enable them to complete the questions as proposed.'' C&B argues for using a 20% ownership threshold or the ability to appoint Board members as the basis for defining Relevant Parties. NAB contends that a publicly traded company should be required to provide only publicly available information about its shareholders. MLB states that the questions should be revised to clarify that PII is sought from only those individuals or entities in the ownership chain with control over the applicant and who participate in ''operations or decision-making related to the applicant or the licensee.''

15. The Committee staff, in response, advises that a 5% threshold is appropriate because in some instances a less-than-ten percent foreign ownership interest—or a collection of such interests—may pose a national security or law enforcement risk. The Committee staff adds that when ownership is widely held, five percent can be a significant interest and is consistent with requirements imposed by other agencies such as the Securities and Exchange Commission, which requires disclosure beyond that threshold. The Committee staff states that a group of foreign entities or persons, each owning nine percent and working together, could easily reach a controlling interest in a company without having to disclose any of their interests to the Committee for certain FCC application types.[18] In addition, the Committee staff states that retaining the current threshold is particularly important with respect to those foreign entities who have been identified by the Commission and the Executive Branch as posing a national security threat.[19] Finally, the Committee staff adds that Commission's ownership rules serve their own purpose—for the Commission's analysis and for its referral threshold—while the Committee reviews the applications for a different purpose, a comprehensive national security and law enforcement analysis as required under Executive Order 13913.

16. While we recognize that requiring the submission of 5% ownership information to the Committee is a lower threshold for information than the 10% ownership threshold generally set out in our rules, we agree with the Committee staff and reject commenters' requests to modify the submission of 5% or greater ownership information or otherwise change the definition to exclude insulated interests. As indicated by the Committee staff, national security and law enforcement analysis is separate and apart from the foreign ownership analysis the Commission conducts under its statutory authority.[20] We also take into account the Committee's expertise in assessing national security and law enforcement concerns and the importance of collecting this information to assess any national security or law enforcement risks under Executive Order 13913. Additionally, consistent with the goal of this proceeding to streamline and expedite consideration of these applications, we believe that a 5% or greater bright line rule avoids the kinds of complex case-by-case inquiries into, for example, the adequacy of insulation criteria that the Commission conducts for section 310(b) reviews. Given our experience, this could otherwise result in potentially extensive Committee delays and may circumvent the Commission's timeframes and streamlined processing we put in place in the *Executive Branch Review Order.* Finally, in our experience, this information has been collected in the past, and we expect applicants for Commission authorizations and licenses to be in a position to exercise reasonable diligence in securing important information from their investors required by the Commission or the Committee.

17. *Definition of Relevant Parties.* We agree that including the current owners of an international section 214 authorization holder or cable landing licensee within the definition of ''Relevant Parties'' goes beyond the

35 FCC Rcd at 14929 (''Have any of the Relevant Parties *or any of their Corporate Officers, Senior Officers, Directors,* or any associated foreign entities . . . '') (emphases added).

[18] FCC Staff/Committee Staff Sept. 7, 2021 *Ex Parte* Letter at 2, n.6 (citing 31 CFR 800.208(b) (2021) (noting for Committee on Foreign Investment in the United States (CFIUS) reviews that in ''examining questions of control in situations where more than one foreign person has an ownership interest in an entity, consideration will be given to factors such as whether the foreign persons are related or have formal or informal arrangements to act in concert''); 31 CFR 800.256(d) (2021) (when determining voting interests for CFIUS critical technology mandatory declarations, providing that the individual holdings of multiple foreign persons who are related or have arrangements to act in concert may be aggregated)).

[19] *Id.* at 2–3, n.7 (citing FCC, List of Equipment and Services Covered by Section 2 of the Secure Networks Act, Mar. 12, 2021, *https://www.fcc.gov/supplychain/coveredlist*).

[20] However, the Commission has employed a 5% ownership standard in other contexts. For example, section 1.767(h)(2) requires all entities owning or controlling 5% or greater interest in a submarine cable system (and using U.S. points of the cable system) to be applicants for, and licensees on, a cable landing license. *See* 47 CFR 1.767(h)(2). In addition, the Commission uses a 5% standard in the foreign ownership review context. *See* 47 CFR 1.5001(i); *Review of Foreign Ownership Policies for Broadcast, Common Carrier and Aeronautical Radio Licensees under Section 310(b)(4) of the Communications Act of 1934, as Amended,* GN Docket 15–236, Report and Order, 31 FCC Rcd 11272, 11284 through 85 & 11293 through 97, paragraphs 22–24 & 44–52 (2016) (*2016 Foreign Ownership Order*), *pet. for recon. dismissed,* 32 FCC Rcd 4780 (2017); *Review of Foreign Ownership Policies for Common Carrier and Aeronautical Radio Licensees Under Section 310(b)(4) of the Communications Act of 1934, as Amended,* IB Docket 11–133, Second Report and Order, 28 FCC Rcd 5741, 5767–72, paragraphs 47–54 (2013) (*2013 Foreign Ownership Second Report and Order*).

scope of the Committee's current triage questions and serves no additional purpose. Attachment B/International Section 214 Assignment or Transfer and Attachment D/Submarine Cable Assignment or Transfer define ''Relevant Parties'' and use the term in a manner that would require information from both the current owners and proposed owners of authorization or license holders. Question 1 in these questionnaires seeks broad information, such as ownership and PII about all Relevant Parties. Several commenters urge the Commission to clarify that the disclosures in these questions do not apply to transferors or assignors. CTIA indicates that the current triage questions only request information concerning the ''Prospective Owner(s)/Controller(s) and Prospective Licensee(s).''

18. We amend Question 1 of the transfer and assignment questionnaires in Attachments B/International Section 214 Assignment or Transfer and D/Submarine Cable Assignment or Transfer. The Committee's national security or law enforcement review is primarily focused on the buyer or new entity obtaining the authorization or license. We therefore remove transferors and assignors (the sellers) from the definition of ''Relevant Parties.'' Accordingly, the term ''Relevant Parties'' will only include ''the Proposed Authorization Holder(s) of an international section 214 authorization or the Proposed Licensee(s) of a cable landing license, and any individual or entity with an ownership interest in the Proposed Authorization Holder(s) or Proposed Licensee(s).'' This change focuses the Standard Questions on the appropriate parties and decreases burdens on the applicants.

19. *Domestic Communications Infrastructure.* We reject USTelecom's request to remove Network Operations Center (NOC) facilities from the definition of ''Domestic Communications Infrastructure.'' USTelecom notes that Domestic Communications Infrastructure includes any NOC facilities, and argues this ''is inconsistent with the many cases where the NOC is placed outside the U.S. (and thus not 'domestic.')[.]'' USTelecom ''urge[s] the Commission to remove NOC facilities from the definition of 'Domestic Communications Infrastructure' and address [sic] as a separate item.'' We disagree. Although a NOC can be located outside of the United States, a foreign NOC can control an entity's Domestic Communications Infrastructure, and is therefore appropriately included within this definition. Information concerning a NOC located outside the United States, including information regarding the individuals and entities with access to that NOC, is critical information to assess the national security and law enforcement concerns of the foreign NOC. As a result, we reject USTelecom's suggestion to remove NOC facilities located outside of the United States from the definition of ''Domestic Communications Infrastructure,'' or to address NOC facilities as a separate item. Accordingly, we retain the current definition.

B. Protection of Submitted Information

20. We concur with MLB that all information submitted in response to the Standard Questions should be treated as business confidential and protected from disclosure and change the instructions accordingly. As proposed, the Standard Questions stated that applicants must ''[s]pecifically identify answers or documents for which a claim of privilege or confidentiality is asserted based on the information containing trade secrets or commercial or financial information.'' MLB notes that ''all of the information submitted by applicants to the Committee should be automatically deemed as business confidential information and properly exempt from disclosure under FOIA and Section 8 of Executive Order 13913.'' Based on our experience and understanding of the responses to such questions from the Executive Branch agencies in the past, we agree that most of the information supplied in response to the Standard Questions is business confidential as it is ''extremely sensitive and proprietary.'' Moreover, no commenter opposed MLB's suggestion. Most importantly, however, the Committee staff—to whom the information will be submitted—agrees that all responses to the Standard Questions submitted to the Committee will be treated as business confidential and the applicant(s) should not have to specifically identify information for such treatment.[21] Consequently, we modify the instructions in all questionnaires to provide that all of the submitted information will be treated as business confidential and that applicants will not have to specifically identify information for such treatment.

21. We decline, however, to take any specific action with regard to MLB's request for ''heightened protection'' of PII and restrictions on sharing it within Committee agencies. The Privacy Act already requires federal agencies to protect PII[22] and Executive Order 13913 explicitly addresses this issue, thereby ensuring the Committee protects this information. In particular, Section 8 of the Executive Order states that ''[i]nformation submitted to the Committee . . . shall not be disclosed beyond Committee Member entities and Committee Advisor entities, except as appropriate and consistent with procedures governing the handling of classified or otherwise privileged or protected information . . . .'' Therefore, we do not believe any additional Commission action is necessary to address this concern.

C. Filings Involving Multiple Applicants

22. Based on comments in the record, we decline to revise and reorganize the Standard Questions with regard to filings involving multiple applicants (joint applicants); however, we clarify and improve the instructions on how applicants can submit joint filings confidentially. USTelecom urges the Commission to make the questionnaires clearer so that questions requiring joint responses can be separated from questions where applicants must respond individually. CTIA asks that the questions be organized so when there are multiple applicants they can clearly see which questions can be answered jointly and which can be separated so sensitive information is not shared. USTelecom requests removal of questions that ask for a list of all government customers and descriptions of services. We recognize that joint applicants have a legitimate interest in preventing the sharing of certain information and identifying which questions an applicant is responsible for answering. Consequently, we will

[21] Information submitted to the Committee may not be shared except under the terms of Executive Order No. 13913.

[22] The Privacy Act generally applies to U.S. citizens and legal permanent residents; however, in 2016 Congress enacted the Judicial Redress Act of 2015, 5 U.S.C. 552a note, which extends the right to pursue certain civil remedies under the Privacy Act to citizens of designated countries or regional economic organizations. Claims under the Judicial Redress Act are limited to those involving ''covered records,'' defined as a record that is transferred—(A) by a public authority of, or private entity within, a country or regional economic organization, or member country of such organization, which at the time the record is transferred is a covered country; and (B) to ''a designated Federal agency or component'' for purposes of preventing, investigating, detecting, or prosecuting criminal offenses. *Id.* § 2(h)(4). The Attorney General is responsible for designating covered countries or regional economic organizations, as well as federal agencies and components for purposes of the Judicial Redress Act. *Id.* § 2(d), (e), (h)(2), and (h)(5). A list of covered countries is available at 84 FR 3493 (Feb. 12, 2019). A list of designated federal agencies and components is available at 82 FR 7860 (Jan. 23, 2017) and includes members of the Committee.

clarify the instructions in the Standard Questions on how joint applicants can file confidentially with the Committee, but we will not reorganize or remove certain questions. This approach is consistent with the instructions in the proposed questionnaires, which state, ''[i]f there are multiple applicants, each applicant should also clearly mark any answers or documents that contain sensitive information that should not be disclosed to the other applicants.''

23. When there are multiple applicants for a single application (such as consortium applicants for a single submarine cable landing license), each applicant should (1) provide a clear statement as to how they have submitted their responses and (2) identify which applicants have filed jointly and which applicants can view each other's business confidential information.[23] For instance, Committee staff recommend that applicants clearly identify, in headings, the group of applicants that have filed together, along with a case name and FCC file number, and suggest that applicants use an applicant-specific identification system, such as Bates Numbering, along with the identification of the FCC file number and case/transaction name(s).[24] We believe that this approach would alert the Committee staff of which information should not be shared and should prevent disclosure of customer lists between joint applicants. We direct the International Bureau to provide, on an as-needed basis, updated instructions on the Commission's website regarding coordination of multiple applicant responses and other issues based on feedback from interested parties.

D. Cross-Referencing Previously Filed Materials

24. We reject commenters' request that applicants generally be allowed to cite to previously filed information in their responses to the Standard Questions rather than resubmit information that was previously filed with the Commission and that remains unchanged. We recognize that allowing applicants to cross-reference to previously filed materials within their responses to questionnaires may ease certain burdens on the applicants. We believe, however, that permitting cross references to previously filed materials may delay Committee staff review of applicants' submissions because Committee staff would then have to locate materials that were previously filed with respect to a different application. Accordingly, we require applicants to provide full and complete responses to the Standard Questions in a complete, self-contained document (or documents). This approach is consistent with Commission staff practice for applications, and it benefits applicants by focusing Committee staff resources on the review of applicants' responses to the Standard Questions. We will, however, allow internal cross-referencing of responses within a single document to streamline the process for applicants. For example, if an applicant provided a response to Question 15, and the applicant's response to Question 27 contains the same information, the applicant may refer back to its earlier response.

25. We also reject NAB's specific request that, for petitioners that have previously been granted a declaratory ruling approving foreign investment, the petitioner be permitted to respond to a streamlined questionnaire that only seeks information on that new investor, rather than having to complete the questionnaire with respect to all Relevant Parties. We decline this request and note that we continue to require petitioners to provide a full and complete Petition for Declaratory Ruling to the Commission, and we similarly require petitioners to submit full and complete responses to the Standard Questions to the Committee. The Committee needs information regarding all owners to conduct its review, including updated information, just as the Commission requires a complete petition with information on all owners, not just the new investors, when reviewing the petition. Consequently, the responses must include the requested information with respect to all Relevant Parties as defined by the Questionnaires.

E. Relationships With Foreign Individuals or Entities

26. *Retain ''Prior Relationship'' in Attachment E/Broadcast Section 310(b) PDR and Remove it from Attachment F/Common Carrier Wireless or Earth Station PDR.* We reject NAB's recommendation ''to eliminate prior relationships'' from Question 3 in Attachment E/Broadcast Section 310(b) PDR, or to ''establish a defined 'look-back' period of six months prior to the date a Section 310(b) petition is filed.'' We will retain the request for information concerning broadcast petitioners' prior relationships, with no time limit or ''defined look-back period,'' as Committee staff advise that this information is necessary for staff's national security and law enforcement review of broadcast applications.[25] Specifically, Committee staff states that this information may identify situations where past agency relationships with foreign principals, such as funding or employment arrangements, may be relevant to an assessment of continuing foreign influence over broadcast content. We note that the legislative history of Section 310(b) reflects particular concern regarding foreign influence over broadcast licensees. However, Commission staff unintentionally added language regarding prior relationships to Attachment F, Question 3. Because Committee staff expresses a particular interest in prior foreign relationships only with regard to broadcasters, we remove the prior relationship language from Attachment F.

27. *Modify and Clarify ''Planned'' Relationships in Attachments A–F.* We agree with commenters that the question asking if applicants have ''planned'' relationships with certain foreign individuals and entities can be improved, and we clarify this in each set of Standard Questions. MLB argues that what constitutes a ''relationship'' outside of funding or a contract is unclear and argues that there should be a timeframe associated with the question. C&B proposes that the question should be limited to relationships that confer foreign government influence over the applicant's operations. C&B also asserts that the question should exclude subscribers to the applicant's service and foreign employees of the applicant who are covered in another question.

28. We clarify that ''planned relationships'' are ''current relationships or those reasonably anticipated by negotiations or that are identified under current business plans'' and clarify that this includes any situations in which contracts have been signed or where the parties are already in negotiations. We decline to place a time limit on this question, as this question should capture any reasonably anticipated future foreign relationships regardless of the timeframe. We find that this change will clarify for applicants the scope of reportable foreign relationships and will improve and facilitate Committee review of applicants' responses to the Standard Questions.

[23] Applicants should provide this information in a cover letter or email (if responses are submitted electronically).

[24] The Committee staff indicated that if co-applicants decide to submit separate Standard Question responses by email, co-applicants should submit them on the same day, so the Committee may easily assess if all expected Standard Question responses for an application have been submitted.

[25] Committee staff also indicated that this information helps the Committee evaluate foreign influence concerns related to the Foreign Agents Registration Act (FARA), 22 U.S.C. 611 *et seq.,* that are specific to broadcasters.

29. *Clarify Foreign Relationships Do Not Include Customers.* As requested by C&B, we clarify that existing or planned relationships/partnerships, and prior relationships/partnerships in the case of broadcast applicants, and funding or service contracts, do not include foreign subscribers to an applicant's retail services. We also clarify that, for the purposes of this question, these relationships do not include foreign employees who are identified in other questions, such as Senior Officers and Directors, and Non-U.S. Individuals with physical access to certain facilities, records, networks, or electronic interfaces.[26] We decline, however, C&B's request to limit the question to only relationships with foreign governments or foreign government owned entities, as foreign individuals and entities also may raise national security and law enforcement concerns.

30. *Limit the Use of ''Foreign Party'' in Attachment E/Broadcast Section 310(b) PDR.* As proposed, the Standard Questions ask if the Applicant or ''Relevant Parties'' have ''existing (or planned) relationships'' with any foreign Individuals, foreign companies, Foreign Governments, and/or any Foreign Government-controlled companies or entities but only Attachment E/Broadcast Section 310(b) PDR ''contains an expansive definition of 'Foreign Party' in Question 3 and incorporates this term in numerous subsequent questions.'' NAB argues that the inclusion of Foreign Party in the questions requires broadcasters to gather extensive information on each Foreign Party even if that party has a limited relationship with the applicant, ''such as a one-time agreement for access to a location for the production of a single program.'' NAB expresses concern about the burden imposed on broadcaster petitioners by the expanded scope of the Standard Questions.

31. We recognize that the broadcaster questionnaire alone seeks detailed information about relationships with Foreign Parties. Committee staff explain that questions 13–17 in Attachment E/Broadcast Section 310(b) PDR are designed to identify situations in which the applicant may be acting as an agent for a foreign principal and are directly related to Committee concerns under FARA. As recommended by Committee staff, we retain the Foreign Parties information requirement in questions 13–17. However, since the Committee staff do not identify the need for such information in connection with the remaining questions, we conclude the burden of producing Foreign Party information in other questions asked in Attachment E/Broadcast Section 310(b) PDR outweighs the benefit of this information to the Committee. Therefore, we remove the reference to ''Foreign Party'' in certain questions of Attachment E/Broadcast Section 310(b) PDR.[27]

F. Background Information Regarding the Applicant(s)

32. Based on the comments in the record, we modify the Standard Questions to clarify the type of background information applicants should provide. Currently, each set of proposed Standard Questions includes several questions regarding the applicant's background and asks if ''the Applicant, any Corporate Officers, Senior Officers, Directors, or any Individual/Entity with an Ownership Interest in the Applicant'' have ''ever been involved or associated with'' a previous application to the Commission or a previous filing with the Committee on Foreign Investment in the United States (CFIUS), or if these individuals or entities have ''ever been convicted of any felony'' or ''been subject to any criminal, administrative, or civil penalties for imposed for violating the regulations of'' a number of government agencies.

33. With respect to prior Commission or CFIUS filings, USTelecom is concerned that the phrase ''involved or associated with'' could include ''any level of activity associated with a filing from corporate officer responsibilities to more mechanical involvement with accomplishing a filing, which seems far outside the scope of concern.'' To clarify and reduce burdens on the applicants, we amend this language to specify that an ''involved'' or ''associated'' Individual or Entity was either the Applicant in a prior Commission or CFIUS filing or listed as an owner in such a prior filing. Modifying the questionnaires accordingly would focus the inquiry to the parties most relevant to any prior Commission or CFIUS filings.

34. We decline USTelecom's recommendation that the Commission provide a two-year time limit for questions concerning previous filings with the Commission or CFIUS, or that the Commission eliminate this question with respect to prior Commission applications. We will not impose any time limit for CFIUS filings as Committee staff state that all information regarding prior CFIUS filings would be relevant to their national security and law enforcement review. We find, however, that we can adopt a ten-year time boundary regarding prior Commission filings, which the Committee indicated would be acceptable. Although we agree that imposing a time limit regarding previous Commission filings is appropriate, we find that USTelecom's proposed two-year limit on such filings is too short and would likely exclude many relevant filings and information. The ten-year time limit will reduce the burdens on the applicant while providing the Committee sufficient relevant information concerning recent Commission filings it requires for its review.

35. We are unpersuaded by USTelecom's argument that the questions regarding criminal, administrative, or civil penalties are ''incredibly broad . . . and could be extremely burdensome to even attempt to answer,'' particularly taking into consideration the age of some communications companies. We therefore reject USTelecom's recommendation that the Commission set parameters on this question ''by limiting the ownership interest threshold by 10% and creating a definitive timeframe of interest, not to exceed two years.'' As we explained above, we are not increasing the numerical ownership threshold from 5% or greater to 10% or greater. As to the time frame, we do not believe it would create an undue burden for applicants to report as to such serious actions taken against them or their officers, directors, or attributable owners, as we would expect them to have records of such actions.[28] Additionally, Committee staff state that no time limits can be placed on the reporting period for this inquiry due to the serious nature of the underlying question, as past felonies or regulatory violations may be indicative of possible future behavior, or may give the Committee staff insight on where to focus any additional questions for the applicant.[29] We agree with the

[26] In their responses to the foreign relationship questions, applicants may want to consider cross-referencing their response to these other foreign employee questions to aid the Committee in its review.

[27] Committee staff did not object to the deletion of ''Foreign Party'' from all other questions in this questionnaire. Specifically, we remove the reference to ''Foreign Party'' from questions 12, 18 through 21, 26, 31 through 34 in Attachment E/Broadcast Section 310(b) PDR.

[28] To the extent that an applicant is unable to provide a complete answer as to relevant criminal, administrative, or civil penalties, as discussed below, it should explain this in its submission to the Committee.

[29] The Committee staff added that placing a time limit from the date of conviction would allow for situations in which an applicant would not be required to disclose a serious offense.

Committee staff's views on this matter and decline to accept USTelecom's recommendations.

G. Provision of Personally Identifiable Information (PII) by Applicants

36. We modify the Standard Questions in Attachment E/Broadcast Section 310(b) PDR to clarify the set of individuals for whom broadcasters must provide PII, as requested by NAB. Each set of Standard Questions requires applicants to provide PII for several categories of individuals involved in the ownership and management of the applicant as well as non-U.S. individuals with access to the applicant's facilities. This PII will be required to be submitted in a separate attachment, Attachment G. This PII is required so that the Committee can conduct investigations of individuals involved in the ownership and operations of the applicant and those non-U.S. individuals with access to facilities.[30] NAB contends that Question 19 in Attachment E/Broadcast Section 310(b) PDR, which seeks information concerning ''any non-U.S. Individual, owners, or management, including independent or third-party Individuals/Entities of the Relevant Party or Foreign Party'' that has access to ''physical facilities or equipment under the Relevant Party's or Foreign Party's control,'' is ''overly broad, unduly burdensome and intrusive.'' NAB argues that Question 19 ''appears to sweep in virtually any non-U.S. employee, all of whom presumably have access to 'physical facilities' of the Relevant Parties. . . .'' NAB suggests that we modify Question 19 ''to describe specific types of facilities or equipment that would give rise to potential Committee concerns and to focus on U.S. facilities only.''

37. We agree with NAB that, as proposed, Question 19 is overly inclusive and could be viewed as applying to any non-U.S. employee with access to any facility of the broadcaster, including production facilities located outside of the United States. Additionally, Committee staff has clarified that it is only concerned with facilities outside of the United States that store, process, or provide access to U.S. person data (including data on current, past, and potential customers) or that are used to broadcast into the United States. Based on this, we believe that narrowing the scope of this question is therefore warranted. Accordingly, we clarify that broadcasters must provide the information listed in Question 19 for non-U.S. Individuals with access to (1) all facilities and equipment in the United States, (2) facilities outside the United States that are used to broadcast into the United States, and (3) facilities both inside and outside the United States that store, process, or provide access to U.S. person data (including data on current, past, and potential U.S. customers).

38. We decline USTelecom's request that we change the PII reporting requirements for individuals with access to submarine cable facilities. USTelecom argues that Question 34 in Attachment C—which seeks information on Non-U.S. Individuals' access to submarine cable facilities, equipment, communications content, and customer records, among other things, including PII concerning those Non-U.S. Individuals with such access—''should be confined to the Domestic Communications Infrastructure (except for the NOC), as it has been in practice in past proceedings.'' USTelecom also argues that because this question ''applies to specific individuals, this will be a constantly changing list given normal personnel activity over time'' and ''in certain foreign jurisdictions, some of the required information may not be legally obtainable from individuals or may be very difficult to provide to the U.S government given the country's own limitations and privacy laws.'' USTelecom urges the Commission to eliminate Question 34 or revise the question to ask generally if non-U.S. individuals will have such access ''without any requirement to identify specific individuals.''

39. We reject USTelecom's suggestion. The Committee staff oppose the modification of this question, stating that submarine cables are U.S. critical infrastructure and that applicants should provide PII and other details about non-U.S. individuals with access to either U.S. or foreign facilities (*e.g.,* cable landing stations, Network Operations Centers, etc.) related to the submarine cable as it is necessary for the Committee's national security and law enforcement analysis. We agree. We also agree with Committee staff that submarine cable operators should have in place access control policies for these critical facilities that will enable them to provide details concerning the individuals with access to their facilities, whether they are located in the United States or in a foreign country. With regard to USTelecom's contention that it would be difficult to answer this question given the changes in personnel activity and limitations imposed by foreign laws, the Standard Questions can only be answered with information known at the time of submission. If there are future changes, we anticipate that a mitigation agreement between the applicant and the Committee could address how the applicant should update the Committee with any necessary information.[31]

40. We agree with USTelecom that questions that require the applicant to identify an Individual to be the Licensee's authorized law enforcement point of contact should be limited to the U.S. cable landing party. This is consistent with the Commission's statement in the *Executive Branch Review Order* that for consortium cables, the consortium must ''identify one U.S. citizen or lawful permanent U.S. resident as a point of contact for lawful requests and an agent for legal service of process for each licensee of the consortium cable.''

H. Information About the Applicant's Services

1. Critical Infrastructure

41. Based on C&B's request, we will update the list of U.S. critical infrastructure sectors outlined in the Standard Questions to track Presidential Policy Directive 21 (PPD–21). Each set of Standard Questions (excluding Attachment E/Broadcast Section 310(b) PDR) asks if the applicant will serve any sectors of U.S. critical infrastructure and includes a checklist of various sectors. C&B notes that ''the listed sectors do not align with the current list of critical infrastructure sectors identified under Presidential Policy Directive 21 (PPD–21).'' PPD–21 establishes a national policy on critical infrastructure security and resilience, and identifies 16 critical infrastructure sectors, not all of which overlap with the sectors listed in the proposed Standard Questions' checklist. Upon closer review and consultation with Committee staff, we agree with C&B that the list of critical infrastructure sectors provided in the Standard Questions should be revised to be consistent with PPD–21. Accordingly, we have modified the Standard Questions to reflect the list of sectors contained in PPD–21.

42. We agree with C&B that additional clarity is needed with regards to the meaning of the word ''serve'' in questions pertaining to serving sectors of U.S. critical infrastructure. C&B

[30] Pursuant to the process set out in the Executive Order, for each application reviewed by the Committee, the Office of the Director of National Intelligence shall produce a written assessment of any threat to national security interests of the United States posed by granting the application or maintaining the license.

[31] Committee staff also state that if an applicant is unable to provide this information, it can explain such limitations in its response.

contends that the intent of Question 36 in Attachment A/International Section 214, which asks whether ''the Applicant [will] serve any sectors of U.S. critical infrastructure,'' is unclear. C&B notes that this question could be interpreted in different ways and asks the Commission to provide clarity as to the meaning of ''serve'' to ''appropriately narrow the scope of the question.'' We modify the question to be consistent between the Attachments to use the phrase ''provide services to,'' which includes situations where the applicant provides service to, has customers in, or participates in the market in certain sectors of U.S. critical infrastructure. We also note that if applicants are unsure whether or to what extent they believe they are providing service to a critical infrastructure sector, applicants should provide an explanatory note in their answers to the Standard Questions explaining to the Committee why they responded in a particular way.

2. Proposed Services Checklist

43. We will not modify the list of services in the Reference Question section in Attachments A/International Section 214, B/International Section 214 Assignment or Transfer, and F/Common Carrier Wireless or Earth Station PDR, but will rename this list to clarify the information targeted by this question. Attachments A/International Section 214, B/International Section 214 Assignment or Transfer, and F/Common Carrier Wireless or Earth Station PDR as proposed included an ''Applicant Services Portfolio Checklist and Reference Questions'' section designed to gather detailed information regarding the types of telecommunication services applicants intend to provide. Applicants indicate with a checkmark the types of services and technologies they intend to offer. C&B contends that some of the named proposed services are not services (such as TDM) or are too generic (such as ''video'' or ''email''). C&B therefore suggests we revise the proposed services checklist ''to add specificity and eliminate redundancies, or remove it altogether.'' Although we agree with C&B that not all items included on this list are strictly services, we find that the list will be useful to the Committee, which has a specific interest in knowing if the applicant will provide any of the items in the checklist, including certain technologies and types of network infrastructure. To address any confusion as to what the list includes, we will rename the list from ''Proposed Services'' to ''Proposed Services/Technologies/Network Infrastructure.'' We do not believe applicants will be unduly burdened in determining how to fill out the checklist, and, as we have discussed, we encourage applicants to explain to the Committee how they interpreted a particular question in providing their response.

3. Reference Questions

44. We do not agree that the ''Reference Questions'' and Questions 35 in Attachments A/International Section 214 and B/International Section 214 Assignment or Transfer and 38 in Attachment F/Common Carrier Wireless or Earth Station PDR are duplicative, but we provide clarification regarding the information sought by each question. MLB believes that the ''Reference Questions'' are duplicative of an earlier question that seeks information concerning the manner in which applicants will deliver services to their customers. Specifically, MLB argues that Reference Question 1 in Attachments A/International Section 214 and B/International Section 214 Assignment or Transfer, as proposed, is nearly the same as Question 35 regarding delivery of services. MLB also asserts that the Reference Questions ask for network infrastructure information that would have already been provided in response to Question 32(b) in Section V. MLB advises omitting the Reference Questions altogether, suggesting they are redundant and ''needlessly expend the resources of applicants and the Committee.'' Although Question 35 and Reference Question 1 appear to be similar, the Committee indicate that they are in fact meant to seek different, albeit related, information. Importantly, Committee staff states that Question 35 is intended to obtain a general description of the services to be provided, whereas the Reference Questions are intended to obtain finer technical detail on the way services are or will be provided with specific reference to each service selected in the services checklist table. Similarly, we find that Question 32(b) is intended to obtain a more general description of the Applicant's network, whereas the Reference Questions are structured to obtain specific technical details, such as equipment models and software update plans. We give deference to the Committee on their need for this information to inform their national security and law enforcement review. Accordingly, we will retain these separate questions but revise Question 35 (now Question 36 in Attachment A/International Section 214) to indicate that this question seeks a general description of the manner in which services will be delivered to customers. To the extent that an applicant believes that its responses to questions are the same, it can cross-reference its responses as directed in the Standard Questions' instructions.

4. Use of Interconnecting Carriers and Peering Relationships

45. We decline to make any changes to questions concerning interconnecting carriers or peering relationships. Questions 33 in Attachment B/International Section 214 Assignment or Transfer, 41 in Attachment C/Submarine Cable Application, and 42 in Attachment D/Submarine Cable Assignment or Transfer ask whether the Proposed Authorization Holder(s) or Applicant(s) ''use interconnecting carriers and/or peering relationships,'' and ask the Applicants to provide details and list the carriers with whom they have these relationships. USTelecom argues that these questions are ''misguided'' because ''it is unclear as to how this information is useful to the determination of a submarine cable's public interest, nor does it evince a clear understanding of what 'interconnecting carriers' do or what 'peering relationships' mean in this case.'' USTelecom contends that ''[t]his is particularly true because [these questions] seek[ ] this information only from the Applicants, not anyone who will purchase the capacity on the system, which for some cables will represent the bulk, if not all, of the traffic carried.'' These types of relationships are relevant to the Committee's national security and law enforcement analysis of the application, even if they do not reach everyone who may use the submarine cable. With regard to CTIA's argument that ''[r]ather than require a comprehensive, detailed list of peering and interconnection relationships . . . the question should allow sufficient flexibility for parties to determine the level of detail they are able and expected to provide,'' we believe that the Standard Questions do provide applicants with flexibility in how they choose to describe peering relationships, and thus do not need to be changed or eliminated.

I. National Security/Law Enforcement Questions

46. We do not make any changes to the questions related to an applicant's national security and law enforcement obligations. Question 19 in Attachments A/International Section 214 and B/International Section 214 Assignment or Transfer asks whether the applicant, ''if required by law, regulation, or license condition,'' would report certain named incidents immediately upon discovery. USTelecom asks what the effect of a

''no'' answer is to Question 19, expressing concern that the question ''appears to be an attempt to compel Applicants to provide information they would not otherwise be legally required to provide'' and if so, USTelecom says it should be made an explicit obligation through other regulatory means. We do not share USTelecom's concerns regarding this question. If Committee staff has any concerns with an answer of ''no,'' they may decide to follow up with Tailored Questions.

47. USTelecom also has concerns with the national security implications of certain questions in the section 214 and submarine cable questionnaires (Attachments A–D). Question 21 in Attachments A/International Section 214 and B/International Section 214 Assignment or Transfer asks if any non-U.S. individuals will have access to any of the applicant's facilities, equipment, customer records, and network control features, among other things, and if so, to provide their identity and certain PII. Question 23 in these questionnaires asks for information about encryption technologies that have been or will be installed in the applicant's network. USTelecom believes that together, Questions 21 and 23 require disclosure of too much network security plan information, and this disclosure could amount to a security risk in and of itself. We find that USTelecom's concern about over-disclosure of network security plans through responses to Questions 21 and 23 is misplaced and we make no changes to these questions. The disclosure in this case is solely to the U.S. government agencies most involved in network security issues and for the purposes of assessing risk to U.S. national security and law enforcement interests. To the extent that an applicant has concerns about co-applicants seeing its responses to Questions 21 and 23, it can mark those responses as sensitive and ask that they not be shared with co-applicants.

48. USTelecom recommends ''greater clarity surrounding the security expectations of applicants,'' citing Question 33 in Attachment C/Submarine Cable Application, which asks ''[w]hat provision will be made to monitor suspicious activity occurring over the paths of the cables,'' as an example. USTelecom believes that the details regarding ''what an applicant can and cannot monitor from a practical standpoint can vary widely depending on the arrangement and technical architecture of the submarine cable equipment,'' and requests that the question be modified to reflect these different arrangements. We understand USTelecom's concern that Question 33 in Attachment C, as written, may not capture the variations in different cable systems' monitoring systems. The Standard Questions must be high-level to a certain extent and applicants may want to consider providing additional details about their monitoring capabilities as part of their response to the Standard Questions to properly frame and explain their responses.

J. Legal Authority for Certain Questions Concerning Broadcasters

49. We reject NAB's argument that the Commission should eliminate certain questions in Attachment E/Broadcast Section 310(b) PDR, ''because they concern issues outside of the scope of the Commission's jurisdiction and are thus not properly the subject of Committee review.'' Specifically, NAB raises concerns with Questions 29,[32] 30,[33] 31,[34] and 34.[35] NAB argues that the ''Committee's review should analyze whether the proposed transaction will implicate national security, law enforcement, foreign policy or trade policy issues arising from the assignment or transfer of the broadcast license, not from other business lines a broadcaster may be involved in or activities the FCC cannot lawfully regulate.'' NAB contends, among other things, that ''the Commission does not regulate consumer data privacy or security of broadcast audiences and has no authority to review broadcasters' data privacy and security practices either generally or in connection with proposed transactions.'' We disagree with NAB that these questions should be excluded from Attachment E/Broadcast Section 310(b) PDR. The Commission considers national security, law enforcement, foreign policy, and trade policy concerns of foreign ownership in excess of the 25% statutory benchmarks in its public interest review of petitions for declaratory rulings under section 310(b)(4) of the Act and refers applications with reportable foreign ownership to the Committee, which has specific expertise in these matters. In this regard, the information solicited by the Standard Questions enables the Committee to assess potential foreign influence of such foreign owners over a licensee as part of the Committee's review of a particular application for national security and law enforcement concerns. Thus, we are not regulating format or content but are assessing whether the public interest would be served by not permitting foreign ownership in accordance with section 310(b) of the Act, and information provided to the Committee concerning the nature of the broadcast services, for example, is relevant to the Committee's review of the potential for such influence by foreign owners.[36] To the extent a broadcast applicant finds that a question raises a particular concern, it should explain that in its response to the Committee, which may send Tailored Questions to the applicant if the Committee requires further explanation.

K. Additional Recommendations Concerning the Submission of the Standard Questions to the Committee

50. By their very nature, Standard Questions that are meant to address a broad range of situations will ask for information that an individual applicant may not find to be specific to its own situation. To the extent that a question is not applicable to an applicant's

[32] Question 29 asks, ''Will programming be rebroadcast via satellite or cable? If yes, provide details.''

[33] Question 30 asks, ''Will programming be available online? If yes, describe the streaming business operation (including what platform(s) will be used to make the programming available online.)''

[34] NAB Comments at 9 through 10 (arguing that Question 31 implicates a Licensee's First Amendment rights as well as the Act's prohibition on the Commission engaging in censorship and stating that ''questions concerning a station's format, target audience, and sources of advertising are not appropriate for Executive Branch review''). Question 31 asks the Applicant to ''[d]escribe the intended viewer/listener base of the Licensee's broadcasts, primary language spoken of the target audience, and other demographics, including: a) An explanation of how services are offered to each category of viewers/listeners and platform; and b) Identification of any specific business or economic sectors that supply advertising or other assistance to either the Licensee or Petitioner.''

[35] NAB Comments at 9, 10–11 (contending that ''the Commission does not regulate consumer data privacy or security of broadcast audiences and has no authority to review broadcasters' data privacy and security practices either generally or in connection with proposed transactions''). Question 34 asks the Applicant to ''[i]ndicate whether any Relevant Party or any of its subsidiaries that offer application or web-based content collect, process, or store any U.S. subscriber data. If so, identify what types of data (*e.g.,* name, address, email address, phone number, credit card number, etc.) are collected, processed, or stored for each U.S. subscriber.'' Among other things, Question 34 also seeks the location of U.S. subscriber data storage, who serves as the custodian and/or has access to such data and those individuals' countries of citizenship, as well as whether U.S. subscriber data is disclosed to third parties, and the security measures that are intended to protect subscriber data from unauthorized access or disclosure.

[36] *See, generally, 2013 Broadcast Clarification Order,* 28 FCC Rcd at 16245 through 46, paragraph 3 (stating that ''[t]he Commission's approach to the benchmark for foreign investments in broadcast licensees has reflected 'heightened concern for foreign influence over or control of [broadcast] licensees which exercise editorial discretion over the content of their transmissions.'' (citing *Market Entry and Regulation of Foreign-Affiliated Entities,* Notice of Proposed Rulemaking, 10 FCC Rcd 4844, 4884, paragraph 99) (1995)).

situation, we encourage applicants to explain this in their responses to the Standard Questions. Similarly, to the extent that an applicant finds a question to be overly broad or unclear in its applicability to the applicant's situation, it should explain that in its response. To the extent the Committee requires further explanation, it can send Tailored Questions to the applicant. Framing responses in this way will help the Committee in its review and assessment of applicants' responses and whether there will be a need for further information from the applicants.

51. Along those lines, commenters also ask whether they can consult with Committee staff regarding how to respond to certain questions, as they currently do. The Committee staff have stated a strong preference against negotiating the questions or responses with applicants before the responses are filed with the Committee or prior to Commission referral of an application. For instance, Committee staff state that there could be situations in which an application might not be referred at all. The Committee staff state that applicants should explain in their submissions the scope of their responses and any limitations in their responses. The Committee staff note that they can coordinate with applicants regarding responses after the Commission refers the application or when the Committee sends any Tailored Questions.

L. Other Revisions to Standard Questions

52. We also make several revisions to the Standard Questions to correct spelling and grammatical mistakes, to correct formatting issues, and to ensure that questions are standardized across the six questionnaires. These revisions correct unintentional drafting errors and do not change the substance of the Standard Questions beyond what has been discussed in this Second Report and Order. We believe that harmonizing the language across the Standard Questions will ease the application process and facilitate Committee review of applications.[37]

IV. Implementation

53. With the adoption of Standard Questions in this Second Report and Order, we direct the International Bureau to work with the Media Bureau and the Wireline Competition Bureau to seek approval from the Office of Management and Budget (OMB) for the Standard Questions and the rules adopted in the *Executive Branch Review Order* that are subject to the Paperwork Reduction Act. Upon completion of OMB review, the International Bureau shall issue a Public Notice informing the public of the effective date of the requirements, including the requirement to file responses to the Standard Questions with the Committee. The International Bureau shall make the Standard Questions available on the Commission's website no later than the time the Public Notice is released. Once the rules are effective, all parties filing applications subject to Executive Branch referral will be required to submit answers to the Standard Questions to the Committee prior to or at the same time that they file their applications with the Commission.

Supplemental Final Regulatory Flexibility Analysis

54. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), we have prepared this Supplemental Final Regulatory Flexibility Analysis (Supplemental FRFA) of the possible significant economic impact on small entities of the Standard Questions and procedures addressed in this Second Report and Order to supplement the Commission's Initial and Final Regulatory Flexibility Analyses in this proceeding. The Commission previously sought written public comment on the proposals in the *Executive Branch Review NPRM,* including comment on the Initial Regulatory Flexibility Analysis (IRFA). The Commission did not receive comments regarding the IRFA. Thereafter, in the *Executive Branch Review Order,* the Commission issued a Final Regulatory Flexibility Analysis (FRFA) conforming to the RFA. Subsequently, the Commission's International Bureau released a public notice seeking comment on specific proposed ''Standard Questions'' for applications and petitions as prescribed by the *Executive Branch Review Order* (Standard Questions Public Notice). As noted in the *Executive Branch Review Order,* standardizing these questions should improve the timeliness and transparency of the Executive Branch review process, thereby lessening the burden on all applicants and petitioners, including small entities. The *Standard Questions Public Notice* included a Supplemental Initial Regulatory Flexibility Analysis (Supplemental IRFA). This Supplemental FRFA supplements the FRFA to reflect the actions taken in this Second Report and Order, which adopts a final set of Standard Questions and conforms to the RFA.[38]

A. Need for, and Objectives of, the Second Report and Order

55. This Second Report and Order adopts a set of standardized national security and law enforcement questions (Standard Questions) that certain applicants and petitioners (together, ''applicants'') with reportable foreign ownership will be required to answer as part of the Executive Branch review process of their applications and petitions (together, ''applications''). To expedite the national security and law enforcement review of such applications, applicants must provide their answers to the Standard Questions directly to the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee)[39] prior to or at the same time they file their applications with the Commission.

56. The *Executive Branch Review Order* specified that the Standard Questions should include the following categories of information: (1) Corporate structure and shareholder information; (2) relationships with foreign entities; (3) financial condition and circumstances; (4) compliance with applicable laws and regulations; and (5) business and operational information, including services to be provided and network infrastructure. The adopted Standard Questions are based on the *Executive Branch Review Order* and the sample questions previously made available in this docket and the comments provided to the Commission regarding those questions. The adopted Standard Questions consist of the following:

- Attachment A—Standard Questions for an International Section 214

[37] CTIA, NAB, and USTelecom ask the Commission to clarify when the 120-day clock starts. We believe that the *Executive Branch Review Order* and the rules clearly state when the 120-day review will begin. *See* Executive Order No. 13913, 85 FR at 19645, § 5(b)(iii); *Executive Branch Review Order,* 35 FCC Rcd at 10958, paragraph 82. *See also* 47 CFR 1.40004(e)(2) (providing that the 120-day review will begin on the date of the Committee's deferral request (under Section 1.40002(b), 47 CFR 1.40002) if it includes a notification that tailored questions are not necessary).

[38] *See* 5 U.S.C. 604.

[39] Executive Order No. 13913 of April 4, 2020, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, 85 FR 19643, 19643–44 (Apr. 8, 2020) (Executive Order 13913) (establishing the ''Committee'' composed of the Secretary of Defense, the Secretary of Homeland Security, and the Attorney General of the Department of Justice, who serves as the Chair, and the head of any other executive department or agency, or any Assistant to the President, as the President determines appropriate, and also providing for Advisors, including the Secretary of State, the Secretary of Commerce, and the United States Trade Representative).

Authorization Application. Standard Questions for an international section 214 authorization application filed pursuant to 47 CFR 63.18, including a modification of an existing authorization;

• Attachment B—Standard Questions for an Application for Assignment or Transfer of Control of an International Section 214 Authorization. Standard Questions for an assignment or transfer of control of an international section 214 authorization application filed pursuant to 47 CFR 63.24;

• Attachment C—Standard Questions for a Submarine Cable Landing License Application. Standard Questions for a cable landing license application filed pursuant to 47 CFR 1.767 including a modification of an existing license;

• Attachment D—Standard Questions for an Application for Assignment or Transfer of Control of a Submarine Cable Landing License. Standard Questions for an assignment or transfer of control of a cable landing license application filed pursuant to 47 CFR 1.767;

• Attachment E—Standard Questions for a Section 310(b) Petition for Declaratory Ruling Involving a Broadcast Licensee. Standard Questions for a petition for declaratory ruling for foreign ownership in a broadcast licensee above the benchmarks in section 310(b) of the Communications Act (the Act) filed pursuant to 47 CFR 1.5000–1.5004;

• Attachment F—Standard Questions for a Section 310(b) Petition for Declaratory Ruling Involving a Common Carrier Wireless or Common Carrier Earth Station Licensee. Standard Questions for a petition for declaratory ruling for foreign ownership in a common carrier wireless or common carrier earth station licensee above the benchmarks in section 310(b) of the Act filed pursuant to 47 CFR 1.5000–1.5004; and

• Attachment G—Personally Identifiable Information (PII) Supplement. Each set of Standard Questions references a supplement to assist the Committee in identifying PII.

57. The Commission adopted the Standard Questions largely as proposed in the *Standard Questions Public Notice,* with some important changes to more narrowly tailor and clarify the instructions and certain questions so as to decrease the burden on applicants. The changes include:

• All Attachments: Modify the definition of ''Senior Officer'' to capture any individual with authority to act on behalf of the entity, rather than referring to specific individuals' titles.

• Attachment A/Question 2 Attachment B/Question 2; Attachment D/Question 3; Attachment E/Question 2; Attachment F/Question 2: For clarity and consistency, modify these questions by adding the term ''Controlling Interest.''

• All Attachments: Remove the term ''Immediate Owner'' from the definitions section as that term is not used in any subsequent questions.

• All Attachments: Correct inadvertent use of inconsistent terms. For example, we have revised all questionnaires so that they are consistent in the use of the defined terms ''Ultimate Owner'' and ''Ultimate Parent.''

• Attachment B/Question 1 and Attachment D/Question 1: Remove transferors and assignors (the sellers) from the definition of ''Relevant Parties.''

• All Attachments: Modify the instructions in all questionnaires to provide that all of the submitted information will be protected from disclosure according to the provisions of Executive Order 13913, Section 8, and that applicants will not have to specifically identify information for such treatment.

• All Attachments: Clarify the instructions for multiple applicants for a single application (such as consortium applicants for a single submarine cable landing license).

• All Attachments: Modify the instructions to allow internal cross-referencing of responses within a single questionnaire to streamline the process for applicants. For example, if an applicant provided a response to Question 15, and the applicant's response to Question 27 contains the same information, the applicant may refer back to its earlier response.

• Attachment F/Question 3: Remove language regarding prior relationships from this question as it was unintentionally added to the proposed questionnaire.

• Attachment A/Question 3; Attachment B/Question 3; Attachment C/Question 8; Attachment D/Question 21; Attachment E/Question 3; Attachment F/Question 3: Clarify that ''planned relationships'' are ''current relationships or those reasonably anticipated by negotiations or that are identified under current business plans'' and clarify that this includes any situations in which contracts have been signed or where the parties are already in negotiations.

• Attachment A/Question 3; Attachment B/Question 3; Attachment C/Question 8; Attachment D/Question 21; Attachment E/Question 3; Attachment F/Question 3: Clarify that existing or planned relationships/partnerships, and prior relationships/partnerships in the case of broadcast applicants, and funding or service contracts, do not include foreign subscribers to an applicant's retail services. Also clarify that, for the purposes of these questions, these relationships do not include foreign employees who are identified in other questions, such as Senior Officers and Directors, and Non-U.S. Individuals with physical access to certain facilities, records, networks, or electronic interfaces.

• Attachment E: Remove the reference to ''Foreign Party'' in questions 12, 18–21, 26, 31–34.

• Attachment A/Questions 7, 9; Attachment B/Questions 7, 9; Attachment C/Questions 12, 14; Attachment D/Questions 13, 15; Attachment E/Questions 5, 7; Attachment F/Questions 7, 9: Amend language pertaining to an applicant's involvement or association with prior Commission or Committee on Foreign Investment in the United States (CFIUS) filings to specify that an ''involved'' or ''associated'' Individual or Entity was either the applicant in a prior Commission or CFIUS filing or listed as an owner in such a prior filing.

• Attachment A/Question 7; Attachment B/Question 7; Attachment C/Question 12; Attachment D/Question 13; Attachment E/Question 5; Attachment F/Question 7: Adopt a ten-year time boundary regarding prior Commission filings that must be disclosed.

• Attachment E/Question 19: Clarify that broadcasters must provide the information listed in Question 19 for non-U.S. Individuals with access to (1) all facilities and equipment in the United States, (2) facilities outside the United States that are used to broadcast into the United States, and (3) facilities both inside and outside the United States that store, process, or provide access to U.S. person data (including data on current, past, and potential U.S. customers).

• Attachment C/Question 37; Attachment D/Question 39: Clarify that for submarine cable applicants, only the U.S. cable landing party need identify an authorized law enforcement point of contact.

• Attachment A/Question 37; Attachment B/Question 36; Attachment C/Question 45; Attachment D/Question 48; Attachment F/Question 38: Update the list of U.S. critical infrastructure sectors outlined in the Standard Questions to track Presidential Policy Directive 21 (PPD–21).

• Attachment A/Section VI; Attachment B/Section VI; Attachment F/Section VI: Rename the list of services in the Reference Questions section from ''Proposed Services'' to ''Proposed Services/Technologies/Network Infrastructure.''

• Attachment A/Question 36; Attachment B/Question 35; Attachment F/Question 37: Revise questions so as to obtain a general description of the manner in which applicants will deliver services to customers.

• Attachment A/Question 37; Attachment B/Question 36; Attachment C/Question 45; Attachment D/Question 48; Attachment F/Question 38: Revise questions to use phrase ''provide services to'' and add a statement clarifying that the phrase ''provide services to'' in these questions includes situations in which the applicant provides service to, has customers in, or participates in the market in sectors of U.S. critical infrastructure.

• All Attachments: Advise applicants that in the event that they find a question to be overly broad or unclear in its applicability, they should explain that in their response.

• All Attachments: Make several revisions to the Standard Questions to correct spelling and grammatical mistakes, to correct formatting issues, and to ensure that questions are standardized across the six questionnaires.

The Standard Questions—with these changes and clarified instructions—will ensure that the Committee has the information it needs to conduct its national security and law enforcement review, while also addressing concerns raised by commenters that certain questions were unclear or overly burdensome.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

58. The Commission did not receive comments specifically addressing the rules and policies proposed in the Supplemental IRFA. Nonetheless, in adopting the Standard Questions reflected in this Second Report and Order, the Commission has considered the potential impact of the rules and procedures proposed in the IRFA on small entities in order to reduce the economic impact of the rules and procedures enacted herein on such entities.

C. Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

59. Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed rules as a result of those comments.

60. The Chief Counsel did not file any comments in response to the proposed Standard Questions in this proceeding.

D. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

61. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that will be affected by rules. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). Initial and Final Regulatory Flexibility Analyses were incorporated into the *Executive Branch Review Order* and the Notice of Proposed Rulemaking associated with that Order. In this Second Report and Order, we hereby incorporate by reference the descriptions and estimates of the number of small entities, as well as the associated analyses, set forth therein.

E. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements for Small Entities

62. This Second Report and Order adopts Standard Questions that would affect reporting, recordkeeping, and other compliance requirements for applicants who file for international section 214 authorizations, submarine cable landing licenses or applications to assign or transfer control of such authorizations, and section 310(b) petitions for declaratory rulings (common carrier wireless, common carrier satellite earth stations, or broadcast). Applicants with reportable foreign ownership will be required to submit responses to standard national security and law enforcement questions and will need to certify in their applications that they have submitted the Standard Questions and will send a copy of their FCC application to the Committee. As noted in the FRFA in connection with the *Executive Branch Review Order,* all applicants for international section 214 authority and submarine cable licenses, regardless of whether they have reportable foreign ownership will be required to certify that they: (1) Will comply with the Communications Assistance for Law Enforcement Act (CALEA); (2) will make certain communications and records available and subject to lawful request or valid legal process under U.S. law; (3) will designate a point of contact in the United States who is a U.S. citizen or lawful permanent resident; (4) will keep all submitted information accurate and complete during application process and after the application is no longer pending for purposes of section 1.65 of the rules, the authorization holder and/or licensee must inform the Commission and the Committee of any contact name changes; and (5) understand that failing to fulfill any condition of the grant or providing materially false information could result in revocation or termination of their authorization and other penalties. Petitioners for broadcast licensee petitions for a section 310(b) declaratory ruling for broadcast licenses will make the last three certifications but will not need to make the first two certifications.

F. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternative Considered

63. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following alternatives, among others: ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

64. In this Second Report and Order, the adopted Standard Questions will help improve the timeliness and transparency of the review process, thus lessening the burden of the licensing process on all applicants, including small entities. Requiring applicants to submit responses to the Standard Questions prior to or at the same time that they file their applications at the Commission (rather than after filing the application at the Commission) should facilitate a faster response by the Executive Branch on its national

security and law enforcement review and advance the shared goal of the Commission and industry, including small entities, to make the Executive Branch review process as efficient as possible. As discussed in the FRFA in the *Executive Branch Review Order,* timeframes for review of FCC applications referred to the Executive Branch have also been adopted, which will help prevent unnecessary delays and make the process more efficient and transparent, which ultimately benefits all applicants, including small entities.

G. Report to Congress

65. The Commission will send a copy of the Second Report and Order, including this Supplemental FRFA, in a report to be sent to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996.

Ordering Clauses

66. *It is ordered* that, pursuant to sections 4(i), 4(j), 214, 303, 309, 310 and 413 of the Communications Act as amended, 47 U.S.C. 154(i), 154(j), 214, 303, 309, 310 and 413, and the Cable Landing License Act of 1921, 47 U.S.C. 34–39, and Executive Order No. 10530, Section 5(a) reprinted as amended in 3 U.S.C. 301, this Second Report and Order *is adopted.*

67. *It is further ordered* that as discussed herein, pursuant to 47 U.S.C. 155(c) and 47 CFR 0.261, the Chief of the International Bureau *is directed* to administer and make available on a public website, a standardized set of national security and law enforcement questions for the Categories of Information set forth in Part 1, Subpart CC of the Commission's rules.

68. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Second Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

69. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Second Report and Order, including the Supplemental Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2021–24944 Filed 12–1–21; 8:45 am]

BILLING CODE 6712–01–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 502, 509, 511, 512, 514, 532, 536, 538, and 552

[GSAR Case 2021–G510; Docket No. GSA–GSAR 2021–0026; Sequence No. 1]

RIN 3090–AK37

General Services Administration Acquisition Regulation (GSAR); Updating References to Commercial Items

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is issuing a final rule amending the General Services Administration Acquisition Regulation (GSAR) to conform to changes in the Federal Acquisition Regulation (FAR) that reflect an updated ''commercial item'' definition pursuant to a section of the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019.

DATES: Effective January 3, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Carroll at 817–253–7858 or *gsarpolicy@gsa.gov,* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite GSAR Case 2021–G510.

SUPPLEMENTARY INFORMATION:

I. Background

This final rule amends the General Services Administration Acquisition Regulation (GSAR) to change instances of ''commercial item(s)'' with commercial product(s), commercial services(s), or both commercial product(s) and commercial service(s) to match similar actions taken in the Federal Acquisition Regulation (FAR).

FAR Case 2018–018 was published as a final rule at 86 FR 61017 on November 4, 2021, to implement section 836 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 to separate the definition of ''commercial item'' into the definitions of ''commercial product'' and ''commercial service.''

It is important to note that the amendment to separate ''commercial item'' with ''commercial product'' and ''commercial service'' does not expand or shrink the universe of products or services that the Government may procure using GSAR part 512, nor does it change the terms and conditions vendors must comply with.

This rule does not add any new solicitation provisions or contract clauses. This rule merely replaces the term ''commercial item(s)'' with ''commercial product(s),'' ''commercial service(s),'' ''commercial product(s) or commercial service(s),'' or ''commercial product(s) and commercial service(s)'' in the GSAR including in part 552, as appropriate. It does not add any new burdens because the case does not add or change any requirements with which vendors must comply.

II. Authority for This Rulemaking

Title 40 of the United States Code (U.S.C.) Section 121 authorizes GSA to issue regulations, including the GSAR, to control the relationship between GSA and contractors.

III. Discussion and Analysis

As changed by FAR Case 2018–018, and as required by section 836 of the NDAA for FY 2019, this final rule replaces instances of commercial item(s) with commercial product(s), commercial service(s), or both commercial product(s) and commercial service(s).

This final rule also replaces all instances of ''non-commercial'' and ''noncommercial'' with ''other than commercial'' as it relates to this rule. This is an editorial change and will provide consistent language to the FAR and throughout the GSAR.

Other minor editorial changes are made in this final rule to provide consistent language.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been reviewed and determined by OMB not to be a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a ''major rule'' may take

effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule has been reviewed and determined by OMB not to be a ''major rule'' under 5 U.S.C. 804(2).

VI. Notice for Public Comment

The statute that applies to the publication of the GSAR is the Office of Federal Procurement Policy statute (codified at title 41 of the United States Code). Specifically, 41 U.S.C. 1707(a)(1) requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This rule is not required to be published for public comment, because GSA is not issuing a new regulation; rather, this rule is merely an editorial change and will provide consistent language to the FAR (pursuant to section 836 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019) throughout the GSAR. The rule does not expand or shrink the universe of products or services that the Government may procure using GSAR part 512, nor does it change the terms and conditions vendors must comply with.

This rule does not add any new solicitation provisions or contract clauses. This rule merely replaces the term ''commercial item(s)'' with ''commercial product(s),'' ''commercial service(s),'' ''commercial product(s) or commercial service(s),'' or ''commercial product(s) and commercial service(s)'' in the GSAR including in part 552, as appropriate. It does not add any new burdens because the case does not add or change any requirements with which vendors must comply.

VII. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) does not apply to this rule, because an opportunity for public comment is not required to be given for this rule under 41 U.S.C. 1707(a)(1) (see Section VI. of this preamble). Accordingly, no regulatory flexibility analysis is required and none has been prepared.

VIII. Paperwork Reduction Act

The final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 502, 509, 511, 512, 514, 532, 536, 538, and 552

Government procurement.

Jeffrey Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy, General Services Administration.

Therefore, GSA amends 48 CFR parts 502, 509, 511, 512, 514, 532, 536, 538, and 552 as set forth below:

■ 1. The authority citation for 48 CFR parts 502, 509, 511, 512, 514, 532, 536, 538, and 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

PART 502—DEFINITIONS OF WORDS AND TERMS

502.101 [Amended]

■ 2. Amend section 502.101 in the introductory text by—
■ a. Removing the words ''that meet'' and adding the words ''that meets'' in its place;
■ b. Removing the words ''commercial item'' and adding the words ''commercial products and commercial services'' in its place; and
■ c. Removing the word ''supply'' and adding the words ''product'' in its place.

PART 509—CONTRACTOR QUALIFICATIONS

509.405–1 [Amended]

■ 3. Amend section 509.405–1 by removing from paragraph (b)(6) ''commercial items.)'' and adding ''commercial products and commercial services).'' in its place.

PART 511—DESCRIBING AGENCY NEEDS

511.602 [Amended]

■ 4. Amend section 511.602 by removing from introductory text of paragraph (d) ''any items'' and adding ''any product or service'' in its place.

PART 512—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 5. Revise the heading for part 512 to read as set forth above.

■ 6. Revise the heading of subpart 512.3 to read as follows:

Subpart 512.3—Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Products and Commercial Services

512.301 [Amended]

■ 7. Amend section 512.301 by—

■ a. Removing from the section heading and paragraph (a) introductory text ''commercial items'' and adding ''commercial products and commercial services'' in its place;

■ b. Removing from paragraph (a)(1) ''Acquisition of Commercial Items'' and ''commercial items'' and adding ''Acquisitions of Commercial Products and Commercial Services'' and ''commercial products and commercial services'' in their places, respectively;

■ c. Removing from paragraph (a)(2) ''Commercial Items'' and ''commercial item'' and adding ''Commercial Products and Commercial Services'' and ''commercial products and commercial services'' in their places, respectively;

■ d. Removing from paragraph (b) ''Commercial Items'' and adding ''Commercial Products and Commercial Services'' in its place; and

■ e. Removing from paragraph (d)(1) ''commercial items'' and adding ''commercial products and commercial services'' in its place.

PART 514—SEALED BIDDING

514.201–2 [Amended]

■ 8. Amend section 514.201–2 by removing from paragraph (b) ''Commercial Items'' and adding ''Commercial Products and Commercial Services'' in its place.

514.270–1 [Amended]

■ 9. Amend section 514.270–1 by removing ''FAR 3.302'' and adding ''FAR 2.101'' in its place.

514.270–4 [Amended]

■ 10. Amend section 514.270–4 in paragraph (d)(3)(ii) by removing ''commercial items'' and adding ''commercial products'' in its place and removing the word ''etc.''.

514.270–7 [Amended]

■ 11. Amend section 514.270–7 by removing from paragraph (d) ''item'' everywhere it appears and adding ''product'' in its place.

PART 532—CONTRACT FINANCING

■ 12. Revise the heading of subpart 532.1 to read as follows:

Subpart 532.1—Financing for Other Than a Commercial Purchase

532.908 [Amended]

■ 13. Amend section 532.908 by removing from paragraph (b)(2) ''not for commercial items'' and adding ''for other than commercial products or commercial services'' in its place.

PART 536—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

536.7104 [Amended]

■ 14. Amend section 536.7104 by removing ''services or items'' and adding ''services or supplies'' in its place.

PART 538—FEDERAL SUPPLY SCHEDULE CONTRACTING

538.271 [Amended]

■ 15. Amend section 538.271 by removing from paragraph (a) ''commercial items as defined in FAR 2.101'' and adding ''commercial products and commercial services'' in its place.

538.273 Amended]

■ 16. Amend section 538.273 by—
■ a. Removing from paragraph (b) introductory text ''Commercial Items'' and adding ''Commercial Products and Commercial Services'' in its place;
■ b. Removing from paragraph (c) introductory text ''Evaluation—Commercial Items'' and adding ''Evaluation—Commercial Products and Commercial Services'' in its place;
■ c. Removing from paragraph (c)(1) ''Commercial Items'' and adding ''Commercial Products and Commercial Services'' in its place;
■ d. Removing from paragraph (d) introductory text ''Conditions—Commercial Items'' and adding ''Conditions—Commercial Products and Commercial Services'' in its place;
■ e. Removing from paragraph (d)(2) ''contemplate items'' and adding the word ''contemplate products'' in its place;
■ f. Removing from paragraphs (d)(19) and (32) ''for items'' and adding ''for products'' in its place; and
■ g. Removing from paragraph (d)(35) ''when items'' and adding ''when products'' in its place.

538.7003 [Amended]

■ 17. Removing from paragraph (a) ''Conditions—Commercial Items'' and adding ''Conditions—Commercial Products and Commercial Services'' in its place.

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 18. Amend section 552.212–4 by revising the section heading, clause heading, and the date of the clause to read as follows:

552.212–4 Contract Terms and Conditions—Commercial Products and Commercial Services (FAR DEVIATION).

* * * * *

Contract Terms and Conditions—Commercial Products and Commercial Services (FAR DEVIATION) (JAN, 2022).

* * * * *

■ 19. Amend section 552.212–71 by—
■ a. Revising the section heading, clause heading, and date of the clause; and
■ b. In paragraph (a) introductory text:
■ i. Removing ''items or components'' and adding ''products, including commercial components, and commercial services'' in its place; and
■ ii. Removing from the last sentence ''The clauses'' and adding ''The GSAR clauses'' in its place.

The revisions read as follows:

552.212–71 Contract Terms and Conditions Applicable to GSA Acquisitions of Commercial Products and Commercial Services.

* * * * *

Contract Terms and Conditions Applicable to GSA Acquisitions of Commercial Products and Commercial Services (JAN, 2022).

* * * * *

■ 20. Amend section 552.212–72 by—
■ a. Revising the section heading, clause heading, and date of the clause; and
■ b. Removing from the introductory text of the clause ''commercial items or components'' and adding ''commercial products, including commercial components, and commercial services'' in its place.

The revisions read as follows:

552.212–72 Contract Terms and Conditions Required To Implement Statutes or Executive Orders Applicable to GSA Acquisition of Commercial Products and Commercial Services.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders Applicable to GSA Acquisition of Commercial Products and Commercial Services (JAN, 2022)

* * * * *

■ 21. Amend section 552.232–25 by:
■ a. Revising the date of the clause; and
■ b. Removing from paragraph (a)(5) introductory text ''Commercial Items'' and adding ''Commercial Products and Commercial Services'' in its place.

The revision reads as follows:

552.232–25 Prompt Payment.

* * * * *

Prompt Payment (JAN, 2022)

* * * * *

■ 22. Amend section 552.238–75 by—
■ a. Revising the section heading, clause heading, and date of the clause; and
■ b. In paragraph (a):
■ i. Revising the first sentence;
■ ii. Removing from the second sentence ''complexity of items'' and adding ''complexity of products or services'' in its place; and
■ iii. Removing from the last sentence ''the item(s)'' and adding ''the products or services'' in its place.

The revisions read as follows:

552.238–75 Evaluation—Commercial Products and Commercial Services (Federal Supply Schedule).

* * * * *

Evaluation—Commercial Products and Commercial Services (Federal Supply Schedule) (JAN, 2022)

(a) The Government may make multiple awards for the supplies or services offered in response to this solicitation that meet the commercial product or commercial service definition in FAR clause 52.202–1.
* * *

* * * * *

■ 23. Amend section 552.238–78 by:
■ a. Revising the date of the clause; and
■ b. Removing from paragraph (d) introductory text ''an item's'' and adding ''an product's'' in its place.

The revision reads as follows:

552.238–78 Identification of Products That Have Environmental Attributes.

* * * * *

Identification of Products That Have Environmental Attributes (JAN, 2022)

* * * * *

■ 24. Amend section 552.238–82 by—
■ a. Revising the date of the clause;
■ b. Removing form paragraph (b)(1)(vii) ''Commercial Items'' and adding ''Commercial Products and Commercial Services'' in its place; and
■ c. Removing from Alternate II, paragraph (b)(1)(v), ''Commercial Items'' and adding ''Commercial Products or Services'' in its place.

The revision reads as follows:

552.238–82 Modifications (Federal Supply Schedules).

* * * * *

Modifications (Federal Supply Schedules) (JAN, 2022)

* * * * *

■ 25. Amend section 552.238–111 by—

■ a. Revising the date of the clause; and

■ b. Removing form paragraph (c) ''Commercial Items'' and adding ''Commercial Products and Commercial Services'' in its place.

The revision reads as follows:

552.238–111 Environmental Protection Agency Registration Requirement.

* * * * *

Environmental Protection Agency Registration Requirement (JAN, 2022)

* * * * *

■ 26. Amend section 552.238–114 by—

■ a. Revising the date of the clause; and

■ b. Removing form paragraph (a)(1) ''Commercial Item'' and adding ''Commercial Products and Commercial Services'' in its place.

The revision reads as follows:

552.238–114 Use of Federal Supply Schedule Contracts by Non-Federal Entities.

* * * * *

Use of Federal Supply Schedule Contracts by Non-Federal Entities (JAN, 2022)

* * * * *

[FR Doc. 2021–25274 Filed 12–1–21; 8:45 am]

BILLING CODE 6820–61–P

Proposed Rules

Federal Register
Vol. 86, No. 229
Thursday, December 2, 2021

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 514

RIN 3141–AA77

Fees

AGENCY: National Indian Gaming Commission, Department of the Interior.

ACTION: Proposed rule.

SUMMARY: The National Indian Gaming Commission proposes to amend agency procedures for calculating the amount of annual fee a gaming operation owes the National Indian Gaming Commission. The proposed amendments will allow a gaming operation to exclude certain promotional credits from the calculation of Assessable Gross Gaming Revenue.

DATES: Written comments on this proposed rule must be received on or before January 3, 2022.

ADDRESSES: You may submit comments by any one of the following methods, however, please note that comments sent by electronic mail are strongly encouraged.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email comments to: information@nigc.gov.*
- *Mail comments to:* National Indian Gaming Commission, 1849 C Street NW, MS 1621, Washington, DC 20240.
- *Fax comments to:* National Indian Gaming Commission at 202–632–0045.

FOR FURTHER INFORMATION CONTACT: Austin Badger at (202) 632–7003 or by fax (202) 632–7066 (these numbers are not toll free).

SUPPLEMENTARY INFORMATION:

I. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (''NIGC'' or ''Commission'') and set out a comprehensive framework for the regulation of gaming on Indian lands. On August 15 1991, the NIGC published a final rule in the **Federal Register** called Annual Fees Payable By Class II Gaming Operations. 58 FR 5831. The rule added a new part to the Commission's regulations to provide direction and guidance to Class II gaming operations to enable them to compute and pay the annual fees as authorized by the Indian Gaming Regulatory Act. The Commission has substantively amended them numerous times, most recently in 2018 (83 FR 2903).

II. Development of the Rule

On, June 9, 2021, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the fee regulations. Prior to consultation, the Commission released proposed discussion drafts of the regulations for review. The proposed amendment to the fee regulations were intended to provide clarity as to whether a tribal gaming operation must include certain promotional credits, commonly referred to as ''free play,'' as ''money wagered'' for purposes of calculating assessable gross revenues. The Commission held two virtual consultation sessions in July of 2021 to receive tribal input on the possible changes.

The Commission reviewed all comments received as part of the consultation process. One comment suggested that rather than allowing a tribal gaming operation to decide whether to exclude the promotional credits, it should make the exclusion mandatory. The Commission rejected this comment for purposes of this proposed rulemaking so as to provide maximum flexibility to tribal gaming operations to decide for themselves whether to exclude the credits or not. That being said, the Commission is especially interested in comments as to whether there would be unintended consequences if the Commission were to allow the tribal gaming operation to decide if it will deduct promotional credits.

III. Regulatory Matters

Regulatory Flexibility Act

The rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions, nor will the proposed rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget as required

by 44 U.S.C. 3501, *et seq.,* and assigned OMB Control Number 3141–0007.

Tribal Consultation

The National Indian Gaming Commission is committed to fulfilling its tribal consultation obligations—whether directed by statute or administrative action such as Executive Order (E.O.) 13175 (Consultation and Coordination with Indian Tribal Governments)—by adhering to the consultation framework described in its Consultation Policy published July 15, 2013. The NIGC's consultation policy specifies that it will consult with tribes on Commission Action with Tribal Implications, which is defined as: Any Commission regulation, rulemaking, policy, guidance, legislative proposal, or operational activity that may have a substantial direct effect on an Indian tribe on matters including, but not limited to the ability of an Indian tribe to regulate its Indian gaming; an Indian tribe's formal relationship with the Commission; or the consideration of the Commission's trust responsibilities to Indian tribes.

Pursuant to this policy, on June 9, 20201, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the fee regulations.

List of Subjects in 25 CFR Part 514

Administrative practice and procedure, Gambling, Indian, Indians—lands, Indians—tribal government, Indians—business and finance.

For the reasons discussed in the Preamble, the Commission proposes to revise its regulations at 25 CFR part 514 as follows:

PART 514—FEES

■ 1. The authority citation for part 514 continues to read as follows:

Authority: 25 U.S.C. 2706, 2710, 2717, 2717a.

■ 2. Amend § 514.4 by revising paragraph (f) and adding paragraph (g) to read as follows:

§ 514.4 How does a gaming operation calculate the amount of the annual fee it owes?

* * * * *

(f) The amounts wagered that the gaming operation can demonstrate were issued by the gaming operation as promotional credits may be excluded from the total amount of money wagered.

(g) Unless otherwise provided by regulation, generally accepted accounting principles shall be used.

Dated: November 18, 2021, Washington, DC.

E. Sequoyah Simermeyer,

Chairman.

[FR Doc. 2021–25838 Filed 12–1–21; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 537

RIN 3141–AA58

Background Investigations for Persons or Entities With a Financial Interest in or Having a Management Responsibility for a Management Contract

AGENCY: National Indian Gaming Commission, Department of the Interior.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Indian Gaming Commission proposes to amend its procedures for processing a request for approval of a management contract under the Indian Gaming Regulatory Act. The proposed amendments make the following changes to the current regulations. The regulations will now require a background investigation of all persons who have 10 percent or more direct or indirect financial interest in a management contract. The regulations will also require a background investigation of all entities with 10 percent or more financial interest in a management contract. The regulations now require a background investigation of any other person or entity with a direct or indirect financial interest in a management contract otherwise designated by the Commission. The regulations authorize the Chair, either by request or unilaterally, to exercise discretion to reduce the scope of the information to be furnished and background investigation to be conducted for certain entities.

DATES: Written comments on this proposed rule must be received on or before January 3, 2022.

ADDRESSES: You may submit comments by any one of the following methods, however, please note that comments sent by electronic mail are strongly encouraged.

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email comments to: information@nigc.gov.*
- *Mail comments to:* National Indian Gaming Commission, 1849 C Street NW, MS 1621, Washington, DC 20240.
- *Fax comments to:* National Indian Gaming Commission at 202–632–0045.

FOR FURTHER INFORMATION CONTACT: Heather McMillan Nakai at (202) 632–7003 or by fax (202) 632–7066 (these numbers are not toll free).

SUPPLEMENTARY INFORMATION:

I. Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal.

II. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (''NIGC'' or ''Commission'') and set out a comprehensive framework for the regulation of gaming on Indian lands. On January 22, 1993, the NIGC published a final rule in the **Federal Register** called *Background Investigations for Person or Entities with a Financial Interest in a Management Contract,* 58 FR 5831. The rule added a new part to the Commission's regulations implementing the mandates of the Indian Gaming Regulatory Act of 1988 by establish the requirements and procedures for the approval of management contracts concerning Indian gaming operations and the conduct of related background investigations. The Commission has substantively amended them numerous times, most recently in 2012 (77 FR 47516).

III. Development of the Rule

On, June 9, 20201, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the management contract process. Prior to consultation, the Commission released proposed discussion drafts of the regulations for review. The proposed amendment to the management contract regulations were intended to improve the Agency's efficiency in processing management agreements and background investigations, clarify existing regulations, and provide guidance on extending management contracts. The Commission held two virtual

consultation sessions in July of 2021 to receive tribal input on the possible changes.

The Commission reviewed all comments and now proposes these changes which it believes will improve the Agency's efficiency in processing background investigations.

IV. Regulatory Matters

Regulatory Flexibility Act

The rulemaking will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rulemaking does not have an effect on the economy of $100 million or more. The proposed rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions, nor will the proposed rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the proposed rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the proposed rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the order.

National Environmental Policy Act

The Commission has determined that the rulemaking does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget as required by 44 U.S.C. 3501, *et seq.,* and assigned Office of Management and Budget (OMB) Control Number 3141–0004.

Tribal Consultation

The National Indian Gaming Commission is committed to fulfilling its tribal consultation obligations—whether directed by statute or administrative action such as Executive Order (E.O.) 13175 (Consultation and Coordination with Indian Tribal Governments)—by adhering to the consultation framework described in its Consultation Policy published July 15, 2013. The NIGC's consultation policy specifies that it will consult with tribes on Commission Action with Tribal Implications, which is defined as: Any Commission regulation, rulemaking, policy, guidance, legislative proposal, or operational activity that may have a substantial direct effect on an Indian tribe on matters including, but not limited to the ability of an Indian tribe to regulate its Indian gaming; an Indian tribe's formal relationship with the Commission; or the consideration of the Commission's trust responsibilities to Indian tribes.

Pursuant to this policy, on June 9, 20201, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the management contract process.

List of Subjects in 25 CFR Part 537

Administrative practice and procedure, Gambling, Indians—business and finance, Indian—Indian lands, Indians—tribal government.

For the reasons discussed in the Preamble, the Commission proposes to amend its regulations at 25 CFR part 537 as follows:

PART 537—BACKGROUND INVESTIGATIONS FOR PERSONS OR ENTITIES WITH A FINANCIAL INTEREST IN, OR HAVING MANAGEMENT RESPONSIBILITY FOR, A MANAGEMENT CONTRACT

■ 1. The authority citation for part 537 continues to read as follows:

Authority: 25 U.S.C. 81, 2706(b)(10), 2710(d)(9), 2711.

■ 2. Amend § 537.1 by revising paragraphs (a)(3) through (5) and adding paragraph (d) to read as follows:

§ 537.1 Applications for approval.

(a) * * *

(3) All persons who have 10 percent or more direct or indirect financial interest in a management contract;

(4) All entities with 10 percent or more financial interest in a management contract; and

(5) Any other person or entity with a direct or indirect financial interest in a management contract otherwise designated by the Commission.

* * * * *

(d) For any of the following entities, or individuals associated with the following entities, the Chair may, upon request or unilaterally, exercise discretion to reduce the scope of the information to be furnished and background investigation to be conducted:

(1) Tribe as defined at 25 CFR 502.13;

(2) Wholly owned tribal entity;

(3) National bank; or

(4) Institutional investor that is federally regulated or is required to undergo a background investigation and licensure by a state or tribe pursuant to a tribal-state compact.

Dated: November 18, 2021, Washington, DC.

E. Sequoyah Simermeyer,

Chairman.

[FR Doc. 2021–25844 Filed 12–1–21; 8:45 am]

BILLING CODE 7565–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2020–0406; FRL–9319–01–R4]

Air Plan Approval; Georgia; 2015 8-Hour Ozone Nonattainment New Source Review Permit Program Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Georgia State Implementation Plan (SIP) submitted by the State of Georgia through the Georgia Environmental Protection Division (GA EPD) on July 2, 2020. EPA is proposing to approve Georgia's certification of existing Nonattainment New Source Review (NNSR) permitting regulations to meet the nonattainment planning

requirements for the 2015 8-hour ozone National Ambient Air Quality Standards (NAAQS) for the Atlanta Area, comprised of the counties of Bartow, Clayton, Cobb, DeKalb, Fulton, Gwinnett, and Henry. This action is being proposed pursuant to the Clean Air Act (CAA or Act) and its implementing regulations.

DATES: Comments must be received on or before January 3, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2020–0406 at *www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include 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 *www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Pearlene Williams, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9144. Ms. Williams can also be reached via electronic mail at *williams.pearlene@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The New Source Review (NSR) program is a preconstruction permitting program that requires certain stationary sources of air pollution to obtain permits prior to beginning construction. The NSR permitting program applies to new construction and modification of existing sources. New construction and modifications that emit ''regulated NSR pollutants'' over certain thresholds are subject to major NSR requirements, while smaller emitting sources and modifications may be subject to minor NSR requirements.

Major NSR permits for sources that are in attainment or unclassifiable areas are referred to as Prevention of Significant Deterioration (PSD) permits. Major NSR permits for sources in nonattainment areas and that emit pollutants above the specified thresholds for which the area is in nonattainment are referred to as NNSR permits.

A new stationary source is subject to major NSR requirements if its potential to emit a regulated NSR pollutant exceeds certain emission thresholds. If it exceeds the applicable threshold, the NSR regulations define it as a ''major stationary source.'' An existing major stationary source triggers major NSR permitting requirements when it undergoes a ''major modification,'' which occurs when a source undertakes a physical change or change in method of operation (*i.e.,* a ''project'') that would result in: (1) A significant emissions increase from the project, and (2) a significant net emissions increase from the source. *See, e.g.,* 40 CFR 51.165(a)(1)(v)(A) and 40 CFR 51.165(a)(1)(xxxix).

On October 1, 2015, EPA promulgated a revised 8-hour NAAQS of 0.070 parts per million (ppm). *See* 80 FR 65292 (October 26, 2015). Upon promulgation of a new or revised ozone NAAQS, section 107(d) of the CAA requires EPA to designate as nonattainment any area that is violating the NAAQS (or that contributes to ambient air quality in a nearby area that is violating the NAAQS). As part of the designations process for the 2015 8-hour ozone NAAQS, the Atlanta Area [1] was designated as a ''Marginal'' ozone nonattainment area, effective August 3, 2018. *See* 83 FR 25776 (June 4, 2018). Areas that were designated as ''Marginal'' ozone nonattainment areas were required to attain the 2015 8-hour ozone NAAQS no later than three years after the effective date of designation. *See* 40 CFR 51.1303.

On December 6, 2018, EPA issued a final rule entitled ''Implementation of the 2015 National Ambient Air Quality Standards for ozone: State Implementation Plan Requirements'' (SIP Requirements Rule), which establishes the requirements that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where air quality exceeds the 2015 8-hour ozone NAAQS. *See* 83 FR 62998; 40 CFR part 51, subpart CC.

Based on the nonattainment designation for the 2015 8-hour ozone standard, Georgia was required to develop a SIP revision addressing the requirements of CAA sections 172(c)(5) and 173 for the Atlanta Area. *See* 42 U.S.C. 7502(c). Section 172(c)(5) of the CAA requires each state with a nonattainment area to submit a SIP revision requiring NNSR permits in the nonattainment area in accordance with the permitting requirements of CAA section 173.[2] The minimum SIP requirements for NNSR permitting for the 2015 8-hour ozone NAAQS are located in 40 CFR 51.165. *See* 40 CFR 51.1314. On July 2, 2020, Georgia submitted a SIP revision addressing, among other things,[3] permit program requirements (*i.e.,* NNSR) for the 2015 8-hour ozone NAAQS for the Atlanta Area. EPA's analysis of how this SIP revision addresses the NNSR requirements for the 2015 8-hour ozone NAAQS is provided below.

II. Analysis of the State's Submittal

Georgia's longstanding SIP-approved NNSR program, established in Rule 391–3–1–.03(8), *Permit Requirements,* applies to the construction and modification of major stationary sources in nonattainment areas. In its July 2, 2020, SIP revision, Georgia certifies that the version of Rule 391–3–1–.03(8) in the SIP satisfies the federal NNSR requirements for the Atlanta Area. EPA approved Georgia's NNSR certification for the 2008 8-hour ozone NAAQS Atlanta metropolitan nonattainment area [4] into the Georgia SIP on March 22, 2017. *See* 82 FR 14611. The SIP-approved version of Rule 391–3–1–.03(8) has been updated three times since that 2017 rulemaking.

On October 16, 2017, this rule was updated to revise NSR permitting regulations to be consistent with federal regulations. EPA approved changes to Rule 391–3–1.03(8), *Permit Requirements,* at paragraph (g), which revised NNSR rules, and at paragraph (d). *See* 82 FR 47993.

In a January 16, 2020, rulemaking, EPA approved additional changes to Georgia's NNSR permitting rules in

[1] The Atlanta nonattainment area for the 2015 8-hour ozone NAAQS consists of the following counties: Bartow, Clayton, Cobb, DeKalb, Fulton, Gwinnett, and Henry.

[2] CAA Section 173 requires, among other things, emissions offsets. The emissions offset ratio for Marginal ozone nonattainment areas is found in CAA section 182(a)(4).

[3] The other elements of this submittal are being addressed in separate rulemakings.

[4] The former Atlanta nonattainment area for the 2008 8-hour ozone NAAQS, which has since been redesignated to attainment, consists of the following counties: Bartow, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Newton, Paulding, and Rockdale.

391–3–1.03(8), reflecting Georgia's redesignation to attainment for the 2008 8-hour ozone NAAQS for metro Atlanta counties, and designation of the Atlanta Area as a ''Marginal'' nonattainment area for the 2015 ozone NAAQS. *See* 85 FR 2646. Specifically, EPA approved changes to NNSR permitting requirements in Rule 391–3–1–.03(8) that removed the NNSR provisions previously applicable to the counties that were part of the Atlanta 1-hour ozone Area and removed references to that provision, since they no longer applied. In addition, permitting requirements were applied to certain electric generating units (EGUs) located in counties within the maintenance area for the 1997 8-hour ozone NAAQS.[5]

Additionally, on September 16, 2020, EPA approved clarifying and ministerial changes to permitting regulations at Rule 391–3–1–.03(8), *Permit Requirements. See* 85 FR 57694. That action also changed the status of five counties under paragraph (e), which specifies counties that are contributing to the ambient air level of ozone in the listed metropolitan Atlanta counties (including the counties in the current nonattainment area for the 2015 8-hour ozone NAAQS), and approved other minor typographical edits to other subparagraphs for consistent formatting.

Lastly, Rule 391–3–1–.03(8)(c) requires emissions offsets for several counties within and surrounding the metropolitan Atlanta Nonattainment Area (including the counties in the current nonattainment area for the 2015 8-hour ozone NAAQS). This rule continues to exceed the required offset ratios for Marginal ozone nonattainment areas in CAA section 182(a)(4).

The current SIP-approved version of Rule 391–3–1–.03(8), *Permit Requirements,* covers the entire Atlanta Area and remains adequate to meet all applicable NNSR requirements for the 2015 8-hour ozone NAAQS. EPA is therefore proposing to approve Georgia's certification that Rule 391–3–1–.03(8) meets the NNSR requirements for implementation of the 2015 ozone NAAQS.

III. Proposed Action

EPA is proposing to approve Georgia's SIP revision addressing the NNSR requirements for the 2015 8-hour ozone NAAQS for the Atlanta Area, submitted on July 2, 2020. EPA has concluded that Georgia's submission fulfills the 40 CFR 51.1314 requirement and meets the requirements of CAA sections 172(c)(5) and 173 and the minimum SIP requirements of 40 CFR 51.165.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This proposed action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen Oxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 26, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

[FR Doc. 2021–26139 Filed 12–1–21; 8:45 am]

BILLING CODE 6560–50–P

[5] An area redesignated from nonattainment to attainment is referred to as a maintenance area.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2020–0401; FRL–9305–01–R4]

Air Plan Approval; Georgia; Emissions Statements Requirements for the 2015 8-Hour Ozone Standard Atlanta Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve state implementation plan (SIP) revisions submitted by the State of Georgia through the Georgia Environmental Protection Division (GA EPD) on July 2, 2020, and November 4, 2021. Both submittals address the emissions statements requirements for the 2015 8-hour ozone national ambient air quality standards (NAAQS) for the Atlanta, Georgia 2015 8-hour ozone nonattainment area (hereinafter referred to as the ''Atlanta Area''). These requirements apply to all ozone nonattainment areas. The Atlanta Area is comprised of seven counties in and around metropolitan Atlanta (Bartow, Clayton, Cobb, DeKalb, Fulton, Gwinnett, and Henry). This action is being proposed pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before January 3, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2020–0401 at *www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*.

EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include 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 *www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Tiereny Bell, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9088. Ms. Bell can also be reached via electronic mail at *bell.tiereny@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On October 1, 2015, EPA promulgated a revised 8-hour primary and secondary ozone NAAQS, strengthening both from 0.075 parts per million (ppm) to 0.070 ppm (the 2015 8-hour Ozone NAAQS). *See* 80 FR 65292 (October 26, 2015). The 2015 8-hour ozone NAAQS is set at 0.070 ppm based on an annual fourth-highest daily maximum 8-hour average concentration averaged over three years. Under EPA's regulations at 40 CFR part 50, the 2015 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth-highest daily maximum 8-hour average ambient air quality ozone concentration is less than or equal to 0.070 ppm. *See* 40 CFR 50.19. Ambient air quality monitoring data for the 3-year period must meet a data completeness requirement. The ambient air quality monitoring data completeness requirement is met when the average percentage of days with valid ambient monitoring data is greater than 90 percent, and no single year has less than 75 percent data completeness as determined using Appendix U of part 50.

Upon promulgation of a new or revised ozone NAAQS, the CAA requires EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient air quality data at the conclusion of the designation process. On April 30, 2018, EPA designated a 7-county area in and around metropolitan Atlanta as a marginal ozone nonattainment area for the 2015 8-hour ozone NAAQS.[1] The Atlanta Area was designated nonattainment for the 2015 8-hour ozone NAAQS on April 30, 2018 (effective August 3, 2018) using 2014–2016 ambient air quality data. *See* 83 FR 25776 (June 4, 2018). On December 6, 2018, EPA finalized a rule titled ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements'' (SIP Requirements Rule) that establishes the requirements that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where air quality exceeds the 2015 8-hour ozone NAAQS.[2] *See* 83 FR 62998 (December 6, 2018); 40 CFR part 51, subpart CC. This rule establishes nonattainment area attainment dates based on Table 1 of section 181(a) of the CAA, including an attainment date of August 3, 2021, three years after the August 3, 2018, designation effective date, for areas classified as marginal for the 2015 8-hour ozone NAAQS. Based on the nonattainment designation, Georgia was required to develop a SIP revision addressing certain CAA requirements for the Atlanta Area, including, pursuant to CAA section 182(a)(3)(B), a SIP revision addressing the emissions statements requirements.

Ground level ozone is not emitted directly into the air but is created by chemical reactions between oxides of nitrogen (NO_X) and volatile organic compounds (VOC) in the presence of sunlight. Emissions from industrial facilities and electric utilities, motor vehicle exhaust, gasoline vapors, and chemical solvents are some of the major sources of NO_X and VOC. Section 182(a)(3)(B) of the CAA requires states with ozone nonattainment areas to submit a SIP revision requiring annual emissions statements to be submitted to the state by the owner or operator of each NO_X and VOC stationary source. However, a state may waive the emissions statements requirements for any class or category of stationary sources which emit less than 25 tons per year (tpy) of VOC or NO_X if the state provides an inventory of emissions as required by CAA section 182 that accounts for emissions from those sources. *See* CAA section 182(a)(3)(B)(ii). The first statement is due three years from the area's nonattainment designation, and subsequent statements are due at least annually thereafter.

On July 2, 2020, Georgia submitted a SIP revision to address the emissions statements requirements related to the 2015 8-hour ozone NAAQS for the Atlanta Area.[3] On June 28, 2021, to correct a deficiency in the July 2, 2020, submittal, GA EPD submitted a draft SIP revision supplementing that SIP submittal along with a parallel processing request.[4] Subsequently, on November 4, 2021, Georgia submitted the draft June 28, 2021, SIP submittal in final form, thus negating the need for EPA to parallel process the draft June 28, 2021, SIP submittal. EPA is proposing to approve the July 2, 2020, SIP submittal as updated by the November 4, 2021, SIP submittal, as meeting the requirements of section 182(a)(3)(B) of the CAA and associated federal regulations. EPA's analysis of these SIP revisions and how they address the emissions statements requirements is discussed in the analysis of state's submittal section of this notice.

II. Analysis of State's Submittal

As discussed above, section 182(a)(3)(B) of the CAA requires states to submit a SIP revision requiring the owner or operator of each NO_X and VOC stationary source located in an ozone nonattainment area to submit to the state annual emissions statements. The first statement is due three years from

[1] The nonattainment area for the 2015 8-hour ozone standard consists of the following counties: Bartow, Clayton, Cobb, DeKalb, Fulton, Gwinnett, and Henry.

[2] The SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2015 8-hour ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress, reasonably available control technology, reasonably available control measures, major nonattainment new source review, emission inventories, and the timing of SIP submissions and compliance with emission control measures in the SIP.

[3] In the July 2, 2020, SIP revision, GA EPD submitted a certification that existing Georgia rules satisfy the permit program requirements in section 172(c)(5) and section 173 of the CAA. GA EPD also provided an emissions inventory to satisfy the requirements in section 182(a)(1) of the CAA. EPA will take action on these SIP revisions in separate rulemakings.

[4] Georgia's July 2, 2020, SIP revision included a request for conditional approval regarding the emissions statements requirements. Under CAA section 110(k)(4), EPA may conditionally approve a SIP revision based on a commitment from a state to adopt specific enforceable measures by a date certain, but not later than one year from the date of approval. Georgia's November 4, 2021, SIP revision supplements the July 2, 2020, submittal described later in this section and renders the conditional approval request moot as discussed in section II.

the area's nonattainment designation, and subsequent statements are due at least annually thereafter.

In 1996, EPA incorporated Georgia Rule 391–3–1–.02(6)(a)4, *Emissions Statements,* into the SIP. *See* 61 FR 3819 (February 2, 1996). At that time, this regulation applied to stationary sources within Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Paulding, and Rockdale Counties. Georgia subsequently amended the regulation to, among other things, include Bartow and Newton Counties thereby covering the entire Atlanta Area. EPA incorporated these amendments into the SIP in 2009. *See* 74 FR 62249 (November 27, 2009). In Georgia's July 2, 2020, SIP revision, Georgia certified that this SIP-approved regulation meets the requirements of CAA Section 182(a)(3)(B) for the Area.[5] Georgia's SIP-approved regulation at 391–3–1–.02(6)(a)4(iii) states that the emissions statements requirements in 391–3–1–.02(6)(a)4 apply to all stationary sources of nitrogen oxides or volatile organic compounds which emit more than 25 tons per calendar of either pollutant and are located in Barrow, Bartow, Carroll, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Hall, Henry, Newton, Paulding, Rockdale, Spalding, or Walton counties. Pursuant to section 182(a)(3)(B), however, emissions statements are required for all sources that emit 25 tons per year or more of either pollutant if the waiver criteria are met. Therefore, Georgia requested conditional approval of its July 2, 2020, SIP revision and committed to satisfy section 182(a)(3)(B) for the 2015 8-hour ozone NAAQS by revising Georgia Rule 391–3–1–.02(6)(a)4(iii) so that emissions reporting is also required for sources that emit exactly 25 tons of VOC or NO_X per calendar year. The State committed to adopt this rule revision no later than one year after EPA's conditional approval of Georgia's July 2, 2020, SIP revision.

On June 28, 2021, Georgia submitted a draft SIP revision for parallel processing to supplement the July 2, 2020 SIP revision. The June 28, 2021, submittal includes the new draft of Georgia Rule 391–3–1–.02(6)(a)4(iii) and states that the aforementioned change to the rule was presented to the Georgia Department of Natural Resources Board of Directors (DNR Board) for adoption at its September 28, 2021, meeting, along with changes to the rule to reflect only the counties comprising the Atlanta Area. The submittal says that the changes will be submitted to EPA as a SIP revision. The draft June 28, 2021, SIP revision was submitted in final form on November 4, 2021.

As allowed by CAA section 182(a)(3)(B)(ii), Georgia waived the emissions statements requirement for stationary sources emitting less than 25 tpy of NO_X or VOC because the State included these emissions in an emissions inventory it submitted to EPA pursuant to CAA section 182(a)(1) for the Atlanta Area. CAA section 182(a)(3)(B)(ii) allows the state to waive the application of emissions statements requirements to any class or category of stationary sources which emit less than 25 tons per year of VOC or NO_X if the State, in its submissions under section 182(a)(1) or 182(a)(3)(A),[6] provides an inventory of emissions from such class or category of sources, based on the use of the emission factors established by the Administrator or other methods acceptable to the Administrator.

Pursuant to CAA Section 182(a)(1), Georgia is required to submit a comprehensive, accurate, current inventory of actual emissions from all sources, as described in CAA section 172(c)(3), in accordance with guidance provided by the Administrator. CAA Section 172(c)(3) states, ''Such plan provisions shall include a comprehensive, accurate, current inventory of actual emissions from all sources of the relevant pollutant or pollutants in such area including such periodic revisions as the Administrator may determine necessary to assure that the requirements of this part are met.'' Georgia's July 2, 2020, SIP revision includes an emissions inventory submitted pursuant to CAA section 182(a)(1) and states that it was prepared consistent with 83 FR 62998, ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements,'' and 40 CFR part 51.1315.'' Stationary sources emitting less than 25 tpy of NO_X or VOC are included in Georgia's inventory in accordance with CAA section 182(a)(3)(B)(ii).

The emissions inventory that GA EPD provided in its submission to satisfy the requirements in section 182(a)(1) of the CAA is included in the docket for this rulemaking. EPA has proposed to approve the emissions inventory portion of the July 2, 2020, SIP submission in a separate rulemaking. Given the waiver criteria in section 182(a)(3)(B)(ii), EPA cannot approve the emissions statement portion of the July 2, 2020, SIP submission as proposed herein unless EPA finalizes approval of the emissions inventory portion of the submission in that separate rulemaking.

EPA has preliminarily determined that Georgia's revised emissions statements regulation meets the requirements under CAA section 182(a)(3)(B) and the SIP Requirements Rule for the 2015 8-hour ozone NAAQS. Therefore, a conditional approval of the July 2, 2020, SIP submittal is no longer necessary. Accordingly, EPA is proposing to approve the July 2, 2020, SIP submittal, as updated by the November 4, 2021, SIP submittal.

III. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference Rule 391–3–1–.02(6)(a)4(iii), state-effective October 25, 2021. EPA has made and will continue to make these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Proposed Action

EPA is proposing to approve the July 2, 2020, SIP revision, as updated by the November 4, 2021, SIP submittal, related to the emissions statements requirements for the 2015 8-hour ozone NAAQS for the Atlanta Area. EPA has preliminarily determined that Georgia's SIP revisions requesting approval meet the requirements of CAA section 182(a)(3)(B).[7] EPA proposes to find that the aforementioned submissions meet the requirements of sections 110 and 182 of the CAA.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided they meet the criteria of the

[5] As discussed in the preamble to the SIP Requirements Rule, a state may rely on emissions statement rules in force and approved by EPA for the 2015 8-hour ozone NAAQS provided that the rules remain adequate and cover all portions of the 2015 ozone NAAQS nonattainment areas. *See* 83 FR 62998 (December 6, 2018).

[6] CAA section 182(a)(3)(A) contains a triennial emissions inventory requirement.

[7] As discussed in section II, EPA cannot approve the emissions statement portion of the July 2, 2020, SIP submission as proposed herein unless EPA finalizes approval of the emissions inventory portion of the submission.

CAA. This proposed action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 26, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

[FR Doc. 2021–26140 Filed 12–1–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

[Docket No. 211129–0246; RTID 0648–XR118]

Endangered and Threatened Wildlife; 90-Day Finding on a Petition To List the Atlantic Humpback Dolphin as Threatened or Endangered Under the Endangered Species Act

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

ACTION: 90-Day petition finding, request for information, and initiation of status review.

SUMMARY: We, NMFS, announce a 90-day finding on a petition to list the Atlantic humpback dolphin (*Sousa teuszii*) as threatened or endangered under the Endangered Species Act (ESA). We find that the petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted. Therefore, we are initiating a status review of the species to determine whether listing under the ESA is warranted. To ensure this status review is comprehensive, we are soliciting scientific and commercial information regarding this species.

DATES: Scientific and commercial information pertinent to the petitioned action must be received by January 31, 2022.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2021–0110 by the following method:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2021–0110 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Interested persons may obtain a copy of the petition online at the NMFS website: *https://www.fisheries.noaa.gov/national/endangered-species-conservation/petitions-awaiting-90-day-findings.*

FOR FURTHER INFORMATION CONTACT: Heather Austin, NMFS Office of Protected Resources, (301) 427–8422, *Heather.Austin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On September 8, 2021, we received a petition from the Animal Welfare Institute, the Center for Biological Diversity, and VIVA Vaquita to list the Atlantic humpback dolphin (*Sousa teuszii*) as a threatened or endangered species under the ESA. The petition asserts that *Sousa teuszii* is threatened by four of the five ESA section 4(a)(1) factors: (1) The present destruction or modification of its habitat; (2) overutilization for commercial purposes; (3) inadequacy of existing regulatory mechanisms; and (4) manmade factors affecting its continued existence. The petition is available online (see **ADDRESSES**).

ESA Statutory, Regulatory, and Policy Provisions and Evaluation Framework

Section 4(b)(3)(A) of the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires, to the maximum extent practicable, that within 90 days of receipt of a petition to list a species as threatened or endangered, the Secretary of Commerce make a finding on whether that petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted, and to promptly publish such finding in the **Federal Register** (16 U.S.C. 1533(b)(3)(A)). When it is found that substantial scientific or commercial information in a petition indicates the petitioned action may be warranted (a ''positive 90-day finding''), we are required to promptly commence a review of the status of the species concerned during which we will conduct a comprehensive review of the best available scientific and commercial information. In such cases, we conclude

the review with a finding as to whether, in fact, the petitioned action is warranted within 12 months of receipt of the petition. Because the finding at the 12-month stage is based on a more thorough review of the available information, as compared to the narrow scope of review at the 90-day stage, a ''may be warranted'' finding does not prejudge the outcome of the status review.

Under the ESA, a listing determination may address a species, which is defined to also include subspecies and, for any vertebrate species, any distinct population segment (DPS) that interbreeds when mature (16 U.S.C. 1532(16)). A joint NMFS–U.S. Fish and Wildlife Service (USFWS) (jointly, ''the Services'') policy clarifies the agencies' interpretation of the phrase ''distinct population segment'' for the purposes of listing, delisting, and reclassifying a species under the ESA (61 FR 4722; February 7, 1996). A species, subspecies, or DPS is ''endangered'' if it is in danger of extinction throughout all or a significant portion of its range, and ''threatened'' if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range (ESA sections 3(6) and 3(20), respectively, 16 U.S.C. 1532(6) and (20)). Pursuant to the ESA and our implementing regulations, we determine whether species are threatened or endangered based on any one or a combination of the following five section 4(a)(1) factors: (1) The present or threatened destruction, modification, or curtailment of habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) inadequacy of existing regulatory mechanisms to address identified threats; (5) or any other natural or manmade factors affecting the species' existence (16 U.S.C. 1533(a)(1), 50 CFR 424.11(c)).

ESA-implementing regulations issued jointly by NMFS and USFWS (50 CFR 424.14(h)(1)(i)) define ''substantial scientific or commercial information'' in the context of reviewing a petition to list, delist, or reclassify a species as ''credible scientific or commercial information in support of the petition's claims such that a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted.'' Conclusions drawn in the petition without the support of credible scientific or commercial information will not be considered ''substantial information.'' In reaching the initial (90-day) finding on the petition, we will consider the information described in sections 50 CFR 424.14(c), (d), and (g) (if applicable).

Our determination as to whether the petition provides substantial scientific or commercial information indicating that the petitioned action may be warranted will depend in part on the degree to which the petition includes the following types of information: (1) Information on current population status and trends and estimates of current population sizes and distributions, both in captivity and the wild, if available; (2) identification of the factors under section 4(a)(1) of the ESA that may affect the species and where these factors are acting upon the species; (3) whether and to what extent any or all of the factors alone or in combination identified in section 4(a)(1) of the ESA may cause the species to be an endangered species or threatened species (*i.e,* the species is currently in danger of extinction or is likely to become so within the foreseeable future), and, if so, how high in magnitude and how imminent the threats to the species and its habitat are; (4) information on adequacy of regulatory protections and effectiveness of conservation activities by States as well as other parties, that have been initiated or that are ongoing, that may protect the species or its habitat; and (5) a complete, balanced representation of the relevant facts, including information that may contradict claims in the petition. *See* 50 CFR 424.14(d).

If the petitioner provides supplemental information before the initial finding is made and states that it is part of the petition, the new information, along with the previously submitted information, is treated as a new petition that supersedes the original petition, and the statutory timeframes will begin when such supplemental information is received. *See* 50 CFR 424.14(g).

We may also consider information readily available at the time the determination is made (50 CFR 424.14(h)(1)(ii)). We are not required to consider any supporting materials cited by the petitioner if the petitioner does not provide electronic or hard copies, to the extent permitted by U.S. copyright law, or appropriate excerpts or quotations from those materials (*e.g.,* publications, maps, reports, letters from authorities). *See* 50 CFR 424.14(c)(6).

The ''substantial scientific or commercial information'' standard must be applied in light of any prior reviews or findings we have made on the listing status of the species that is the subject of the petition (50 CFR 424.14(h)(1)(iii)). Where we have already conducted a finding on, or review of, the listing status of that species (whether in response to a petition or on our own initiative), we will evaluate any petition received thereafter seeking to list, delist, or reclassify that species to determine whether a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted despite the previous review or finding. Where the prior review resulted in a final agency action—such as a final listing determination, 90-day not-substantial finding, or 12-month not-warranted finding—a petition will generally not be considered to present substantial scientific and commercial information indicating that the petitioned action may be warranted unless the petition provides new information or analysis not previously considered. *See* 50 CFR 424.14(h)(1)(iii).

At the 90-day finding stage, we do not conduct additional research, and we do not solicit information from parties outside the agency to help us in evaluating the petition. We will accept the petitioners' sources and characterizations of the information presented if they appear to be based on accepted scientific principles, unless we have specific information in our files that indicates the petition's information is incorrect, unreliable, obsolete, or otherwise irrelevant to the requested action. Information that is susceptible to more than one interpretation or that is contradicted by other available information will not be dismissed at the 90-day finding stage, so long as it is reliable and a reasonable person conducting an impartial scientific review would conclude it supports the petitioners' assertions. In other words, conclusive information indicating the species may meet the ESA's requirements for listing is not required to make a positive 90-day finding. We will not conclude that a lack of specific information alone necessitates a negative 90-day finding if a reasonable person conducting an impartial scientific review would conclude that the unknown information itself suggests the species may be at risk of extinction presently or within the foreseeable future.

To make a 90-day finding on a petition to list a species, we first evaluate whether the information presented in the petition, in light of the information readily available in our files, indicates that the petitioned entity constitutes a ''species'' eligible for listing under the ESA. Next, if we conclude the petition presents substantial scientific or commercial information suggesting that the petitioned entity may constitute a

''species,'' we evaluate whether the information indicates that the species may face an extinction risk such that listing, delisting, or reclassification may be warranted; this may be indicated in information expressly discussing the species' status and trends, or in information describing impacts and threats to the species. We evaluate whether the petition presents any information on specific demographic factors pertinent to evaluating extinction risk for the species (*e.g.,* population abundance and trends, productivity, spatial structure, age structure, sex ratio, diversity, current and historical range, habitat integrity or fragmentation), and the potential contribution of identified demographic risks to extinction risk for the species. We then evaluate whether the petition presents information suggesting potential links between these demographic risks and the causative impacts and threats identified in section 4(a)(1) of the ESA.

Information presented on impacts or threats should be specific to the species and should reasonably suggest that one or more of these factors may be operative threats that act or have acted on the species to the point that it may warrant protection under the ESA. Broad statements about generalized threats to the species, or identification of factors that could negatively impact a species, do not constitute substantial information indicating that listing may be warranted. We look for information indicating that not only is the particular species exposed to a factor, but that the species may be responding in a negative fashion; then we assess the potential significance of that negative response.

Many petitions identify risk classifications made by nongovernmental organizations, such as the International Union on the Conservation of Nature (IUCN), the American Fisheries Society, or NatureServe, as evidence of extinction risk for a species. Risk classifications by such organizations or made under other Federal or state statutes may be informative, but such classification alone may not provide the rationale for a positive 90-day finding under the ESA. For example, as explained by NatureServe, their assessments of a species' conservation status do ''not constitute a recommendation by NatureServe for listing under the U.S. ESA'' because NatureServe assessments ''have different criteria, evidence requirements, purposes, and taxonomic coverage than official lists of endangered and threatened species'', and therefore these two types of lists should not be expected to ''coincide'' (*https://explorer.natureserve.org/AboutTheData/DataTypes/ConservationStatusCategories*). Additionally, species classifications under IUCN and the ESA are not equivalent; data standards, criteria used to evaluate species, and treatment of uncertainty are also not necessarily the same. Thus, when a petition cites such classifications, we will evaluate the source of information that the classification is based upon in light of the standards on extinction risk and impacts or threats discussed above.

Taxonomy

The petition presents information on the taxonomy of the species, including information and references regarding the earliest description of the species primarily on differences in the skull compared to other humpback dolphins known at the time (Kükenthal 1891, Collins 2015, Collins *et al.* 2017). The distinctness of the species from other humpback dolphins has been questioned over the years (Ross *et al.* 1995), but more recent genetic and morphological work (Jefferson and Van Waerebeek 2004, Mendez *et al.* 2013, Jefferson and Rosenbaum 2014) has clarified the taxonomy of the genus *Sousa* and provides multiple lines of evidence that *S. teuszii* is a species separate from the other three of the genus *Sousa: S. plumbea* (Indian Ocean humpback dolphin), *S. chinensis* (Indo-Pacific humpback dolphin), and *S. sahulensis* (Australian humpback dolphin) (Jefferson and Rosenbaum 2014). Thus, we conclude that the petitioned entity, *S. teuszii,* constitutes a taxonomically distinct species eligible for listing under the ESA.

Distribution, Habitat, and Life History

The Atlantic humpback dolphin is described as an obligate shallow water dolphin and is endemic to the tropical and subtropical eastern Atlantic nearshore waters (<30 m) of western Africa, ranging from Western Sahara to Angola (Collins 2015, Weir and Collins 2015). This species is the only member of the genus that occurs outside of the Indo-Pacific region (Mendez *et al.* 2013, Jefferson and Rosenbaum 2014, Collins 2015). Although each of the 19 countries between (and including) Western Sahara and Angola are presumed to be part of the species' natural range, the current distribution is uncertain given incomplete research coverage, including an absence of survey effort in many areas. Currently, there are only confirmed records of occurrence in the following 13 countries: Western Sahara, Mauritania, Senegal, The Gambia, Guinea-Bissau, Guinea, Togo, Benin, Nigeria, Cameroon, Gabon, Republic of the Congo, and Angola (Minton *et al.* 2020). The 6 countries with no confirmed records (Sierra Leone, Liberia, Côte d'Ivoire, Ghana, mainland Equatorial Guinea, and the Democratic Republic of the Congo) are poorly studied and have received little or no systematic cetacean or coastal research (Collins *et al.* 2017). Work conducted in Ghana by Van Waerebeek *et al.* (2009) confirms the absence of *S. teuszii* records, which may be due to localized extirpation of the species in Ghanaian waters. The species is not known to occur around any of the larger offshore islands of the Gulf of Guinea, including Sao Tome and Principe or Bioko (Fernando Póo) and Annabon (Pagalu) (Van Waerebeek *et al.* 2004). Eleven putative ''management stocks'' (*i.e* subpopulations) of *S. teuszii* have been recognized based on localities or countries where the species has been recorded and evidence of gaps in the species' range (Van Waerebeek *et al.* 2004, Collins 2015, Collins *et al.* 2017).

Migrations and movements are poorly understood largely because tagging work has never been done on this species (Collins *et al.* 2017). Localized movements have been linked to feeding opportunities facilitated by tides, where Atlantic humpback dolphins feed primarily on coastal, estuarine, and reef-associated fishes (Busnel 1973, Collins 2015, Collins *et al.* 2017). Large-scale migrations are rarely documented but have been inferred using local accounts and sightings from fishermen, and smaller-scale shifts in abundance have been postulated (based on fragmentary evidence) (Collins 2015, Collins *et al.* 2017). However, movements across national boundaries have been documented, and records elsewhere suggest transboundary movements (Collins 2015, Collins *et al.* 2017).

The Atlantic humpback dolphin has specific habitat requirements, which could limit its resilience and ability to escape environmental and anthropogenic stressors (Collins 2015). It occurs exclusively in shallow (<30 m) depths, in warm nearshore waters (average sea surface temperatures ranging from 15.8° to 31.8° Celsius), and in dynamic habitats strongly influenced by tidal patterns (*e.g.,* sandbanks, deltas, estuaries, and mangrove systems) (Collins 2015, Weir and Collins 2015, Taylor *et al.* 2020).

Data and information regarding life history and reproduction parameters are almost nonexistent for this species. An estimated generation length of 18.4 years is given for the Atlantic humpback dolphin, although a figure closer to 25 years is provided for the Indo-Pacific humpback dolphin (*S. chinensis*) and

Indian Ocean humpback dolphin (*S. plumbea*) (Collins 2015, Collins *et al.* 2017). Births are thought to occur in March and April, based upon observations of juveniles (Van Waerebeek *et al.* 2004, Collins 2015). The species is suspected to be sexually dimorphic (males larger at maturity and with a more prominent dorsal hump), but the current sample size (~20 individuals) is too small to assess this statistically (Jefferson and Rosenbaum 2014).

Abundance and Population Trends

Abundance data are very limited for *S. teuszii* and robust abundance estimates are lacking for most stocks. However, approximate, general estimates have been made for the 11 recognized stocks (which are subjective and based on the knowledge of a limited number of researchers) and range from the tens to low hundreds of individuals per stock (Collins 2015, Collins *et al.* 2017).

Comprehensive reviews conducted by Collins (2015) and Collins *et al.* (2017) on all available *S. teuszii* population biology data, reinforce general inferences of small total population size. These reviews concluded that the species probably includes fewer than 3,000 individuals (Collins 2015, Collins *et al.* 2017). If it is assumed that 50 percent of these are mature individuals, then the number of mature individuals in the total population would be no more than 1,500 (Collins *et al.* 2017, Brownell *et al.* 2019).

Because robust abundance estimates for this species are lacking, there are no quantitative assessments of population trends and status. However, the evidence of recent work in some areas and a consensus of expert opinions indicate that most stocks of *S. teuszii* are small and that all stocks have experienced significant declines in recent decades (Collins 2015, Collins *et al.* 2017). Limited research effort for each putative *S. teuszii* stock has either identified significant mortality or yielded strong evidence to infer it (Van Waerebeek *et al.* 2004, Collins 2015, Collins *et al.* 2017). According to Collins (2015) and Collins *et al.* (2017), artisanal fishing bycatch and directed takes are the principal causes of these declines, although these authors also suggest that habitat loss is likely a contributing factor as well. Reported dolphin bycatch has been coupled with observed or suspected declines of *S. teuszii* in Guinea-Bissau, which together with neighboring Guinea, is believed to host the largest population of the species (Collins 2015, Collins *et al.* 2017).

In summary, while data on abundance and population trends are largely absent, the information presented in the petition indicates that the species consists of small, fragmented stocks, and may be declining across its range.

Analysis of ESA Section 4(a)(1) Factors

The petition asserts that *S. teuszii* is threatened by four of the five ESA section 4(a)(1) factors: The present destruction or modification of its habitat due to pollution and development, overutilization for commercial purposes via fisheries bycatch, inadequacy of existing regulatory mechanisms, and manmade factors affecting its continued existence, including fisheries bycatch and prey depletion, deliberate capture, coastal development, and anthropogenic noise. Information in the petition and readily available in our files indicates that the primary threat facing the species is fisheries bycatch. Therefore, we focus our discussion below on the evidence of this particular threat. However, we note that in the status review for this species, we will evaluate all ESA section 4(a)(1) factors to determine whether any one or a combination of these factors are causing declines in the species or are likely to substantially negatively affect the species within the foreseeable future to such a point that the Atlantic humpback dolphin is at risk of extinction or likely to become so in the foreseeable future.

Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

According to information cited in the petition and readily available in our files, the greatest threat to the Atlantic humpback dolphin is fisheries bycatch. Bycatch of Atlantic humpback dolphins in artisanal gillnets is considered widespread throughout the species' range (Collins 2015, Collins *et al.* 2017, Jefferson 2019). This threat has been identified or suspected throughout much of the species' range and for as long as the species has been studied (Van Waerebeek *et al.* 2004, Collins 2015, Collins *et al.* 2017, Brownell *et al.* 2019, Jefferson 2019).

Work in Conkouati Douli National Park (Republic of the Congo) provides some indication of the potential scale of *S. teuszii* bycatch and substantial bycatch risk for the species (Collins 2015). An intensive monitoring, enforcement, and cooperative (incentivized) reporting program identified 19 dolphins that were caught as bycatch over 5 years across all artisanal landing sites (n = 14) along a 60-km stretch of protected beach (Collins 2015). Out of the 19 dolphins caught as bycatch, 10 were identified as *S. teuszii,* and the testimony of fishermen showed that all were caught in gillnets less than 1 kilometer from shore (Collins 2015, Collins *et al.* 2017). While mortality figures have been reported for other areas including Banc d'Arguin and the Saloum Delta, the monitoring of bycatch in these aforementioned areas is either non-existent or limited to very few landing sites (Van Waerebeek *et al.* 2004, Collins 2015, Collins *et al.* 2017). Thus, the reported bycatch figures are likely to be underestimates of the true level of mortality.

Although there is no evidence of any organized, directed fisheries for *S. teuszii,* there is a concern that bycatch can develop into ''directed entanglement'' or ''non-target-deliberate acquisition'', where fishermen may intentionally try to catch Atlantic humpback dolphins in gillnets originally intended for other species (especially if there is a market for such catches) (Clapham and Van Waerebeek 2007, Collins 2015). While the scale of this practice is unknown, the use of cetaceans for human consumption has been documented in West Africa which provides a potential market for cetacean products and reflects general fisheries declines (Van Waerebeek *et al.* 2004, Clapham and Van Waerebeek 2007, Collins 2015, Jefferson 2019). Clapham and Van Waerebeek (2007) noted that market surveys conducted in West African coastal nations indicated that the sale and consumption of cetacean and sea turtle products is common. Additionally, these sales contribute to the economic viability of gillnet fisheries in Ghana, which includes killing of live entangled animals, and using dolphin meat as bait (Van Waerebeek *et al.* 2004, Clapham and Van Waerebeek 2007, Collins 2015). However, it is important to note that because captures may be concealed, given legal prohibitions, acquiring reliable data from surveys remains a challenge in some areas (Van Waerebeek *et al.* 2004, Collins 2015, Collins *et al.* 2017).

The extensive spread of migrant fishermen across western Africa over the past few decades is a related concern, which can augment existing fisheries bycatch issues in areas (or even bring these issues to areas where they did not previously exist) (Collins 2015, Collins *et al.* 2017). Migrant fishermen (including those who move within countries) may not abide by local regulations, injunctions, taboos, or laws, and are often better equipped and more aggressive in their exploitation of local resources (Collins 2015). They have

been implicated in the captures of *S. teuszii* in areas adjacent to the Banc d'Arguin (Collins 2015). Additionally, Collins (2015) notes that migrant fishermen from Senegal, Guinea (Conakry), and Sierra Leone have been found exploiting waters of Guinea-Bissau, which does not have a strong fishing tradition, and thus the artisanal fishing tradition is limited in this country's waters. However, captures of dolphins and manatees, along with declines of nesting sea turtles have been reported, thus raising concern for *S. teuszii* (Collins 2015, Collins *et al.* 2017).

In general, declines in other target fish species may affect the Atlantic humpback dolphin population by increasing artisanal fishing effort and pressure, leading to increased bycatch risk for the species (Collins 2015, Collins *et al.* 2017). Industrial fisheries compound this issue by competing for increasingly scant resources, as well as fishing in zones set aside for artisanal fishermen and areas where dolphins are known to occur (Collins 2015, Collins *et al.* 2017). For example, Collins (2015) notes that trawlers fishing illegally within Conkouati Douli National Park (Republic of the Congo) impel artisanal fishermen to set their nets closer to shore (for fear of losing their nets in trawls), raising bycatch risks for coastal species, like *S. teuszii.*

Overall, the information presented in the petition and briefly summarized here regarding the Atlantic humpback dolphin's specific habitat requirements, low estimated abundance, fragmented distribution, and the immediate threat of fisheries bycatch and potential targeted harvest lead us to conclude that listing the species as threatened or endangered may be warranted.

Petition Finding

After reviewing the petition, the literature cited in the petition, and other information readily available in our files, we find that listing *S. teuszii* as a threatened or endangered species may be warranted. Therefore, in accordance with section 4(b)(3)(A) of the ESA and NMFS' implementing regulations (50 CFR 424.14(h)(2)), we will commence a status review of this species. During the status review, we will determine whether *S. teuszii* is in danger of extinction (endangered) or likely to become so in the foreseeable future (threatened) throughout all or a significant portion of its range. As required by section 4(b)(3)(B) of the ESA, within 12 months of the receipt of the petition (September 8, 2021), we will make a finding as to whether listing the Atlantic humpback dolphin as an endangered or threatened species is warranted. If listing is warranted, we will publish a proposed rule and solicit public comments before developing and publishing a final rule.

Information Solicited

To ensure that the status review is based on the best available scientific and commercial data, we are soliciting comments and information from interested parties on the status of the Atlantic humpback dolphin. Specifically, we are soliciting information in the following areas:

(1) Historical and current abundance and population trends of *S. teuszii* throughout its range;

(2) Historical and current distribution and population structure of *S. teuszii;*

(3) Information on *S. teuszii* site fidelity, population connectivity, and movements within and between populations (including estimates of genetic diversity across and within populations);

(4) Historical and current condition of *S. teuszii* habitat;

(5) Information on *S. teuszii* life history and reproductive parameters;

(6) Data on *S. teuszii* diet and prey;

(7) Information and data on common *S. teuszii* disease(s) and/or contaminant exposure;

(8) Historical and current data on *S. teuszii* catch, bycatch, and retention in industrial, commercial, artisanal, and recreational fisheries throughout its range;

(9) Past, current, and potential threats, including any current or planned activities that may adversely impact *S. teuszii* over the short-term or long-term;

(10) Data on trade of *S. teuszii* products; and

(11) Management, regulatory, or conservation programs for *S. teuszii,* including mitigation measures related to any known or potential threats to the species throughout its range.

We request that all data and information be accompanied by supporting documentation such as maps, bibliographic references, or reprints of pertinent publications. Please send any comments in accordance with the instructions provided in the **ADDRESSES** section above. We will base our findings on a review of the best available scientific and commercial data, including relevant information received during the public comment period.

References Cited

A complete list of all references cited herein is available upon request (See **FOR FURTHER INFORMATION CONTACT**).

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: November 29, 2021.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2021–26225 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 211122–0241;RTID 0648–XX073]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; 2022 and Projected 2023 Specifications

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes Atlantic bluefish specifications for the 2022 fishing year, and projected specifications for fishing year 2023, as recommended by the Mid-Atlantic Fishery Management Council. This action is necessary to establish allowable harvest levels to prevent overfishing while enabling optimum yield, using the best scientific information available. This rule also informs the public of the proposed fishery specifications and provides an opportunity for comment.

DATES: Comments must be received by December 17, 2021.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2021–0107, by the following method:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *https://www.regulations.gov,* and enter ''NOAA–NMFS–2021–0107'' in the Search box;

2. Click the ''Comment'' icon, complete the required fields; and

3. Enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying

information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). If you are unable to submit your comment through *www.regulations.gov,* contact Cynthia Ferrio, Fishery Policy Analyst, *Cynthia.Ferrio@noaa.gov.*

The Mid-Atlantic Fishery Management Council prepared a draft environmental assessment (EA) for this action that describes the proposed measures and other considered alternatives. The EA also provides an economic analysis, as well as an analysis of the biological, economic, and social impacts of the proposed measures and other considered alternatives. Copies of the specifications document, including the EA and information on the economic impacts of the proposed measures, are available on request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. These documents are also accessible via the internet at *http://www.mafmc.org/supporting-documents.*

FOR FURTHER INFORMATION CONTACT: Cynthia Ferrio, Fishery Policy Analyst, (978) 281–9180.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission jointly manage the Atlantic Bluefish Fishery Management Plan (FMP). The FMP requires the specification of an acceptable biological catch (ABC), commercial and recreational annual catch limits (ACL), commercial and recreational annual catch targets (ACT), a commercial quota, a recreational harvest limit (RHL), and any other management measures, for up to three years at a time. This action proposes bluefish catch limit specifications for the 2022 fishing year, and projects specifications for 2023, based on Council and Commission recommendations.

These proposed specifications are based on a 2021 assessment update and the recent Amendment 7 to the Bluefish FMP, as well as recommendations from the Council's Scientific and Statistical Committee (SSC) and the Bluefish Monitoring Committee. Amendment 7 was adopted by the Council and Commission in early June 2021, and the final rule published on November 24, 2021, 86 FR 66977. This amendment would implement management measures that affect these proposed specifications, including a rebuilding plan and reallocation of annual quotas between fishery sectors and among states. These proposed specifications were developed based on Amendment 7 measures, and these specifications would implement the first year of the rebuilding plan as well as begin the phasing in of the reallocation of commercial quota to the states in 2022.

There was a 3.65 million-lb (1,656-mt) overage of the fishery ACL caused by recreational catch in 2020. Because the bluefish fishery is overfished, the accountability measure (AM) required by the FMP at 50 CFR 648.163(d)(1) is a pound-for-pound payback of the overage against the soonest possible year's recreational ACT as a single-year adjustment. The 2020 overage AM would therefore be applied to the 2022 specifications under this proposed action. No sector transfer is allowed through these specifications because the stock is still overfished and new sector transfer provisions of Amendment 7 do not allow transfer in this situation. No changes are proposed to recreational management measures because the expected recreational landings under the existing measures are very close to fully achieving the proposed RHL.

Proposed Specifications

This action proposes the Council's recommendations for 2022 and projected 2023 bluefish catch specifications, which are consistent with the SSC and Monitoring Committee recommendations (Table 1). These proposed specifications would increase the fishery ABC by about 55 percent in 2022, and by 21 percent the following year in 2023. The commercial quota and RHL are also proposed to increase by 28 percent and 67 percent in 2022, respectively, and again by 21 percent and 59 percent in 2023.

TABLE 1—COMPARISON OF 2021, PROPOSED 2022, AND PROJECTED 2023 BLUEFISH SPECIFICATIONS *

	2021		2022 (Proposed)		2023 (Projected)	
	Million lb	Metric tons	Million lb	Metric tons	Million lb	Metric tons
Overfishing Limit	32.98	17,228	40.56	18,399	45.17	20,490
ABC = Fishery ACL	16.28	7,385	25.26	11,460	30.62	13,890
Commercial ACL = Commercial ACT	2.77	1,255	3.54	1,604	4.29	1,945
Recreational ACL = Recreational ACT	13.51	6,130	21.73	9,856	26.34	11,945
Recreational Accountability Measures	0	0	3.65	1,656	0	0
Commercial Total Allowable Landings (TAL)	2.77	1,255	3.54	1,604	4.29	1,945
Recreational TAL	8.34	3,785	13.89	6,298	22.14	10,044
Sector Transfer	0	0	0	0	0	0
Commercial Quota	2.77	1,255	3.54	1,604	4.29	1,945
RHL	8.34	3,785	13.89	6,298	22.14	10,044

* Specifications are derived from the ABC in metric tons (mt). When values are converted to millions of pounds the numbers may slightly shift due to rounding. The conversion factor used is 1 mt = 2204.6226 lb.

Table 2 provides the proposed commercial state allocations based on the Council-recommended coastwide commercial quotas for 2022 and 2023, and the phased-in changes to the percent share allocations to the states specified in Amendment 7. No states exceeded their allocated quota in 2020, or are projected to do so in 2021; therefore, no accountability measures for the commercial fishery are required for the 2022 fishing year at this time.

TABLE 2—PROPOSED 2022 AND PROJECTED 2023 BLUEFISH STATE COMMERCIAL QUOTA ALLOCATIONS

State	2022 (Proposed)			2023 (Projected)		
	Percent share	Quota (lb)	Quota (kg)	Percent share	Quota (lb)	Quota (kg)
Maine	0.59	20,819	9,443	0.51	21,807	9,892
New Hampshire	0.39	13,655	6,194	0.36	15,331	6,954
Massachusetts	7.20	254,748	115,552	7.69	329,578	149,494
Rhode Island	7.21	254,956	115,646	7.61	326,165	147,946
Connecticut	1.24	43,885	19,906	1.22	52,094	23,629
New York	11.72	414,693	188,102	13.06	560,031	254,026
New Jersey	14.68	519,158	235,486	14.54	623,295	282,722
Delaware	1.68	59,442	26,962	1.48	63,572	28,836
Maryland	2.85	100,698	45,676	2.69	115,409	52,349
Virginia	11.02	389,802	176,811	10.16	435,625	197,596
North Carolina	32.06	1,133,855	514,308	32.05	1,374,077	623,271
South Carolina	0.04	1,590	721	0.05	2,344	1,063
Georgia	0.02	805	365	0.04	1,544	700
Florida	9.31	329,137	149,294	8.55	366,585	166,280
Total	100.00	3,537,096	1,604,400	100.01	4,287,109	1,944,600

As previously mentioned, no changes to the recreational management measures are proposed in this action, as the expected recreational landings of 13.58 million lb (6,160 mt) under the existing measures are likely to achieve the proposed RHL. All other federal management measures would also remain unchanged under this action.

The projected specifications for 2023 are based on the available data and the second year of the rebuilding plan model. However, there is a research track stock assessment scheduled for bluefish in 2022. The Council will review the projected 2023 specifications in light of any new information, including this assessment, to determine if changes need to be made prior to their implementation. NMFS will publish a notice prior to the 2023 fishing year to confirm these limits as projected or announce any necessary changes.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Atlantic Bluefish FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This action is exempt from review under E.O. 12866 because it contains no implementing regulations.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows.

The Council conducted an evaluation of the potential socioeconomic impacts of the proposed measures in conjunction with an EA. There are no proposed regulatory changes in this bluefish action, so none are considered in the evaluation. The proposed specifications would increase bluefish catch limits in both 2022 and 2023 compared to 2021 to allow greater operational flexibility in the fishery, while still adhering to the rebuilding plan implemented by Amendment 7. This action would also incorporate the quota reallocation changes implemented by Amendment 7, allocating 86 percent of the ACL to the recreational sector and 14 percent to the commercial sector, as well as beginning the 7-year phased-in reallocation of commercial quota among the states in 2022.

This action would affect entities that participate in commercial bluefish fishing (those that hold commercial bluefish permits), and those with federal for-hire (party/charter) recreational fishing permits for bluefish. Vessels may hold multiple fishing permits and some entities own multiple vessels and/or permits. According to the Northeast Fisheries Science Center commercial ownership database, 526 affiliate firms landed bluefish during the 2018–2020 period (the most recent and complete data available), with 521 of those commercial entities categorized as small businesses and 5 categorized as large businesses. For the recreational for-hire fishery, 361 for-hire affiliate firms generated revenues from recreational fishing for various species during 2018–2020. All of those business affiliates are categorized as small businesses, but it is not possible to derive the proportion of overall revenues for these for-hire firms resulting from fishing activities for an individual species such as bluefish. Nevertheless, given the popularity of bluefish as a recreational species in the Mid-Atlantic and New England, it is likely that revenues generated from bluefish may be somewhat important for many of these firms at certain times of the year.

Overall, proposed specifications for 2022 and projected specifications for 2023 are expected to provide similar fishing opportunities when compared to the 2021 fishing year. Although these catch limits are increasing, there are no proposed changes to other management measures, such as recreational bag limits, that are likely to change fishing behavior. Entities issued a commercial bluefish permit may experience a slight positive impact related to potentially higher landings throughout the course of the entire year. However, because state allocations are changing, there might be different amounts of quota available regionally compared to past years. Often, fishing behavior and short term landings are based on market conditions, which are not expected to substantially change as a result of these specifications. As such, the proposed action is not expected to have an impact on the way the fishery operates or the revenue of small entities. Overall, analyses indicate that the proposed specifications will not substantially change: Fishing effort, the risk of overfishing, prices/revenues, or fishery behavior. Additionally, this action will not have a significant impact on small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This action would not establish any new reporting or record-keeping requirements.

This proposed rule contains no new information collection requirements under the Paperwork Reduction Act of 1995.

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

Dated: November 23, 2021.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2021–25901 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 86, No. 229
Thursday, December 2, 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 and Nutrition Service

Agency Information Collection Activities: 2023 Farm to School Census

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a revision of a currently approved collection (OMB Number 0584–0646) for the 2023 Farm to School Census.

DATES: Written comments must be received on or before January 31, 2022.

ADDRESSES: Comments may be sent to: Amy Rosenthal, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314. Comments may also be via email to Amy Rosenthal at *amy.rosenthal@usda.gov*. Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Amy Rosenthal at *amy.rosenthal@usda.gov,* 703–305–2245.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall 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 that were 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 those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: 2023 Farm to School Census.

OMB Number: 0584–0646.

Expiration Date: 3/31/22.

Type of Request: Revision of a currently approved collection.

Abstract: Section 18 of the Richard B. Russell National School Lunch Act authorized and funded USDA to establish a farm to school program in order to assist eligible entities, through grants and technical assistance, in implementing farm to school programs that improve food and agriculture education as well as access to local foods in schools. This work is housed within the FNS Office of Community Food Systems (OCFS). As part of the Farm to School Program's authorization, OCFS collects and disseminates information on farm to school activity throughout the country. OCFS conducted a national census of farm to school activity in 2013, 2015, and 2019. The Farm to School Census provides the only nationally-representative data available on farm to school participation and activities in the United States.

The 2023 Farm to School Census (Census) will collect and synthesize data from a national census of SFAs to better understand the characteristics of SFAs participating in farm to school and the scope and details of the activities they engage in (*e.g.,* local food procurement, gardening, agriculture education). The Census will be distributed to all public [1] and private SFAs (including residential child care institutions) participating in the National School Lunch Program (NSLP) in the 50 states, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, the U.S. Virgin Islands, and Washington, DC.

The primary mode of data collection will be an online survey, distributed to SFA directors. (SFA directors will also have the option to complete the survey over the phone.) The online survey is expected to take 30 minutes to complete. Census questions will be based on prior Farm to School Census instruments, from the iterations conducted in 2019 (the currently approved collection, OMB Number 0584–0646), 2015 (OMB Number 0584–0593), and 2013 (OMB Number 0536–0069). Questions will be removed, added or adjusted based on current research interests and to make the instrument as streamlined as possible.

To construct the contact list for the Census, State Child Nutrition (CN) directors will be sent a list of all SFAs in their State or territory, based on the most recently available FNS data. They will be asked to (1) add or remove any SFAs that have begun or ended participation in the NSLP and (2) provide contact information for the director of each SFA. State CN directors will also be asked to forward a notification email and two email reminders about the Census to SFAs. Directors of State agriculture departments will also be sent one email to notify them of the Census and request their assistance in encouraging SFAs in their State to complete it.

Non-respondents will receive a reminder phone call and up to ten reminder emails. Phone calls, during which SFAs will have the opportunity to complete the Census over the phone, will be conducted by trained interviewers. Staff will also be available for technical and completion assistance via a toll-free phone number.

Affected Public: The affected public includes State, Local, and Tribal Government (directors of public SFAs participating in the NSLP, State Child Nutrition directors, State Agriculture directors); Business or Other For Profit (directors of private SFAs participating in the NSLP); and Not for Profit (directors of not for profit SFAs participating in the NSLP).

Estimated Number of Respondents: The estimated number of respondents is 18,612. This includes 12,137 respondents and 6,475 non-respondents. The number of unique respondents expected to provide data for this study

[1] Public includes charter schools that operate NSLP.

are 9,862 State/local government respondents (56 CN directors, 56 State Agriculture directors, 9,750 directors of public SFAs), 1,625 business respondents (directors of private SFAs), and 650 not for profit respondents (directors of not for profit SFAs). These numbers are based on an estimated 65% response rate to the survey for SFAs (based on the 2019 Census response rate) and a 100% response rate to requests to State CN and Agriculture directors

Estimated Number of Responses per Respondent: All respondents will be asked to respond to each specific data collection activity only once (with the exception of the two requests to CN directors to send reminder emails and 2 reminder emails from CN directors to SFAs). The overall average number of responses per respondent across the entire collection is 14.7.

Estimated Total Annual Responses: The estimated number of total annual responses is 274,111.

Estimated Time per Response: The estimated time of response varies from 2 minutes (for some emails) to 30 minutes (for completion of the Census survey), as shown in the burden table below. The estimated time per response is 4.75 minutes (0.08 hours).

Estimated Total Annual Burden on Respondents: 21,722 hours. This includes 15,750 hours for respondents and 5,972 hours for non-respondents. See the table below (Table 1) for estimated total annual burden for each type of respondent.

Cynthia Long,

Administrator, Food and Nutrition Service.

BILLING CODE 3410–30–P

Table 1: Burden Table:

Respondent Type	Respondent Description	Data Collection Activity	Sample Size	Responsive						Non-Responsive				Total Annual Hour Burden
				Number of respondents	Frequency of Response	Total Annual Responses	Hours per Response	Annual Burden (hours)	Number of non-respondents *	Frequency of Response	Total Annual Responses	Hours per Response	Annual Burden (hours)	
State/local government	State Child Nutrition directors	Recruitment email from FNS to State Child Nutrition Directors	56	56	1	56	0.0668	3.74	0	0	0	0.00	0.00	3.67
		Recruitment email from Study Team to State Child Nutrition Directors [1]	56	56	1	56	1.00	56.00	0	0	0	0.00	0.00	55.00
		Pre-Census Recruitment Email from State Child Nutrition Directors to SFAs	56	56	1	56	0.50	28.00	0	0	0	0.00	0.00	27.50
		Census Reminder Emails from State Child Nutrition Directors to SFAs	56	56	2	112	0.50	56.00	0	0	0	0.00	0.00	55.00
	State Agriculture directors	Recruitment email from FNS to State Department of Agriculture	56	56	1	56	0.50	28.00	0	0	0	0.00	0.00	27.50
		Subtotal (States)	**112**	**112**	**3**	**336**	**0.51**	**171.74**	**0**	**0.00**	**0**	**0.00**	**0.00**	**168.67**
	SFA directors: Public schools	Pre-Census recruitment email from State Child Nutrition Directors to SFAs	15,000	9,750	1	9,750	0.0668	651.30	5,250	1	5,250	0.0334	175.35	826.65
		Census introductory email from Study Team to SFAs	15,000	9,750	1	9,750	0.0668	651.30	5,250	1	5,250	0.0334	175.35	826.65
		Census preparation worksheet	15,000	4,875	1	4,875	0.50	2,437.50	10,125	1	10,125	0.0334	338.18	2,775.68
		Census survey pretest	9	9	1	9	1.50	13.50	0	0	-	0.00	0.00	13.50
		Census survey	15,000	9,750	1	9,750	0.50	4,875.00	5,250	1	5,250	0.0501	263.03	5,138.03
		Census Frequently Asked Questions (FAQ)	15,000	7,500	1	7,500	0.25	1,875.00	7,500	1	7,500	0.0334	250.50	2,125.50
		Census reminder email #1	14,100	846	1	846	0.0501	42.38	13,254	1	13,254	0.0334	442.68	485.07
		Census reminder email #2	13,254	795	1	795	0.0501	39.84	12,459	1	12,459	0.0334	416.12	455.96
		Census reminder email #3	12,459	748	1	748	0.0501	37.45	11,711	1	11,711	0.0334	391.16	428.61
		Census reminder email #4	11,711	703	1	703	0.0501	35.20	11,009	1	11,009	0.0334	367.69	402.89
		Census reminder email #5	11,009	661	1	661	0.0501	33.09	10,348	1	10,348	0.0334	345.62	378.72

		Census reminder email #6	10,348	621	1	621	0.0501	31.11	9,727	1	9,727	0.0334	324.89	355.99
		Census reminder email #7	9,727	584	1	584	0.0501	29.24	9,144	1	9,144	0.0334	305.39	334.63
		Census reminder email #8	9,144	549	1	549	0.0501	27.49	8,595	1	8,595	0.0334	287.07	314.56
		Census reminder emails from State Child Nutrition Directors to SFAs	15,000	9,750	2	19,500	0.0668	1,302.60	5,250	2	10,500	0.0334	350.70	1,653.30
		Census follow-up telephone script #1	8,595	1,719	1	1,719	0.0501	86.12	6,876	1	6,876	0.0334	229.66	315.78
		Census follow-up telephone script #2	6,876	1,375	1	1,375	0.0501	68.90	5,501	1	5,501	0.0334	183.73	252.62
		Census thank you email	9,750	9,750	1	9,750	0.0334	325.65	0	0	0	0.00	0.00	325.65
		Subtotal (SFAs: Public Schools)	**15,000**	**9,750**	**8**	**79,483**	**0.16**	**12,562.67**	**5,250**	**27.14**	**142,498**	**0.03**	**4,847.11**	**17,409.78**
	Subtotal (All State/local government)		**15,112**	**9,862**	**8**	**79,819**	**0.16**	**12,734.41**	**5,250**	**27.14**	**142,498**	**0.03**	**4,847.11**	**17,578.45**
Business	SFA directors: Private schools	Pre-Census recruitment email from State Child Nutrition Directors to SFAs	2,500	1,625	1	1,625	0.0668	108.55	875	1	875	0.0334	29.23	137.78
		Census introductory email from Study Team to SFAs	2,500	1,625	1	1,625	0.0668	108.55	875	1	875	0.0334	29.23	137.78
		Census preparation worksheet	2,500	813	1	813	0.50	406.25	1,688	1	1,688	0.0334	56.36	462.61
		Census survey	2,500	1,625	1	1,625	0.50	812.50	875	1	875	0.0501	43.84	856.34
		Census Frequently Asked Questions (FAQ)	2,500	1,250	1	1,250	0.25	312.50	1,250	1	1,250	0.0334	41.75	354.25
		Census reminder email #1	2,350	141	1	141	0.0501	7.06	2,209	1	2,209	0.0334	73.78	80.84
		Census reminder email #2	2,209	133	1	133	0.0501	6.64	2,076	1	2,076	0.0334	69.35	75.99
		Census reminder email #3	2,076	125	1	125	0.0501	6.24	1,952	1	1,952	0.0334	65.19	71.43
		Census reminder email #4	1,952	117	1	117	0.0501	5.87	1,835	1	1,835	0.0334	61.28	67.15
		Census reminder email #5	1,835	110	1	110	0.0501	5.52	1,725	1	1,725	0.0334	57.60	63.12
		Census reminder email #6	1,725	103	1	103	0.0501	5.18	1,621	1	1,621	0.0334	54.15	59.33
		Census reminder email #7	1,621	97	1	97	0.0501	4.87	1,524	1	1,524	0.0334	50.90	55.77
		Census reminder email #8	1,524	91	1	91	0.0501	4.58	1,432	1	1,432	0.0334	47.85	52.43
		Census reminder emails from State Child Nutrition Directors to SFAs	2,500	1,625	2	3,250	0.0668	217.10	875	2	1,750	0.0334	58.45	275.55

		Census follow-up telephone script #1	1,432	286	1	286	0.0501	14.35	1,146	1	1,146	0.0334	38.28	52.63
		Census follow-up telephone script #2	1,146	229	1	229	0.0501	11.48	917	1	917	0.0334	30.62	42.10
		Census thank you email	1,625	1,625	1	1,625	0.0334	54.28	0	0	0	0.00	0.00	54.28
	Subtotal (Business)		**2,500**	**1,625**	**8**	**13,246**	**0.16**	**2,091.53**	**875**	**27.14**	**23,750**	**0.03**	**807.85**	**2,899.38**
Not for Profit	SFA directors: Not for profit schools	Pre-Census recruitment email from State Child Nutrition Directors to SFAs	1,000	650	1	650	0.0668	43.42	350	1	350	0.0334	11.69	55.11
		Census introductory email from Study Team to SFAs	1,000	650	1	650	0.0668	43.42	350	1	350	0.0334	11.69	55.11
		Census preparation worksheet	1,000	500	1	500	0.50	250.00	500	1	500	0.0334	16.70	266.70
		Census survey	1,000	650	1	650	0.50	325.00	350	1	350	0.0501	17.54	342.54
		Census Frequently Asked Questions (FAQ)	1,000	500	1	500	0.25	125.00	500	1	500	0.0334	16.70	141.70
		Census reminder email #1	940	56	1	56	0.0501	2.83	884	1	884	0.0334	29.51	32.34
		Census reminder email #2	884	53	1	53	0.0501	2.66	831	1	831	0.0334	27.74	30.40
		Census reminder email #3	831	50	1	50	0.0501	2.50	781	1	781	0.0334	26.08	28.57
		Census reminder email #4	781	47	1	47	0.0501	2.35	734	1	734	0.0334	24.51	26.86
		Census reminder email #5	734	44	1	44	0.0501	2.21	690	1	690	0.0334	23.04	25.25
		Census reminder email #6	690	41	1	41	0.0501	2.07	648	1	648	0.0334	21.66	23.73
		Census reminder email #7	648	39	1	39	0.0501	1.95	610	1	610	0.0334	20.36	22.31
		Census reminder email #8	610	37	1	37	0.0501	1.83	573	1	573	0.0334	19.14	20.97
		Census reminder emails from State Child Nutrition Directors to SFAs	1,000	650	2	1,300	0.0668	86.84	350	2	700	0.0334	23.38	110.22
		Census follow-up telephone script #1	573	115	1	115	0.0501	5.74	458	1	458	0.0334	15.31	21.05
		Census follow-up telephone script #2	458	92	1	92	0.0501	4.59	367	1	367	0.0334	12.25	16.84
		Census thank you email	650	650	1	650	0.0334	21.71	0	0	0	0.00	0.00	21.71
	Subtotal (Not for profit)		**1,000**	**650**	**8**	**5,473**	**0.17**	**924.11**	**350**	**26.64**	**9,325**	**0.03**	**317.30**	**1,241.41**
TOTAL REPORTING BURDEN			**18,612**	**12,137**	**8**	**98,538**	**0.16**	**15,750**	**6,475**	**27.12**	**175,572**	**0.03**	**5,972**	**21,719**

[FR Doc. 2021–26195 Filed 12–1–21; 8:45 am]
BILLING CODE 3410–30–C

DEPARTMENT OF AGRICULTURE

Forest Service

Boundary Establishment for Upper White Salmon National Wild and Scenic River, Gifford Pinchot National Forest, Skamania County, Washington

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of availability.

SUMMARY: In accordance with Section 3(b) of the Wild and Scenic Rivers Act, the Forest Service, U.S. Department of Agriculture, is transmitting the final boundary of Upper White Salmon National Wild and Scenic River to Congress.

FOR FURTHER INFORMATION CONTACT: Information may be obtained by contacting John Ransom, Regional Land Surveyor, by telephone at 503–808–2420 or via email at *john.ransom@usda.gov.* Alternatively, contact Kyung Koh Willis on the Gifford Pinchot National Forest at 360–891–5177 or *kyung.willis@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: The Upper White Salmon Wild and Scenic River boundary description is available for review on the Gifford Pinchot National Forest website: *https://www.fs.usda.gov/detail/giffordpinchot/landmanagement/resourcemanagement/?cid=stelprdb5172066.*

Due to COVID–19 health and safety protocols to protect employees and visitors, many Forest Service offices are closed to the public. The Upper White Salmon Wild and Scenic River boundary is available for review at the following offices, if arrangements are made in advance: USDA Forest Service, Yates Building, 14th and Independence Avenues SW, Washington, DC 20024, phone—800–832–1355; Pacific Northwest Regional Office, 1220 SW Third Avenue, Portland, OR 97204, phone—503–808–2468; and Gifford Pinchot National Forest Supervisor's Office, 1501 E Evergreen Blvd., Vancouver, WA 98661, phone—360–891–5000. Please contact the appropriate office prior to arrival.

The Upper White Salmon Wild and Scenic Rivers Act (Pub. L. 109–44) of August 2, 2005 designated Upper White Salmon, Washington as a National Wild and Scenic River, to be administered by the Secretary of Agriculture. As specified by law, the boundary will not be effective until ninety days after Congress receives the transmittal.

Dated: November 26, 2021.

Sandra Watts,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2021–26181 Filed 12–1–21; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Boundary Establishment for Comprehensive River Management Plan for Crescent Creek National Wild and Scenic River, Deschutes National Forest, Klamath County, Oregon

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of availability.

SUMMARY: In accordance with section 3(b) of the Wild and Scenic Rivers Act, the Forest Service, U.S. Department of Agriculture, is transmitting the final boundary of Crescent Creek National Wild and Scenic River to Congress and providing notice of availability of the Comprehensive River Management Plan.

FOR FURTHER INFORMATION CONTACT: Information may be obtained by contacting John Ransom, Regional Land Surveyor, by telephone at 503–808–2420 or via email at *john.ransom@usda.gov.* Alternatively, contact the Deschutes National Forest Supervisor's Office at 541–383–5300 or the Deschutes National Forest website: *https://www.fs.usda.gov/contactus/deschutes/about-forest/contactus.* 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: The Crescent Creek Wild and Scenic River boundary description and Comprehensive River Management Plan are available for review on the Deschutes National Forest website: *https://www.fs.usda.gov/project/?project=47575.*

Due to COVID–19 health and safety protocols to protect employees and visitors, many Forest Service offices are closed to the public. The Crescent Creek Wild and Scenic River boundary and Comprehensive River Management Plan are available for review at the following offices, if arrangements are made in advance: USDA Forest Service, Yates Building, 14th and Independence Avenues SW, Washington, DC 20024, phone—800–832–1355; Pacific Northwest Regional Office, 1220 SW Third Avenue, Portland, OR 97204, phone—503–808–2468; and Deschutes National Forest Supervisor's Office, 63095 Deschutes Market Road, Bend, OR 97701, phone—541–383–5300. Please contact the appropriate office prior to arrival.

The Omnibus Oregon Wild and Scenic Rivers Act of 1988 (Pub. L. 100–557) of October 28, 1988 designated Crescent Creek, Oregon as a National Wild and Scenic River, to be administered by the Secretary of Agriculture. As specified by law, the boundary will not be effective until ninety days after Congress receives the transmittal.

Dated: November 26, 2021.

Sandra Watts,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2021–26177 Filed 12–1–21; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Office of the Under Secretary for Economic Affairs

Request for Comments on the First Annual Report of the Advisory Committee on Data for Evidence Building

AGENCY: Office of the Under Secretary for Economic Affairs, Department of Commerce.

ACTION: Request for comments.

SUMMARY: The Foundations for Evidence-Based Policymaking Act of 2018 requires Federal agencies to modernize their data management practices to develop and support evidence-based policymaking. The Act requires the Director of the Office of Management and Budget (OMB), or the head of an agency designated by the Director, to establish the Advisory Committee on Data for Evidence Building (Advisory Committee). In a letter dated September 3, 2019, OMB delegated managerial and administrative responsibility for this Federal advisory committee to the Department of Commerce Office of Under Secretary for Economic Affairs (OUSEA). The Advisory Committee is required to deliver publicly available annual reports on its activities and findings to the OMB Director. The Advisory Committee submitted its first-year report on October 29, 2021. This FRN requests comments from the public on the Advisory Committee's first annual report.

DATES: Comments must be received by December 31, 2021.

ADDRESSES: You may submit comments by emailing *Evidence@bea.gov*. Begin with the phrase ''Comments for the Advisory Committee on Data for Evidence Building;'' and indicate which section(s) of the report your comments address. Comments by fax or paper delivery will not be accepted.

Privacy Note: Comments submitted in response to this notice may be made available to the public through relevant websites. Therefore, commenters should only include information they wish to make publicly available on the internet. Do not submit confidential business information or otherwise sensitive or protected information.

Please note the confidentiality of routine communication and responses to this public comment request are treated as public comments and may therefore be made publicly available, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Gianna Marrone, Program Analyst, U.S. Department of Commerce, 4600 Silver Hill Road (BE–64), Suitland, MD 20746; phone (301) 278–9282; email *Evidence@bea.gov.*

SUPPLEMENTARY INFORMATION:

Request for Comments

The Advisory Committee submitted its first-year report to the Director of the Office of Management and Budget on October 29, 2021. The report is also available publicly on the Advisory Committee's website. The report summarizes the Committee's first-year activities and resulting findings, laying out a vision for a National Secure Data Service and the future of data sharing, data linkages, and privacy enhancing techniques across Federal agencies and with state and local governments. The report describes recommended actions that can be taken today to build towards that vision while also articulating the path that the Committee intends to take across the next year to further develop recommendations for implementing the vision.

Over the past 12 months, the Committee has engaged in extensive fact-finding, including examining the recommendations of the Commission on Evidence-Based Policymaking and the implications of their partial implementation through the Evidence Act; leveraging the expertise of its members; hearing from researchers, government leaders, other experts, and the public; conducting virtual site visits to existing data facilities; and beginning to collaboratively synthesize the different perspectives and use cases into a coherent understanding of the current state and future needs for the use of data for evidence building. The Committee members recognize their efforts as a work-in-progress that will continue across the next 12 months.

This request for comments offers researchers, evaluators, contractors, government entities, and other interested parties the opportunity to inform the Committee's second-year plans. This is a general solicitation of comments from the public. The FRN commentors may respond to any section of the report. Please clearly indicate which section(s) of the report you address in your response and provide evidence to support assertions, where practicable.

Dated: November 29, 2021.

Authority: 5 U.S.C. 315.

Alyssa Holdren,

Designated Federal Official, Advisory Committee on Data for Evidence Building.

[FR Doc. 2021–26161 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–MN–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Federal Economic Statistics Advisory Committee

AGENCY: Bureau of Economic Analysis, U.S. Department of Commerce.

ACTION: Notice of request for nominations.

SUMMARY: The Under Secretary for Economic Affairs requests nominations of individuals to the Federal Economic Statistics Advisory Committee (FESAC). The Under Secretary for Economic Affairs in coordination with the Directors of the Department's statistical agencies, the Bureau of Economic Analysis and the U.S. Census Bureau, as well as the Commissioner of the U.S. Department of Labor's Bureau of Labor Statistics will consider nominations received in response to this notice, as well as from other sources. The **SUPPLEMENTARY INFORMATION** section of this notice provides Committee and membership criteria.

DATES: Nominations for the FESAC will be accepted on an ongoing basis and will be considered as and when vacancies arise.

ADDRESSES: Please submit nominations by email to *Gianna.marrone@bea.gov* (subject line ''FESAC Nomination'').

FOR FURTHER INFORMATION CONTACT: Gianna Marrone, Committee Management Official, Department of Commerce, Bureau of Economic Analysis, telephone 301–278–9282, email: *gianna.marrone@bea.gov*.

SUPPLEMENTARY INFORMATION: The Federal Economic Statistics Advisory Committee (the ''Committee'') was established in accordance with the Federal Advisory Committee Act (Title 5, United States Code, Appendix 2). The following provides information about the Committee, membership, and the nomination process.

Objectives and Scope of FESAC Activities

The Committee advises the Directors of the Department's statistical agencies, the Bureau of Economic Analysis (BEA) and the U.S. Census Bureau, as well as the Commissioner of the U.S. Department of Labor's Bureau of Labor Statistics (BLS) on statistical methodology and other technical matters related to the design, collection, tabulation, and analysis of federal economic statistics.

Description of the FESAC Member Duties

The Committee functions solely as an advisory committee to the senior officials of BEA, the Census Bureau, and BLS (the agencies). Important aspects of the committee's responsibilities include, but are not limited to:

a. Recommending research to address important technical problems arising in federal economic statistics

b. Identifying areas in which better coordination of the agencies' activities would be beneficial;

c. Exploring ways to enhance the agencies' economic indicators to make them timelier, more accurate, and more specific to meeting changing demands and future data needs;

d. Improving the means, methods, and techniques to obtain economic information needed to produce current and future economic indicators; and

e. Coordinating, in its identification of agenda items, with other existing academic advisory committees chartered to provide agency-specific advice, for the purpose of avoiding duplication of effort.

The Committee meets once or twice a year, budget permitting. Additional meetings may be held as deemed necessary by the Under Secretary for Economic Affairs or the Designated Federal Official. All Committee meetings are open to the public in accordance with the Federal Advisory Committee Act.

FESAC Membership

FESAC will comprise approximately 16 members who serve at the pleasure

of the Secretary. Members shall be appointed by the Under Secretary for Economic Affairs in consultation with the agencies. Committee members shall be professionals in appropriate disciplines, including economists, statisticians, survey methodologists, computer scientists, data scientists, and behavioral scientists who are experts in their fields, recognized for their scientific, professional, and operational achievements and objectivity. Membership will represent data users with expertise from the public sector, academia, and the private sector. Members will be chosen to achieve a balanced membership that will meet the needs of the agencies.

Members shall serve as Special Government Employees (SGEs) and shall be subject to ethics rules applicable to SGEs.

A FESAC member term is three years.

Members may serve more than one term as described in the FESAC Charter, available at: *https://apps.bea.gov/fesac/*.

Compensation for Members

Members of the Committee serve without compensation but may receive reimbursement for Committee-related travel and lodging expenses.

Solicitation of Nominations

The Committee is currently filling one or more positions on the FESAC.

The Under Secretary of Economic Affairs, in consultation with the agencies will consider nominations of all qualified individuals to ensure that the Committee includes the areas of experience noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership on the Committee. Nominations shall state that the nominee is willing to serve as a member and carry out the duties of the Committee. A nomination package should include the following information for each nominee:

1. A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.,* what specific attributes recommend the nominee for service in this capacity), and the nominee's field(s) of experience

2. a biographical sketch of the nominee;

3. a copy of the nominee's curriculum vitae; and

4. the name, return address, email address, and daytime telephone number at which the nominator can be contacted.

The Committee aims to have a balanced representation among its members, considering such factors as geography, age, sex, race, ethnicity, technical expertise, community involvement, and knowledge of programs and/or activities related to FESAC. Individuals will be selected based on their expertise in or representation of specific areas as needed by FESAC.

All nomination information should be provided in a single, complete package. Interested applicants should send their nomination package to Gianna Marrone, Committee Management Official, at *Gianna.Marrone@bea.gov* (subject line ''FESAC Nomination'').

Dated: November 29, 2021.

Sabrina L. Montes,

Bureau of Economic Analysis, Designated Federal Official, Federal Economic Statistics Advisory Committee.

[FR Doc. 2021–26213 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–57–2021]

Foreign-Trade Zone (FTZ) 75—Phoenix, Arizona; Authorization of Production Activity; VIAVI Solutions, Inc. (Optically Variable Pigments); Chandler, Arizona

On July 29, 2021, VIAVI Solutions, Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 75, in Chandler, Arizona.

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 44345, August 12, 2021). On November 26, 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: November 26, 2021.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2021–26150 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–56–2021]

Foreign-Trade Zone (FTZ) 38—Spartanburg County, South Carolina; Authorization of Production Activity; BMW Manufacturing Company, LLC (Passenger Motor Vehicles); Spartanburg, South Carolina

On July 28, 2021, BMW Manufacturing Company, LLC submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 38A, in Spartanburg, South Carolina.

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 43520, August 9, 2021). On November 26, 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: November 26, 2021.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2021–26151 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–122–858]

Certain Softwood Lumber Products From Canada: Final Results of the Countervailing Duty Administrative Review, 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that producers and exporters of certain softwood lumber products (softwood lumber) from Canada received countervailable subsidies during the period of review, January 1, 2019, through December 31, 2019.

DATES: Applicable December 2, 2021.

FOR FURTHER INFORMATION CONTACT: Jonathan Hall-Eastman (Canfor), John Hoffner (JDIL), Kristen Johnson/Samuel Brummitt (Resolute), and Laura Griffith (West Fraser), AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401

Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1468, (202) 482–3315, (202) 482–4793/(202) 482–7851, and (202) 482–6430, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the preliminary results of this countervailing duty (CVD) administrative review of softwood lumber from Canada on May 27, 2021, and invited interested parties to comment.[1] For a summary of the events that occurred since the *Preliminary Results* and a full discussion of the issues raised by parties for the final results, *see* the Issues and Decision Memorandum.[2]

Scope of the Order [3]

The product covered by the *Order* is certain softwood lumber products from Canada. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.

Analysis of Subsidy Programs and Comments Received

Commerce conducted this CVD administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). The subsidy programs under review, and the issues raised in case and rebuttal briefs submitted by the interested parties, are discussed in the Issues and Decision Memorandum. A list of the issues that the parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice at Appendix I. Based on our analysis of the comments received from the interested parties, we made changes to the subsidy rates calculated for certain respondents. For a discussion of these changes, *see* the Issues and Decision Memorandum.

Rate for Non-Selected Companies Under Review

Because the rates calculated for the companies selected for individual review are above *de minimis* and not based entirely on facts available, we applied a subsidy rate based on a weighted average of the subsidy rates calculated for the reviewed companies using sales data submitted by those companies to calculate a rate for the companies not selected for review. This is consistent with the methodology that we would use in an investigation to establish the all-others rate, pursuant to section 705(c)(5)(A) of the Act. A list of all non-selected companies is included in Appendix II.

For further information on the calculation of the non-selected rate, *see* ''Final *Ad Valorem* Rate for Non-Selected Companies under Review'' in the Issues and Decision Memorandum.

Final Results of Administrative Review

In accordance with section 751(a)(1)(A) and of the Act and 19 CFR 351.221(b)(5), we determine that the following total estimated countervailable subsidy rates exist for 2019:

Companies	Subsidy rate 2019 *ad valorem* (percent)
Canfor Corporation and its cross-owned affiliates [4]	2.42
J.D. Irving, Limited and its cross-owned affiliates [5]	3.41
Resolute FP Canada Inc. and its cross-owned affiliates [6]	18.07
West Fraser Mills Ltd. and its cross-owned affiliates [7]	5.06
Non-Selected Companies	6.31

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.244(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise covered by this review.

Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a).

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for the companies subject to this review. For all non-reviewed companies, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposits, when imposed, shall remain in effect until further notice.

Administrative Protective Order (APO)

This notice also serves as a final reminder to parties subject to APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing and publishing these final results of administrative review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4) and 351.221(b)(5).

Dated: November 23, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

[1] *See Certain Softwood Lumber Products from Canada: Preliminary Results and Partial Rescission of the Countervailing Duty Administrative Review; 2019,* 86 FR 28556 (May 27, 2021) (*Preliminary Results*).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Administrative Review of the Countervailing Duty Order on Certain Softwood Lumber Products from Canada; 2019,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum). The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, members of the public may access the IDM at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

[3] *See Certain Softwood Lumber Products from Canada: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 83 FR 347 (January 3, 2018) (*Order*).

[4] Commerce finds the following companies to be cross-owned with Canfor Corporation: Canadian Forest Products., Ltd. and Canfor Wood Products Marketing, Ltd.

[5] Commerce finds the following companies to be cross-owned with J.D. Irving, Limited: Miramichi Timber Holdings Limited, The New Brunswick Railway Company, Rothesay Paper Holdings Ltd., and St. George Pulp & Paper Limited.

[6] Commerce finds the following companies to be cross-owned with Resolute: Resolute Growth Canada Inc., Produits Forestiers Maurice SEC., and Resolute Forest Products Inc.

[7] Commerce finds the following companies to be cross-owned with West Fraser: West Fraser Timber Co., Ltd., Blue Ridge Lumber Inc., Sunpine Inc., Sundre Forest Products Inc., Manning Forest Products, and West Fraser Alberta Holdings.

Appendix II

Non-Selected Exporters/Producers

1. 1074712 BC Ltd.
2. 258258 B.C. Ltd., dba Pacific Coast Cedar Products
3. 5214875 Manitoba Ltd.
4. 752615 B.C Ltd., Fraserview Remanufacturing Inc., dba Fraserview Cedar Products.
5. 9224–5737 Quebec Inc. (aka A.G. Bois)
6. A.B. Cedar Shingle Inc.
7. Absolute Lumber Products, Ltd.
8. AJ Forest Products Ltd.
9. Alberta Spruce Industries Ltd.
10. Aler Forest Products, Ltd.
11. Alpa Lumber Mills Inc.
12. AM Lumber Brokerage
13. American Pacific Wood Products
14. Anbrook Industries Ltd.
15. Andersen Pacific Forest Products Ltd.
16. Anglo-American Cedar Products, Ltd.
17. Antrim Cedar Corporation
18. Aquila Cedar Products, Ltd.
19. Arbec Lumber Inc.
20. Aspen Planers Ltd.
21. B&L Forest Products Ltd.
22. B.B. Pallets Inc.
23. Babine Forest Products Limited
24. Bakerview Forest Products Inc.
25. Bardobec Inc.
26. BarretteWood Inc.
27. Barrette-Chapais Ltee
28. Benoit & Dionne Produits Forestiers Ltee
29. Best Quality Cedar Products Ltd.
30. Blanchet Multi Concept Inc.
31. Blanchette & Blanchette Inc.
32. Bois Aise de Montreal Inc.
33. Bois Bonsai Inc.
34. Bois Daaquam Inc.
35. Bois D'oeuvre Cedrico Inc. (aka Cedrico Lumber Inc.)
36. Bois et Solutions Marketing SPEC, Inc.
37. Boisaco Inc.
38. Boscus Canada Inc.
39. BPWood Ltd.
40. Bramwood Forest Inc.
41. Brink Forest Products Ltd.
42. Brunswick Valley Lumber Inc.
43. Busque & Laflamme Inc.
44. C&C Wood Products Ltd.
45. Caledonia Forest Products Inc.
46. Campbell River Shake & Shingle Co., Ltd.
47. Canadian American Forest Products Ltd.
48. Canadian Wood Products Inc.
49. Canasia Forest Industries Ltd
50. Canusa cedar inc.
51. Canyon Lumber Company, Ltd.
52. Careau Bois Inc.
53. Carrier & Begin Inc.
54. Carrier Forest Products Ltd.
55. Carrier Lumber Ltd.
56. Cedar Valley Holdings Ltd.
57. Cedarline Industries, Ltd.
58. Central Alberta Pallet Supply
59. Central Cedar Ltd.
60. Central Forest Products Inc.
61. Centurion Lumber, Ltd.
62. Chaleur Sawmills LP
63. Channel-ex Trading Corporation
64. Clair Industrial Development Corp. Ltd.
65. Clermond Hamel Ltee
66. CNH Products Inc.
67. Coast Clear Wood Ltd.
68. Coast Mountain Cedar Products Ltd.
69. Columbia River Shake & Shingle Ltd./Teal Cedar Products Ltd., dba The Teal Jones Group
70. Commonwealth Plywood Co. Ltd.
71. Comox Valley Shakes Ltd./Comox Valley Shakes (2019) Ltd.
72. Conifex Fibre Marketing Inc.
73. Cowichan Lumber Ltd.
74. CS Manufacturing Inc., dba Cedarshed
75. CWP—Industriel Inc.
76. CWP—Montreal Inc.
77. D & D Pallets, Ltd.
78. Dakeryn Industries Ltd.
79. Decker Lake Forest Products Ltd.
80. Delco Forest Products Ltd.
81. Delta Cedar Specialties Ltd.
82. Devon Lumber Co. Ltd.
83. DH Manufacturing Inc.

84. Direct Cedar Supplies Ltd.
85. Doubletree Forest Products Ltd.
86. Downie Timber Ltd.
87. Dunkley Lumber Ltd.
88. EACOM Timber Corporation
89. East Fraser Fiber Co. Ltd.
90. Edgewood Forest Products Inc.
91. ER Probyn Export Ltd.
92. Eric Goguen & Sons Ltd.
93. Falcon Lumber Ltd.
94. Fontaine Inc.
95. Foothills Forest Products Inc.
96. Fornebu Lumber Company Inc.
97. Fraser Specialty Products Ltd.
98. FraserWood Inc.
99. FraserWood Industries Ltd.
100. Furtado Forest Products Ltd.
101. G & R Cedar Ltd.
102. Galloway Lumber Company Ltd.
103. Gilbert Smith Forest Products Ltd.
104. Glandell Enterprises Inc.
105. Goat Lake Forest Products Ltd.
106. Goldband Shake & Shingle Ltd.
107. Golden Ears Shingle Ltd.
108. Goldwood Industries Ltd.
109. Goodfellow Inc.
110. Gorman Bros. Lumber Ltd.
111. Groupe Crete Chertsey Inc.
112. Groupe Crete Division St-Faustin Inc.
113. Groupe Lebel Inc.
114. Groupe Lignarex Inc.
115. H.J. Crabbe & Sons Ltd.
116. Haida Forest Products Ltd.
117. Harry Freeman & Son Ltd.
118. Hornepayne Lumber LP
119. Imperial Cedar Products, Ltd.
120. Imperial Shake Co. Ltd.
121. Independent Building Materials Dist.
122. Interfor Corporation
123. Island Cedar Products Ltd
124. Ivor Forest Products Ltd.
125. J&G Log Works Ltd.
126. J.H. Huscroft Ltd.
127. Jan Woodlands (2001) Inc.
128. Jasco Forest Products Ltd.
129. Jazz Forest Products Ltd.
130. Jhajj Lumber Corporation
131. Kalesnikoff Lumber Co. Ltd.
132. Kan Wood, Ltd.
133. Kebois Ltee/Ltd.
134. Keystone Timber Ltd.
135. Kootenay Innovative Wood Ltd.
136. L'Atelier de Readaptation au Travail de Beauce Inc.
137. Lafontaine Lumber Inc.
138. Langevin Forest Products Inc.
139. Lecours Lumber Co. Limited
140. Ledwidge Lumber Co. Ltd.
141. Leisure Lumber Ltd.
142. Les Bois d'oeuvre Beaudoin Gauthier inc.
143. Les Bois Martek Lumber
144. Les Bois Traites M.G. Inc.
145. Les Chantiers de Chibougamau Ltd.
146. Leslie Forest Products Ltd.
147. Lignum Forest Products LLP
148. Linwood Homes Ltd.
149. Longlac Lumber Inc.
150. Lulumco Inc.
151. Magnum Forest Products, Ltd.
152. Maibec inc.
153. Manitou Forest Products Ltd.
154. Marwood Ltd.
155. Materiaux Blanchet Inc.
156. Matsqui Management and Consulting Services Ltd., dba Canadian Cedar Roofing Depot
157. Metrie Canada Ltd.
158. Mid Valley Lumber Specialties, Ltd.
159. Midway Lumber Mills Ltd.
160. Mill & Timber Products Ltd.
161. Millar Western Forest Products Ltd.
162. Mobilier Rustique (Beauce) Inc.
163. MP Atlantic Wood Ltd.
164. Multicedre ltee
165. Murray Brothers Lumber Company Ltd
166. Nakina Lumber Inc.
167. National Forest Products Ltd.
168. New Future Lumber Ltd.
169. Nicholson and Cates Ltd
170. Norsask Forest Products Limited Partnership
171. North American Forest Products Ltd. (located in Abbotsford, British Columbia)
172. North Enderby Timber Ltd.
173. Oikawa Enterprises Ltd.
174. Olympic Industries, Inc./Olympic Industries Inc-Reman Code/Olympic Industries ULC/Olympic Industries ULC-Reman/Olympic Industries ULC-Reman Code
175. Oregon Canadian Forest Products
176. Pacific Coast Cedar Products, Ltd.
177. Pacific Pallet, Ltd.
178. Pacific Western Wood Works Ltd.
179. Parallel Wood Products Ltd.
180. Pat Power Forest Products Corporation
181. Phoenix Forest Products Inc.
182. Pine Ideas Ltd.
183. Pioneer Pallet & Lumber Ltd.
184. Porcupine Wood Products Ltd.
185. Power Wood Corp.
186. Precision Cedar Products Corp.
187. Prendiville Industries Ltd. (aka, Kenora Forest Products)
188. Produits Forestiers Petit Paris Inc.
189. Produits forestiers Temrex, s.e.c.
190. Produits Matra Inc. and Sechoirs de Beauce Inc.
191. Promobois G.D.S. inc.
192. Quadra Cedar
193. Rayonier A.M. Canada GP
194. Rembos Inc.
195. Rene Bernard Inc.
196. Richard Lutes Cedar Inc.
197. Rielly Industrial Lumber Inc.
198. S & K Cedar Products Ltd.
199. S&R Sawmills Ltd
200. S&W Forest Products Ltd.
201. San Industries Ltd.
202. Sawarne Lumber Co. Ltd.
203. Scierie P.S.E. lnc.
204. Scierie St-Michel inc.
205. Scierie West Brome Inc.
206. Scotsburn Lumber Co. Ltd.
207. Scott Lumber Sales
208. Serpentine Cedar Ltd.
209. Sexton Lumber Co. Ltd.
210. Sigurdson Forest Products Ltd.
211. Silvaris Corporation
212. Silver Creek Premium Products Ltd.
213. Sinclar Group Forest Products Ltd.
214. Skana Forest Products Ltd.
215. Skeena Sawmills Ltd
216. Sound Spars Enterprise Ltd.
217. South Beach Trading Inc.
218. Specialiste de Bardeau de Cedre Inc.
219. Spruceland Millworks Inc.
220. Star Lumber Canada Ltd.
221. Sundher Timber Products Ltd.
222. Surrey Cedar Ltd.
223. T.G. Wood Products, Ltd.
224. Taan Forest LP/Taan Forest Products
225. Taiga Building Products Ltd.
226. Tall Tree Lumber Company
227. Tembec Inc.
228. Temrex Produits Forestiers s.e.c.
229. Terminal Forest Products Ltd.
230. The Wood Source Inc.
231. Tolko Industries Ltd. and Tolko Marketing and Sales Ltd.
232. Trans-Pacific Trading Ltd.
233. Triad Forest Products Ltd.
234. Twin Rivers Paper Co. Inc.
235. Tyee Timber Products Ltd.
236. Universal Lumber Sales Ltd.
237. Usine Sartigan Inc.
238. Vaagen Fibre Canada, ULC
239. Valley Cedar 2 Inc./Valley Cedar 2 ULC
240. Vancouver Island Shingle, Ltd.
241. Vancouver Specialty Cedar Products Ltd.
242. Vanderhoof Specialty Wood Products Ltd.
243. Visscher Lumber Inc
244. W.I. Woodtone Industries Inc.
245. Waldun Forest Product Sales Ltd.
246. Watkins Sawmills Ltd.
247. West Bay Forest Products Ltd.
248. West Wind Hardwood Inc.
249. Western Forest Products Inc.
250. Western Lumber Sales Limited
251. Western Wood Preservers Ltd.
252. Weston Forest Products Inc.
253. Westrend Exteriors Inc.
254. Weyerhaeuser Co.
255. White River Forest Products L.P.
256. Winton Homes Ltd.
257. Woodline Forest Products Ltd.
258. Woodstock Forest Products/Woodstock Forest Products Inc.
259. Woodtone Specialties Inc.
260. Yarrow Wood Ltd.

[FR Doc. 2021–26152 Filed 12–1–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–857]

Certain Softwood Lumber Products From Canada: Final Results of Antidumping Duty Administrative Review; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that producers and/or exporters subject to this administrative review made sales of subject merchandise at less than normal value during the period of review (POR), January 1, 2019, through December 31, 2019.

DATES: Applicable December 2, 2021.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen (Canfor) or Maisha Cryor (West Fraser), AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration,

Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2769 or (202) 482–5831, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* on May 27, 2021.[1] This review covers 273 producers/exporters of subject merchandise, including two mandatory respondents, Canfor,[2] and West Fraser.[3] For events subsequent to the *Preliminary Results, see* Commerce's Issues and Decision Memorandum.[4] The final weighted-average dumping margins are listed below in the ''Final Results of Review'' section of this notice. Commerce conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The product covered by this review is softwood lumber from Canada. For a full description of the scope, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case briefs filed in this administrative review are addressed in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is appended to this notice. The Issues and Decision Memorandum is a public document and is available electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Services System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum is also accessible on the internet at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on our review of the record and comments received from interested parties regarding our *Preliminary Results,* Commerce has made the following changes to the *Preliminary Results:*

- For Canfor, we corrected a ministerial error where we should have relied on the consolidated customer code but relied on a non-consolidated customer code.
- For Canfor, we updated the market prices for electricity used to value related party transactions involving steam and electricity to be based both on electricity transactions in both Alberta and British Columbia, rather than only in Alberta.
- We reduced the total cost of manufacturing for Canfor by the closure costs of its Vavenby sawmill.
- In calculating Canfor's interest expense, we included the losses on certain derivative investments.
- For West Fraser, we corrected a ministerial error regarding the manner in which we assigned the intended byproduct offset amount to the total cost of manufacturing.
- For West Fraser, we corrected an error with how we calculated the byproduct offset.
- For West Fraser, we made an adjustment to its total cost of manufacturing to account for seed purchases from a joint venture company.
- For West Fraser, we are relying on the alternative grade group product code to ensure a more accurate comparison of comparison market and U.S. market sales.
- For West Fraser, we are determining West Fraser's margin using the mixed method comparison method based upon the percentage of sales that passed the Cohen's *d* test.

Final Results of Review

As a result of this administrative review, we are assigning the following weighted-average dumping margins to the manufacturers/exporters listed below for the period of January 1, 2019, through December 31, 2019:

Exporter/producer	Weighted-average margin (percent)
Canfor Corporation/Canadian Forest Products Ltd./Canfor Wood Products Marketing Ltd	17.12
West Fraser Mills Ltd., Blue Ridge Lumber Inc./Manning Forest Products Ltd./and Sundre Forest Products Inc	6.06
Non-Selected Companies	11.59

Assessment Rates

Pursuant to section 751(a)(2)(A) the Act and 19 CFR 351.212(b)(1), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

We intend to calculate importer- (or customer-) specific assessment rates on the basis of the ratio of the total amount of antidumping duties calculated for each importer (or customer's) examined sales and the total entered value of the sales in accordance with 19 CFR 351.212(b)(1). Where an importer- (or customer-) specific rate is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Generally, when calculating margins for non-selected respondents, Commerce looks to section 735(c)(5) of the Act for guidance, which provides instructions for calculating the all-others margin in an investigation. Section 735(c)(5)(A) of the Act provides that when calculating the all-others margin, Commerce will exclude any zero and *de minimis* weighted-average dumping margins, as well as any weighted-average dumping margins based on total facts available. Accordingly, Commerce's usual practice has been to average the margins for selected respondents, excluding margins that are zero, *de minimis,* or based entirely on facts available.

In this review, we calculated a weighted-average dumping margin of 17.12 percent for Canfor and 6.06 percent for West Fraser. In accordance with section 735(c)(5)(A) of the Act, Commerce assigned the weighted-average of these two calculated weighted-average dumping margins, 11.59 percent, to the non-selected companies in these final results. The rate calculated for the non-selected companies is calculated based on the simple average of the margins of the two individually examined companies.[5] Accordingly, we have applied a rate of 11.59 percent to the non-selected companies.[6] A list of all non-selected companies is included in Attachment II.

Commerce's ''reseller policy'' will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did

[1] *See Certain Softwood Lumber Products from Canada: Preliminary Results of Antidumping Duty Administrative Review,* 86 FR 28551 (May 27, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] As described in the *Preliminary Results* PDM, we have treated Canfor Corporation, Canadian Forest Products Ltd., and Canfor Wood Products Marketing Ltd. (collectively, Canfor) as a single entity. *See Preliminary Results* PDM.

[3] As described in the *Preliminary Results* PDM, we have treated West Fraser Mills Ltd., Blue Ridge Lumber Inc., Manning Forest Products Ltd., and Sundre Forest Products Inc. (collectively, West Fraser) as a single entity. *See Preliminary Results* PDM at 6–7.

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of Certain Softwood Lumber Products from Canada'' (Issues and Decision Memorandum), dated concurrently with, and hereby adopted by, this notice.

[5] For more information regarding the calculation of this margin, *see* Memorandum, ''Calculation of the Rate for Non-Examined Companies,'' dated concurrently with this notice.

[6] *Id.*

not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[7]

The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise under review and for future cash deposits of estimated duties, where applicable. Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies under review will be equal to the weighted-average dumping margin listed above in the ''Final Results of Review'' section; (2) for merchandise exported by producers or exporters not covered in this review but covered in a previously completed segment of this proceeding, the cash deposit rate will continue to be the company-specific rate published in the final results for the most recent period in which that producer or exporter participated; (3) if the exporter is not a firm covered in this review or in any previous segment of this proceeding, but the producer is, then the cash deposit rate will be that established for the producer of the merchandise in these final results of review or in the final results for the most recent period in which that producer participated; and (4) if neither the exporter nor the producer is a firm covered in this review or in any previously completed segment of this proceeding, then the cash deposit rate will be 6.58 percent *ad valorem,* the all-others rate established in the less than fair value investigation.[8] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice is the only reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h).

Dated: November 23, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy & Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

Appendix II

Non-Selected Exporters/Producers

1. 0729670 B.C. Ltd. DBA Anderson Sales
2. 1074712 BC Ltd.
3. 258258 B.C. Ltd., dba Pacific Coast Cedar Products
4. 5214875 Manitoba Ltd.
5. 752615 B.C Ltd
6. 9224–5737 Quebec Inc. (aka A.G. Bois)
7. A.B. Cedar Shingle Inc.
8. Absolute Lumber Products Ltd.
9. AJ Forest Products Ltd.
10. Alberta Spruce Industries Ltd.
11. Aler Forest Products Ltd.
12. Alpa Lumber Mills Inc.
13. American Pacific Wood Products
14. Anbrook Industries Ltd.
15. Andersen Pacific Forest Products Ltd.
16. Anglo American Cedar Products Ltd.; Anglo-American Cedar Products Ltd.
17. Antrim Cedar Corporation
18. Aquila Cedar Products Ltd.
19. Arbec Lumber Inc.
20. Aspen Planers Ltd.

[7] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[8] *See Certain Softwood Lumber Products from Canada: Final Affirmative Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances,* 82 FR 51806 (November 8, 2017).

21. B&L Forest Products Ltd.
22. B.B. Pallets Inc.
23. Babine Forest Products Limited
24. Bakerview Forest Products Inc.
25. Bardobec Inc.
26. Barrette-Chapais Ltee
27. BarretteWood Inc.
28. Benoît & Dionne Produits Forestiers Ltee (aka Benoît & Dionne Forest Products Ltd.)
29. Best Quality Cedar Products Ltd.
30. Blanchet Multi Concept Inc.
31. Blanchette & Blanchette Inc.
32. Bois Aisé de Montréal Inc.
33. Bois Bonsaï Inc.
34. Bois Daaquam Inc.
35. Bois D'oeuvre Cedrico Inc. (aka Cedrico Lumber Inc.)
36. Bois et Solutions Marketing SPEC, Inc.
37. Boisaco Inc.
38. Boscus Canada Inc.
39. Boucher Bros. Lumber Ltd.
40. BPWood Ltd.
41. Bramwood Forest Inc.
42. Brink Forest Products Ltd.
43. Brunswick Valley Lumber Inc.
44. Busque & Laflamme Inc.
45. C&C Wood Products Ltd.
46. Caledonia Forest Products Inc.
47. Campbell River Shake & Shingle Co. Ltd.
48. Canadian American Forest Products Ltd.
49. Canadian Wood Products Inc.
50. Canasia Forest Industries Ltd.
51. Canusa Cedar Inc.
52. Canyon Lumber Company Ltd.
53. Careau Bois Inc.
54. Carrier & Begin Inc.
55. Carrier Forest Products Ltd.
56. Carrier Lumber Ltd.
57. Carter Forest Products Inc.
58. Cedar Valley Holdings Ltd.
59. Cedarline Industries Ltd.
60. Central Alberta Pallet Supply
61. Central Cedar Ltd.
62. Central Forest Products Inc.
63. Centurion Lumber Ltd.
64. Chaleur Sawmills LP
65. Channel-ex Trading Corporation
66. Clair Industrial Development Corp. Ltd.
67. Clermond Hamel Ltée
68. CNH Products Inc.
69. Coast Clear Wood Ltd.
70. Coast Mountain Cedar Products Ltd.
71. Commonwealth Plywood Co. Ltd.
72. Comox Valley Shakes Ltd.
73. Conifex Fibre Marketing Inc.
74. Cowichan Lumber Ltd.
75. CS Manufacturing Inc. (dba Cedarshed)
76. CWP—Industriel Inc.
77. CWP—Montréal Inc.
78. D & D Pallets Ltd.
79. Dakeryn Industries Ltd.
80. Decker Lake Forest Products Ltd.
81. Delco Forest Products Ltd.
82. Delta Cedar Specialties Ltd.
83. Devon Lumber Co. Ltd.
84. DH Manufacturing Inc.
85. Direct Cedar Supplies Ltd.
86. Doubletree Forest Products Ltd.
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88. Dunkley Lumber Ltd.
89. EACOM Timber Corporation
90. East Fraser Fiber Co. Ltd.
91. Edgewood Forest Products Inc.
92. ER Probyn Export Ltd.
93. Eric Goguen & Sons Ltd.
94. Falcon Lumber Ltd.
95. Fontaine Inc.
96. Foothills Forest Products Inc.
97. Fornebu Lumber Company Inc.
98. Fraser Specialty Products Ltd.
99. Fraserview Cedar Products
100. FraserWood Inc.
101. FraserWood Industries Ltd.
102. Furtado Forest Products Ltd.
103. G & R Cedar Ltd.
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105. Glandell Enterprises Inc.
106. Goat Lake Forest Products Ltd.
107. Goldband Shake & Shingle Ltd.
108. Golden Ears Shingle Ltd.
109. Goldwood Industries Ltd.
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113. Groupe Crête ivision St-Faustin Inc.
114. Groupe Lebel Inc.
115. Groupe Lignarex Inc.
116. H.J. Crabbe & Sons Ltd.
117. Haida Forest Products Ltd.
118. Harry Freeman & Son Ltd.
119. Hornepayne Lumber LP
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121. Imperial Shake Co. Ltd.
122. Independent Building Materials Distribution Inc.
123. Interfor Corporation
124. Island Cedar Products Ltd.
125. Ivor Forest Products Ltd.
126. J&G Log Works Ltd.
127. J.D. Irving, Limited
128. J.H. Huscroft Ltd.
129. Jan Woodlands (2001) Inc.
130. Jasco Forest Products Ltd.
131. Jazz Forest Products Ltd.
132. Jhajj Lumber Corporation
133. Kalesnikoff Lumber Co. Ltd.
134. Kan Wood Ltd.
135. Kebois Ltée/Ltd
136. Keystone Timber Ltd.
137. Kootenay Innovative Wood Ltd.
138. Lafontaine Lumber Inc.
139. Langevin Forest Products Inc.
140. Lecours Lumber Co. Limited
141. Ledwidge Lumber Co. Ltd.
142. Leisure Lumber Ltd.
143. Les Bois d'oeuvre Beaudoin Gauthier Inc.
144. Les Bois Martek Lumber
145. Les Bois Traités M.G. Inc.
146. Les Chantiers de Chibougamau Ltee
147. Les Produits Forestiers D&G Ltee (aka D&G Forest Products Ltd.)
148. Leslie Forest Products Ltd.
149. Lignum Forest Products LLP
150. Linwood Homes Ltd.
151. Longlac Lumber Inc.
152. Lulumco Inc.
153. Magnum Forest Products Ltd.
154. Maibec Inc.
155. Manitou Forest Products Ltd.
156. Marcel Lauzon Inc.
157. Marwood Ltd.
158. Materiaux Blanchet Inc.
159. Matsqui Management and Consulting Services Ltd., dba Canadian Cedar Roofing Depot
160. Metrie Canada Ltd.
161. Mid Valley Lumber Specialties Ltd.
162. Midway Lumber Mills Ltd.
163. Mill & Timber Products Ltd.
164. Millar Western Forest Products Ltd.
165. Mobilier Rustique (Beauce) Inc.
166. MP Atlantic Wood Ltd.
167. Multicedre Ltee
168. Murray Brothers Lumber Company Ltd.
169. Nakina Lumber Inc.
170. National Forest Products Ltd.
171. New Future Lumber Ltd.
172. Nicholson and Cates Ltd.
173. Norsask Forest Products Limited Partnership
174. North American Forest Products Ltd. (located in Abbotsford, British Columbia)
175. North American Forest Products Ltd. (located in Saint-Quentin, New Brunswick)
176. North Enderby Timber Ltd.
177. Oikawa Enterprises Ltd.
178. Olympic Industries Inc.
179. Olympic Industries ULC
180. Oregon Canadian Forest Products
181. Pacific Coast Cedar Products Ltd.
182. Pacific Pallet Ltd.
183. Pacific Western Wood Works Ltd.
184. Parallel Wood Products Ltd.
185. Pat Power Forest Products Corporation
186. Phoenix Forest Products Inc.
187. Pine Ideas Ltd.
188. Pioneer Pallet & Lumber Ltd.
189. Porcupine Wood Products Ltd.
190. Portbec Forest Products Ltd.
191. Power Wood Corp.
192. Precision Cedar Products Corp.
193. Prendiville Industries Ltd. (aka Kenora Forest Products)
194. Produits Forestiers Petit Paris Inc.
195. Produits forestiers Temrex, s.e.c.
196. Produits Matra Inc.
197. Promobois G.D.S. Inc.
198. Rayonier A.M. Canada GP
199. Rembos Inc.
200. Rene Bernard Inc.
201. Resolute Growth Canada Inc./Forest Products Mauricie LP, Société en commandite Scierie Opitciwan/Resolute-LP Engineered Wood Larouche Inc./ Resolute-LP Engineered Wood St-Prime Limited Partnership/Resolute FP Canada Inc.
202. Richard Lutes Cedar Inc.
203. Rielly Industrial Lumber Inc.
204. Roland Boulanger & Cie Ltee
205. S & K Cedar Products Ltd.
206. S&R Sawmills Ltd.
207. S&W Forest Products Ltd.
208. San Industries Ltd.
209. Sawarne Lumber Co. Ltd.
210. Scierie Alexandre Lemay & Fils Inc.
211. Scierie P.S.E. Inc.
212. Scierie St-Michel Inc.
213. Scierie West Brome Inc.
214. Scotsburn Lumber Co. Ltd.
215. Sechoirs de Beauce Inc.
216. Serpentine Cedar Ltd.
217. Serpentine Cedar Roofing Ltd.
218. Sexton Lumber Co. Ltd.
219. Sigurdson Forest Products Ltd.
220. Silvaris Corporation
221. Silver Creek Premium Products Ltd.
222. Sinclar Group Forest Products Ltd.
223. Skana Forest Products Ltd.
224. Skeena Sawmills Ltd.
225. Sound Spars Enterprise Ltd.
226. South Beach Trading Inc.
227. Specialiste du Bardeau de Cedre Inc.
228. Spruceland Millworks Inc.
229. Star Lumber Canada Ltd.

230. Sundher Timber Products Ltd.
231. Surrey Cedar Ltd.
232. T.G. Wood Products Ltd.
233. Taan Forest Limited Partnership (aka Taan Forest Products)
234. Taiga Building Products Ltd.
235. Tall Tree Lumber Company
236. Teal Cedar Products Ltd.
237. Tembec Inc.
238. Terminal Forest Products Ltd.
239. The Teal Jones Group
240. The Wood Source Inc.
241. Tolko Industries Ltd.; Tolko Marketing and Sales Ltd.; Gilbert Smith Forest Products Ltd.
242. Trans-Pacific Trading Ltd.
243. Triad Forest Products Ltd.
244. Twin Rivers Paper Co. Inc.
245. Tyee Timber Products Ltd.
246. Universal Lumber Sales Ltd.
247. Usine Sartigan Inc.
248. Vaagen Fibre Canada ULC
249. Valley Cedar 2 Inc.
250. Vancouver Island Shingle Ltd.
251. Vancouver Specialty Cedar Products Ltd.
252. Vanderhoof Specialty Wood Products Ltd.
253. Visscher Lumber Inc.
254. W.I. Woodtone Industries Inc.
255. Waldun Forest Product Sales Ltd.
256. Watkins Sawmills Ltd.
257. West Bay Forest Products Ltd.
258. West Fraser Timber Co. Ltd.
259. West Wind Hardwood Inc.
260. Western Forest Products Inc.
261. Western Lumber Sales Limited
262. Western Wood Preservers Ltd.
263. Weston Forest Products Inc.
264. Westrend Exteriors Inc.
265. Weyerhaeuser Co.
266. White River Forest Products L.P.
267. Winton Homes Ltd.
268. Woodline Forest Products Ltd.
269. Woodstock Forest Products
270. Woodtone Specialties Inc.
271. Yarrow Wood Ltd.

[FR Doc. 2021–26149 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–970]

Multilayered Wood Flooring From the People's Republic of China: Notice of Initiation of Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on a request from Zhejiang Yuhua Timber Co. Ltd. (Yuhua), A-Timber Flooring Company Limited (A-Timber) and Mullican Flooring Co. (Mullican) (collectively, Yuhua *et al.*), the Department of Commerce (Commerce) is initiating a changed circumstances review (CCR) of the antidumping duty (AD) order on multilayered wood flooring (MLWF), from the People's Republic of China (China).

DATES: Applicable December 2, 2021.

FOR FURTHER INFORMATION CONTACT: Alexis Cherry, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0607.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 2011, Commerce published the AD order on MLWF from China.[1] Under the *Order,* merchandise produced and exported by Yuhua has been excluded and is not subject to antidumping duty cash deposits. On September 1, 2021, Yuhua, A-Timber, and Mullican, respectively a producer, exporter, and importer of the subject merchandise, requested that Commerce initiate an expedited CCR, pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act), 19 CFR 351.216, and 19 CFR 251.221(c)(3). Specifically, Yuhua *et al.* request that Commerce clarify that MLWF produced by Yuhua and sold through A-Timber be considered as merchandise which is ''produced and exported'' by Yuhua, and thus, excluded from the *Order.* Yuhua *et al.* asserts that this clarification is necessary because U.S. Customs and Border Protection has only as of late 2020 begun requiring the posting of cash deposits and the classification of such merchandise as ''Type 3'' entries subject to antidumping duties under the *Order.* On October 14, 2021, the American Manufacturers of Multilayered Wood Flooring (the petitioner) filed a letter in support of Yuhua *et al.*'s CCR request.[2] On October 15, 2021, Commerce extended the deadline to initiate this CCR.[3]

Scope of the Order

Multilayered wood flooring is composed of an assembly of two or more layers or plies of wood veneer(s)[4] in combination with a core.[5] The several layers, along with the core, are glued or otherwise bonded together to form a final assembled product. Multilayered wood flooring is often referred to by other terms, *e.g.,* ''engineered wood flooring'' or ''plywood flooring.'' Regardless of the particular terminology, all products that meet the description set forth herein are intended for inclusion within the definition of subject merchandise. All multilayered wood flooring is included within the definition of subject merchandise, without regard to: Dimension (overall thickness, thickness of face ply, thickness of back ply, thickness of core, and thickness of inner plies; width; and length); wood species used for the face, back and inner veneers; core composition; and face grade. Multilayered wood flooring included within the definition of subject merchandise may be unfinished (*i.e.,* without a finally finished surface to protect the face veneer from wear and tear) or ''prefinished'' (*i.e.,* a coating applied to the face veneer, including, but not exclusively, oil or oil-modified or water-based polyurethanes, ultraviolet light cured polyurethanes, wax, epoxy-ester finishes, moisture-cured urethanes and acid curing formaldehyde finishes). The veneers may be also soaked in an acrylic-impregnated finish. All multilayered wood flooring is included within the definition of subject merchandise regardless of whether the face (or back) of the product is smooth, wire brushed, distressed by any method or multiple methods, or hand-scraped. In addition, all multilayered wood flooring is included within the definition of subject merchandise regardless of whether or not it is manufactured with any interlocking or connecting mechanism (for example, tongue-and-groove construction or locking joints). All multilayered wood flooring is included within the definition of the subject merchandise regardless of whether the product meets a particular industry or similar standard.

The core of multilayered wood flooring may be composed of a range of materials, including but not limited to hardwood or softwood veneer, particleboard, medium-density fiberboard, high density fiberboard (HDF), stone and/or plastic composite, or strips of lumber placed edge-to-edge.

[1] *See Multilayered Wood Flooring from the People's Republic of China: Notice of Amended Final Affirmative Determination of Sales at Less than Fair Value and Antidumping Duty Order,* 76 FR 76690 (December 8, 2011), as amended in *Multilayered Wood Flooring from the People's Republic of China,* 77 FR 5484 (February 3, 2012) (collectively, the *Order*).

[2] *See* Petitioner's Letter, ''Multilayered Wood Flooring from the People's Republic of China: Letter in Support of Request for Changed Circumstances Review,'' dated October 14, 2021.

[3] *See* Commerce's Letter, ''Request for a Changed Circumstance Review Antidumping Duty Order on Multilayered Wood Flooring from the People's Republic of China: Extension of Initiation Deadline,'' dated October 15, 2021.

[4] A ''veneer'' is a thin slice of wood, rotary cut, sliced or sawed from a log, bolt or flitch. Veneer is referred to as a ply when assembled.

[5] Commerce Interpretive Note: Commerce interprets this language to refer to wood flooring products with a minimum of three layers.

Multilayered wood flooring products generally, but not exclusively, may be in the form of a strip, plank, or other geometrical patterns (*e.g.,* circular, hexagonal). All multilayered wood flooring products are included within this definition regardless of the actual or nominal dimensions or form of the product. Specifically excluded from the scope are cork flooring and bamboo flooring, regardless of whether any of the sub-surface layers of either flooring are made from wood. Also excluded is laminate flooring. Laminate flooring consists of a top wear layer sheet not made of wood, a decorative paper layer, a core-layer of HDF, and a stabilizing bottom layer. Imports of the subject merchandise are provided for under the following subheadings of the Harmonized Tariff Schedule of the United States (HTSUS):[6] 4412.31.0520; 4412.31.0540; 4412.31.0560; 4412.31.0620; 4412.31.0640; 4412.31.0660; 4412.31.2510; 4412.31.2520; 4412.31.2610; 4412.31.2620; 4412.31.3175; 4412.31.4040; 4412.31.4050; 4412.31.4060; 4412.31.4070; 4412.31.4075; 4412.31.4080; 4412.31.4140; 4412.31.4160; 4412.31.4175; 4412.31.5125; 4412.31.5135; 4412.31.5155; 4412.31.5165; 4412.31.5175; 4412.31.5225; 4412.31.6000; 4412.31.9100; 4412.32.0520; 4412.32.0540; 4412.32.0560; 4412.32.0565; 4412.32.0570; 4412.32.0640; 4412.32.0665; 4412.32.2510; 4412.32.2520; 4412.32.2525; 4412.32.2530; 4412.32.2610; 4412.32.2625; 4412.32.3125; 4412.32.3135; 4412.32.3155; 4412.32.3165; 4412.32.3175; 4412.32.3185; 4412.32.3225; 4412.32.5600; 4412.32.5700; 4412.39.1000; 4412.39.3000; 4412.39.4011; 4412.39.4012; 4412.39.4019; 4412.39.4031; 4412.39.4032; 4412.39.4039; 4412.39.4051; 4412.39.4052; 4412.39.4059; 4412.39.4061; 4412.39.4062; 4412.39.4069; 4412.39.5010; 4412.39.5030; 4412.39.5050; 4412.94.1030; 4412.94.1050; 4412.94.3105; 4412.94.3111; 4412.94.3121; 4412.94.3131; 4412.94.3141; 4412.94.3160; 4412.94.3171; 4412.94.4100; 4412.94.5100; 4412.94.6000; 4412.94.7000; 4412.94.8000; 4412.94.9000; 4412.94.9500; 4412.99.0600; 4412.99.1020; 4412.99.1030; 4412.99.1040; 4412.99.3110; 4412.99.3120; 4412.99.3130; 4412.99.3140; 4412.99.3150; 4412.99.3160; 4412.99.3170; 4412.99.4100; 4412.99.5100; 4412.99.5105; 4412.99.5115; 4412.99.5710; 4412.99.6000; 4412.99.7000; 4412.99.8000; 4412.99.9000; 4412.99.9500; 4418.71.2000; 4418.71.9000; 4418.72.2000; 4418.72.9500; 4418.74.2000; 4418.74.9000; 4418.75.4000; 4418.75.7000; 4418.79.0100; and 9801.00.2500. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive.

Initiation of Changed Circumstances Review

Pursuant to section 751(b) of the Act, Commerce will conduct a CCR upon receipt of a request from an interested party[7] that shows changed circumstances sufficient to warrant a review of an order. In accordance with 19 CFR 351.216(d), Commerce determines that the questions raised by Yuhua *et al.* concerning the appropriateness of excluding A-Timber's sales of subject merchandise from the *Order* constitute a sufficient basis to conduct a CCR of the *Order.* Therefore, in accordance with section 751(b)(1)(A) of the Act and 19 CFR 351.216(d) and (e), we are initiating a CCR based upon the information contained in Yuhua *et al.*'s submission.

In the event that Commerce determines an expedited action is warranted, 19 CFR 351.221(c)(3)(ii) permits Commerce to combine the notice of initiation of the review and the preliminary results of review into a single notice. However, we are not combining this notice of initiation with the preliminary results, pursuant to 19 CFR 351.221(c)(3)(ii), because Commerce has determined that it is necessary to issue a questionnaire to Yuhua *et al.* regarding A-Timber's role in the sales channel for subject merchandise and provide interested parties with an opportunity to comment. After examining any comments and following up with any additional questionnaires as needed, we intend to issue the preliminary results of this CCR.

Preliminary and Final Results of the CCRs

Commerce intends to publish in the **Federal Register** a notice of the preliminary results of this AD CCR in accordance with 19 CFR 351.221(b)(4) and (c)(3)(i). Commerce will set forth its preliminary factual and legal conclusions in that notice. Unless extended, Commerce will issue the final results of this CCR in accordance with the time limits set forth in 19 CFR 351.216(e).

Notification to Interested Parties

This initiation notice is published in accordance with section 751(b)(1) of the Act, 19 CFR 351.216(d), and 19 CFR 351.221(b)(1). Further, interested parties are reminded that the next opportunity to request an administrative review of entries that may be examined in this CCR is December 2021.[8] Should Commerce receive a timely request for review and initiate an administrative review with respect to such entries, those entries would remain suspended from liquidation pursuant to 19 CFR 351.212. Thus, to ensure fulsome consideration of the issues raised in Yuhua *et al.*'s request for a CCR, interested parties are encouraged to follow Commerce's procedures in the forthcoming notice of opportunity to request administrative review of the *Order* in requesting a review of the relevant entries.

Dated: November 23, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–26020 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–DS–P

[6] On October 31, 2018, we added the following HTS numbers to update the ACE Case Reference File: 4412.33.0640, 4412.33.0665, 4412.33.0670, 4412.33.2625, 4412.33.2630, 4412.33.3225, 4412.33.3235, 4412.33.3255, 4412.33.3275, 4412.33.3285, 4412.33.5700, 4412.34.2600, 4412.34.3225, 4412.34.3235, 4412.34.3255, 4412.34.3275, 4412.34.3285, 4412.34.5700, 4418.74.2000, 4412.74.9000, 4418.75.4000, and 4418.75.7000. See Memorandum, ''Multilayered Wood Flooring from the People's Republic of China (A–570–970): Request from Customs and Border Protection to Update the ACE AD/CVD Case Reference File,'' dated October 31, 2018.

[7] Yuhua, *et al.* reported in its September 1, 2021 request for a CCR that Yuhua, A-Timber and Mullican are respectively the producer, an exporter and an importer of MLWF. As such,Yuhua *et al.* is an interested party within the meaning of section 771(9)(A) of the Act and 19 CFR 351.102(b)(29)(i) and (ii).

[8] *See* 19 CFR 351.213(b)(1). The anniversary month of the *Order* is December.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB605]

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 Highly Migratory Species (HMS) Hammerhead Sharks Post Data Workshop Webinar.

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 Post Data Workshop Webinar has been scheduled for Thursday, January 13, 2022, from 12 p.m. until 3 p.m., ET.

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/9700126668632435333.*

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 Post Data Workshop Webinar are as follows: Discuss any data issues or concerns remaining from the 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: November 29, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–26185 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 211122–0242; RTID 0648–XR113]

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Black Teatfish (*Holothuria nobilis*) as Threatened or Endangered Under the Endangered Species Act

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

ACTION: Notice of 12-month finding and availability of status review document for the black teatfish (*Holothuria nobilis*).

SUMMARY: We, NMFS, have completed a comprehensive status review under the Endangered Species Act (ESA) for the black teatfish (*Holothuria nobilis*). After reviewing the best scientific and commercial data available, including the *H. nobilis* Status Review Report, we have determined that listing *H. nobilis* as a threatened or endangered species under the ESA is not warranted at this time.

DATES: This finding was made on December 2, 2021.

ADDRESSES: The *H. nobilis* Status Review Report associated with this determination, its references, and the petition can be accessed electronically online at: *https://www.fisheries.noaa.gov/species/black-teatfish#conservation-management.*

FOR FURTHER INFORMATION CONTACT: Celeste Stout, NMFS Office of Protected Resources, 301–427–8436.

SUPPLEMENTARY INFORMATION:

Background

On May 14, 2020, we received a petition from the Center for Biological Diversity to list black teatfish (*H. nobilis*) as a threatened or endangered species under the ESA. The petition asserted that *H. nobilis* is threatened by four of the five ESA section 4(a)(1) factors: (1) The present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial purposes; (3) inadequacy of existing regulatory mechanisms; and (4) other natural or manmade factors.

On August 10, 2020, NMFS published a 90-day finding for *H. nobilis* with our determination that the petition presented substantial scientific and commercial information indicating that

the petitioned action may be warranted (85 FR 48144). We also announced the initiation of a status review of the species, as required by section 4(b)(3)(a) of the ESA, and requested information to inform the agency's decision on whether this species warrants listing as endangered or threatened under the ESA. We received information from the public in response to the 90-day finding and incorporated the information into both the Status Review Report (NMFS 2021) and this 12-month finding.

Listing Determinations Under the ESA

We are responsible for determining whether *H. nobilis* is threatened or endangered under the ESA (16 U.S.C. 1531 *et seq.*). To be considered for listing under the ESA, a group of organisms must constitute a ''species,'' which is defined in section 3 of the ESA to include any subspecies of fish or wildlife or plants, and any distinct population segment (DPS) of any species of vertebrate fish or wildlife which interbreeds when mature (16 U.S.C. 1532(16)). Because *H. nobilis* is an invertebrate species, the ESA does not permit listing its populations as DPSs.

Section 3 of the ESA defines an endangered species as any species which is in danger of extinction throughout all or a significant portion of its range and a threatened species as one which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range 16 U.S.C. 1532(6), 16 U.S.C. 1532(20). Thus, in the context of the ESA, we interpret an ''endangered species'' to be one that is presently in danger of extinction. A ''threatened species,'' on the other hand, is not presently in danger of extinction, but is likely to become so in the foreseeable future (that is, at a later time). In other words, the primary statutory difference between a threatened and endangered species is the timing of when a species is in danger of extinction, either presently (endangered) or not presently but in the foreseeable future (threatened).

When we consider whether a species qualifies as threatened under the ESA, we must consider the meaning of the term ''foreseeable future.'' Regulations at 50 CFR 424.11(d) state that the foreseeable future extends only so far into the future as we can reasonably determine that both the future threats and the species' responses to those threats are likely. What constitutes the foreseeable future for a particular species depends on case-specific factors such as the the species' life-history characteristics, threat-projection timeframes, and environmental variability. That is, the foreseeability of a species' future status is case specific and depends upon both the foreseeability of threats to the species and foreseeability of the species' response to those threats.

The statute requires us to determine whether any species is endangered or threatened throughout all or a significant portion of its range as a result of any one or a combination of any of the following five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence (16 U.S.C. 1533(a)(1)). We are also required to make listing determinations based solely on the best scientific and commercial data available, after conducting a review of the species' status and after taking into account efforts, if any, being made by any state or foreign nation (or subdivision thereof) to protect the species (16 U.S.C. 1533(b)(1)(A)).

To determine whether *H. nobilis* warrants listing under the ESA, we completed a Status Review Report (NMFS 2021), which summarizes the taxonomy, distribution, abundance, life history, and biology of the species. The Status Review Report (NMFS 2021) also identifies threats or stressors affecting the status of the species, and provides a description of fisheries and fisheries management. NMFS then assessed the threats affecting *H. nobilis* as well as demographic risk factors (abundance and trends, population growth rate or productivity, spatial structure and connectivity, and genetic diversity) as part of an extinction risk analysis (ERA). The results of the ERA from the Status Review Report (NMFS 2021) are discussed below. The Status Review Report incorporates information received in response to our request for information (85 FR 48144, August 10, 2020) and comments from three independent peer reviewers. Information from the Status Review Report is summarized below in the Biological Review section.

Biological Review

This section provides a summary of key biological information presented in the Status Review Report (NMFS 2021).

Species Description

Sea cucumbers are characterized by a suboval body arched dorsaly and flattened ventrally, a thick and rigid tegument, a large number of ventral podia arranged tightly and without order, small dorsal papillae, and anal teeth (Purcell *et al.* 2012). The mouth, surrounded by tentacles, is ventral (Purcell *et al.* 2012). The main characteristic that distinguishes teatfish from other sea cucumber species is the presence of lateral protuberances (''teat-like'') on their body tegument (outer body covering) visible in their live and processed forms (Purcell *et al.* 2012; Conand pers. comm. 2017 in CITES 2019).

H. nobilis is black dorsally with white blotches and spots on the sides of the animal and around the lateral protrusions ('teats'). *H. nobilis* has between 6 to 10 characteristic large lateral protrusions at the ventral margins. The average length of *H. nobilis* is about 35 cm, but has been observed at up to 60 cm. The presence of dorsal podia are sparse and small, while the ventral podia are numerous, short and greyish. The tegument is usually covered by fine sand. The mouth is ventral, with 20 stout tentacles and the anus is surrounded by five small calcareous teeth.

Range, Distribution, and Habitat Use

H. nobilis occurs in tropical coral reef flats and outer reef slopes at depths between 0 and 40 meters, with a preference for hard substrates (Lawrence *et al.* 2004; Idreesbabu and Sureshkumar 2017; Eriksson *et al.* 2012; Conand *et al.* 2013; CITES 2019). While *H. nobilis* has occasionally been observed in seagrass (Purcell *et al.* 2012), seagrass is not considered the desired habitat of the species. Lawrence *et al.* (2004) state that while seagrass beds may be important to most of the main commercial species of sea cucumber, *H. nobilis* is one of the exceptions as it had only been found on coral substrate. Further, *H. nobilis* is considered to be strongly associated with a single habitat variable (*i.e.* hard substrate; Eriksson *et al.* 2012). Thus, the primary habitat for *H. nobilis* is widely considered to be coral reefs (flats/slopes; Conand 2008). *H. nobilis* is commonly seen covered by sand, though this species does not bury itself (Conand 2008). *H. nobilis* is distributed throughout the Indian Ocean, including along the east coast of Africa (Egypt, Sudan, Somalia, Kenya, Eritrea, Djibouti, Tanzania, Mozambique, Zanzibar, and South Africa); the Red and Arabian Seas (Israel, Jordan, Saudi Arabia, Oman, Yemen); and the coastal waters of Madagascar, Mayotte, Mauritius, La Reunion, Seychelles, Comoros, Chagos, Sri Lanka, the

Maldives, and the west coast of India (See Figure 5 in NMFS 2021; CITES 2019; Conand *et al.* 2013; Uthicke *et al.* 2004). The species does not occur in the waters of the United States or its overseas territories.

Diet and Feeding

H. nobilis like other sea cucumbers of the order Holothuriida are deposit and detritus feeders. They digest organic matter in the sediment such as bacteria, cyanobacteria, decaying plant matter, copepods, diatoms, foraminiferans, and fungi. Using their retractile tentacles, they ingest the top few millimeters of sediment and excrete less organic rich sediment (Anderson *et al.* 2011; Purcell *et al.* 2016; Webster & Hart 2018).

Reproductive Biology

Teatfish are gonochoristic (*i.e.* separate sex) broadcast spawners, meaning males and females release their gametes into the water column and fertilization occurs externally (Conand 1981; Conand 1986; Toral-Granda 2006). *H. nobilis* do not exhibit sexual dimorphism, and sex of individual animals must be determined through microscopic examination of the gonads.

Teatfish have slow growth rates, maturing at about 3–7 years, and are thought to live for several decades (Conand *et al.* 2013, FAO 2019). Conand *et al.* (2013) reported that *H. nobilis* mature at around 4 years of age. Reproductive fitness is positively correlated with body size, with larger individuals having larger gonads that produce more gametes, thus exhibiting higher fecundity (CITES 2019). As adults, they are non-migratory and relatively sedentary (FAO 2019).

Environmental cues (*e.g.,* tidal conditions, lunar phases, temperature fluctuations) and chemical cues trigger the release of gametes (Purcell *et al.* 2010). *H. nobilis* is believed to reproduce annually during the cold season (Purcell, Samyn & Conand 2012; Conand *et al.* 2013; CITES 2019). Successful fertilization depends upon sufficient population density and proximity of adults (Purcell *et al.* 2010; Purcell *et al.* 2011; CITES 2019; FAO 2019). Minimum population densities for successful reproduction have yet to be determined (Purcell *et al.* 2011).

The oocytes of most sea cucumber species, which include teatfish, are small (< 200 µm in diameter) and are neutrally buoyant in the water column (Purcell *et al.* 2010). Fertilized *H. nobilis* eggs quickly develop into free-swimming larvae—sometimes within a day (Purcell *et al.* 2010). These larvae spend 50–90 days in planktonic stage feeding on algae and may be widely dispersed by ocean currents (Conand 2009; Purcell *et al.* 2010; CITES 2019). One breeding trial found that the planktonic period of *H. nobilis* ranged from 44–51 days (Minami 2011). After metamorphosis, sea cucumbers settle on the seafloor (Conand 2009; Purcell *et al.* 2010).

Population Structure

H. nobilis was once considered to be *H. fuscogilva,* another species of teatfish, but was separated in 1980 (Cherbonnier 1980). In 2004, *H. nobilis* was once again separated. *H. nobilis* now only occurs in the indian Ocean, while *H. whitmaei,* occurs in the Pacific Ocean (Uthicke *et al.* 2004). The two black teatfish (*H. whitmaei,* with distribution in the Pacific Ocean, and *H. nobilis,* with distribution in the Indian Ocean) appear to be allopatric with a genetic distance of 9.2 percent, implying a divergence during the Pliocene of approximately 1.8–4.6 million years ago (Uthicke *et al.* 2004). Further molecular analyses support the distinction between *H. nobilis* and *H. fuscogilva* as different species (Ahmed *et al.* 2016). Apart from these genetic data indicating separation of *H. nobilis* and *H. whitmaei* (Uthicke *et al.* 2004), there is very limited additional species-specific information regarding the population structure or genetics of *H. nobilis* populations.

Abundance and Trends

Few standardized datasets documenting changes in teatfish species densities exist for any range countries. This is due mostly to a lack of detailed historical data on early harvests (Friedman *et al.* 2011). Sea cucumber fisheries are largely made up of artisanal fishers living in remote locations far removed from the enforcement of centralized fisheries management agencies and therefore have generally not been monitored long-term. Additionally, few countries record catches or exports by species, making it difficult to determine the utilization of a single species. Despite sea cucumbers high commercial value, there have been no obvious extirpations of teatfish (type of sea cucumber) species at the national scale. However, declines in densities of teatfish (individuals per hectare) are reported from time series and snap-shot studies, and depletion of stocks have been observed (Kinch *et al.* 2008; Hasan and El-Rady, 2012; Friedman *et al.* 2011; Lane and Limbong, 2013; Ducarme 2016; FAO 2019). It is also important to note that similar to other teatfish species, *H. nobilis* is thought to be naturally rare when compared to other species of sea cucumber (Purcell, pers. comm. 2019 in CITES 2019; CITES 2019; Conand *et al.* 2013; Uthicke *et al.* 2004).

While data on abundance and population trends for teatfish are lacking, they are even more sparse for *H. nobilis* (Anderson *et al.* 2011). The mean density of *H. nobilis* in areas where the species has been observed/surveyed (*e.g.,* Chagos, Egypt, Eritrea, Madagascar, Mayotte, Saudi Arabia, Seychelles, Sri Lanka, and Zanzibar) ranges from approximately 0.12 to 10 individuals per hectare (CITES 2019). It is thought that *H. nobilis* once occurred at much greater densities (Conand 2018), with anecdotal reports from sea cucumber collectors indicating that sea cucumbers, in general, were historically larger in size and more abundant (Mmbaga 2013). Throughout the range of *H. nobilis,* this species is considered less abundant relative to previous surveys or anecdotal data or its status is uncertain or unknown based on a lack of data. In fact, in 18 of the 25 countries where *H. nobilis* is reported to occur, the abundance of the species and trends in abundance is very limited or unknown. The information available for the other seven range countries (*i.e,* Chagos, Egypt, Madagascar, Mayotte, Saudi Arabia, Seychelles, and Tanzania) indicates that there are possible declines in abundance with one exception—the Seychelles, where it is reported to be stable (Conand *et al.* 2013, FAO 2019, CITES 2019). Overall, while some quantitative data are available, the abundance and density trends of *H. nobilis* across its range are poorly understood. Abundance information by country is summarized in Table 1 of NMFS 2021.

Extinction Risk Analysis

NMFS relied on the best information available to conduct an extinction risk analysis through evaluation of four demographic viability factors and five threats-based listing factors. In determining the extinction risk of a species, it is important to consider both the demographic risks facing the species as well as current and potential threats that may affect the species' status. To this end, a demographic analysis was conducted for *H. nobilis* and considered alongside the information presented on threats as detailed in the Status Review Report (NMFS 2021).

A demographic risk analysis is an assessment of the manifestation of past threats that have contributed to the species' current status and informs the consideration of the biological response of the species to present and future threats. This analysis evaluated the population viability characteristics and

trends available for *H. nobilis,* such as abundance, growth rate/productivity, spatial structure, connectivity, and diversity to determine the potential risks these demographic factors pose to the species. The information from this demographic risk analysis in conjunction with the available information on the section 4(a)(1) factors was then synthesized to determine an overall risk of extinction for *H. nobilis.*

The appropriate time horizon for evaluating whether a species is more likely than not to be at a high level of risk in the ''foreseeable future'' depends on various case-and species-specific factors. For example, the time horizon may reflect certain life history characteristics (*e.g.,* long generational time or late age-at-maturity) and may also reflect the time frame or rate over which identified threats are likely to impact the biological status of the species (*e.g.,* the rate of disease spread). The appropriate time horizon coincides with the period of time over which reliable projections can be made as to the specific threats facing the species as well as the species' response, but it is not limited to the period that status can be quantitatively modeled or predicted within predetermined limits of statistical confidence. Reliable projections may be qualitative in nature.

The ''foreseeable future'' for this extinction risk analysis was considered to extend out several decades (>30 years). Because of the species' life history traits, with longevity estimated to be several decades, age of sexual maturity ranging from three to seven years, density-dependent reproduction and potentially low rates of recruitment, it would likely take more than a few decades for any recent management actions to be realized and reflected in population abundance. Similarly, the impact of present threats to the species could be realized in the form of noticeable population declines within this timeframe, as demonstrated in the available survey and fisheries data (see Populations and Abundance section in NMFS 2021). As the main potential operative threats to the species are overutilization and the inadequacy of existing regulatory mechanisms, this timeframe would allow for reliable predictions regarding the impact of current levels of fishery-related mortality on the biological status of the species. Additionally, this time frame allows for consideration of the impacts on habitat from climate change while the significance of these effects are still uncertain.

The ability to determine and assess risk factors to a marine species is often limited when quantitative estimates of abundance and life history information are lacking. Therefore, in assessing threats and subsequent extinction risk of a data-limited species such as *H. nobilis,* we include both qualitative and quantitative information. In assessing extinction risk to *H. nobilis,* we considered the demographic viability factors developed by McElhany *et al.* (2000) and the risk matrix approach developed by Wainwright and Kope (1999) to organize and summarize extinction risk considerations. In this approach, the collective condition of individual populations is considered at the species level according to four demographic viability factors: Abundance, productivity, spatial structure/connectivity, and diversity. These viability factors reflect concepts that are well-founded in conservation biology and that individually and collectively provide strong indicators of extinction risk.

Using these concepts, we evaluated extinction risk by assigning a risk level to each of the four demographic viability factors and five threats-based listing factors. The levels are defined as follows:

- *Low risk:* Based on the best available information, it is unlikely this threat is causing negative impacts to the species at the population level throughout its range, such that it is not likely to be affecting extinction risk for the species:
- *Moderate risk:* Based on the best available information, this threat is likely causing negative impacts to the species at the population level in at least some portion of its range, such that it may be affecting extinction risk for the species; and
- *High risk:* Based on the best available information, this threat is likely causing negative impacts to the species at the population level throughout its range, such that it is likely affecting extinction risk for the species.

Aditionally, we provided a confidence rating to the impact of each threat as well as the demographic factors based on the available information. The confidence rating scores were adapted from Lack *et al.* (2014) and are defined as follows:

- 0 (no confidence) = No information;
- 1 (low confidence) = Very limited information;
- 2 (medium confidence) = Some reliable information available, but reasonable inference and extrapolation required; and
- 3 (high confidence) = Reliable information with little to no extrapolation or inference required.

We also considered the potential interactions among demographic and listing factors. Finally, we examined the levels assigned to each demographic and listing factor along with the uncertainty rating to determine the overall risk of extinction (see *Extinction Risk Determination* below).

Demographic Risk Analysis

Abundance

As discussed in the Abundance and Trends section of the Status Review Report, across the range of *H. nobilis,* the species is either considered less abundant, or its status is unknown based on a lack of data, with the exception of the Seychelles (see Table 1 in NMFS 2021). In fact, in 18 of the 25 countries where *H. nobilis* is reported to occur, the abundance of the species and trends in abundance are unknown due to a lack of data. Similar to other teatfish species, *H. nobilis* is thought to be naturally rare when compared to other species of sea cucumber (Purcell, pers. comm. 2019 in CITES 2019; CITES 2019; Conand *et al.* 2013; Uthicke *et al.* 2004).

H. nobilis has not been reported to be extirpated from any range countries but has been observed to no longer occur at several survey locations within some some countries across its range, including Geyser Bank in Mayotte and Eel Garden in Egypt (see Table 1 in NMFS 2021; CITES 2019; Conand *et al.* 2013; Uthicke *et al.* 2004). Throughout the species's range, the historical abundance of *H. nobilis* is uncertain, but the abundance of other sea cucumber species have been reported to be declineing (Kinch *et al.* 2008; Hasan and El-Rady, 2012; Friedman *et al.* 2011; Lane and Limbong, 2013; Ducarme 2016; FAO 2019). The available data indicate population declines or possible population declines of *H. nobilis* at survey locations in Chagos, Egypt, Madagascar, Mayotte, Saudi Arabia, and Tanzania. In Chagos at Salomon atoll, there was a decrease in density from 83 ind. ha^{-1} to 10 ind. ha^{-1} from 2002–2006 (Price *et al.* 2010). In Egypt, at Wadi Quny and Eel Garden in the Gulf of Aqaba the species was observed at densities of 0.7 ind. ha^{-1} and 1.3 ind. ha^{-1} respectively in 2002, but were not observed at these locations in 2006 (Hasan & El-Rady, 2012). However, confirmed reports of the species were made off Pharoan Island in April 2015 (Hasan & Johnson 2019) and *H. nobilis* has been reported to be commonly seen by divers as recently as 2019 in Egypt's waters (FAO 2019). For Madagascar, there are anecdotal reports that *H. nobilis* is assumed to be depleted as

very few specimens have been seen in the past several years (Conand pers. comm. 2010 in Conand *et al.* 2013). In Mayotte, the species was reported to be observed less frequently in 2016 than in 2005, 2012, and 2015, however, we do not have reported density numbers (Mulochau 2018; FAO 2019). Off the coast of Saudi Arabia, *H. nobilis* was not documented in 2004's harvested species but had been present in the harvest record from 1999–2003. However, in 2006 *H. nobilis* was observed at 3 of 18 surveyed sites along the coast of Saudi Arabia (Hasan 2008; Hasan 2009). For Tanzania, there are anecdotal reports that *H. nobilis* once previously dominated the sea cucumber fishery, but now it is reported to comprise a very small percentage of the total catch (Conand & Muthiga 2007). The abundance of *H. nobilis* in the Seychelles is reported to be stable (Conand *et al.* 2013; FAO 2019; CITES 2019).

Adult density is critical to the species' persistence because the species needs a sufficient density to successfully reproduce (Conand & Muthiga 2007; Purcell *et al.* 2010; Purcell *et al.* 2011). However, due to the limited species-specific information on *H. nobilis* throughout its range it is not possible to determine whether current densities are adequate to allow for successful reproduction. Research is required to determine minimum population densities for positive rates of population growth (Friedman *et al.* 2011). Overall, while some quantitative data are available, the abundance and density trends of *H. nobilis* across their range are poorly understood.

Productivity

Teatfish generally exhibit low natural mortality rates, low to moderate population growth rates, and variable success of larval survival and recruitment, resulting in generally low productivity (CITES 2019; FAO 2019). While larger individuals may be considered highly fecund, teatfish experience high levels of larval mortality (Uthicke, 2004; FAO 2019). Additionally, successful reproduction is highly dependent on adult density (Conand & Muthiga 2007; Purcell *et al.* 2010; Purcell *et al.* 2011). How productivity may affect the extinction risk of *H. nobilis* specifically is challenging to determine given the lack of species-specific information. As stated ealier, there have been documented abundance declines (see Table 1 in MNFS 2021) in Chagos (Saloman Atoll), Mayotte, Egypt (Wadi Quny and Eel Gardens in the Gulf of Aqaba); however, divers have reported commonly seeing *H. nobilis* in Egypt's waters as recently as 2019 (FAO 2019). The remaining 22 range countries do not have species-specific abundance or population growth data. While population declines due to overharvest could negatively affect the species's reproduction and survival, we do not have the data to determine if this is currently affecting *H. nobilis,* as minimum population densities for successful reproduction have yet to be determined (Purcell *et al.* 2011).

Spatial Structure/Connectivity

H. nobilis has a relatively large range, occurring throughout the Indian Ocean, including along the east coast of Africa, the Red and Arabian Seas, the coastal waters of Madagascar and the west coast of India (CITES 2019; Conand *et al.* 2013; Uthicke *et al.* 2004). While there have been reports of population declines, no widespread extirpations or a reduction of range have been reported. Additionally, no information is available on the population structure of *H. nobilis* within its range or the connectivity of populations throughout its range. We considered using other species of teatfish as a reference for connectivity. Skillings *et al.* 2014, discussed the connectivity of *H. whitmaei* and *H. atra* in the Hawaiian Islands and showed that species with similar range sizes do not predict relative dispersal ability. Both species appeared to share similar life history traits, similar minimum larval duration, occupy the same habitats, are both wide ranging, and are closely related, yet they did not have similar levels of population structuring based on analyses of their genetic data. Thus, differences in population structure may stem from subtle, species-specific differences in habitat usage, population size, or life history that also have large impacts on genetic structure (Skillings *et al* 2014). Given these species-dependent results, it would be inappropriate to use another species of teatfish as a proxy for determining if current spatial structure and connectivity of populations are contributing to the extinction risk of *H. nobilis*.

Diversity

We could not find any information regarding *H. nobilis* specific genetic diversity. Without any genetic analyses to determine diversity or effective population size, we are unable to conclude whether low genetic diversity is a threat contributing to the species' risk of extinction.

Summary of Demographic Risk Analysis

In the Status Review Report the risk rating to the species for Abundance, Productivity, and Spatial Distribution/Spatial Connectivity was unknown with a confidence rating of 1 and for Genetic Diversity the rated risk to the species was also unknown with a confidence rating of 0. Thus, we conclude that, while *H. nobilis* will likly experience future reductions in abundance due to overutilization for international trade (discussed in the Analysis of Section 4(a)(1) Factors section), we are unable to reliably predict the biological or behavioral response of *H. nobilis* to this change, and we therefore do not have reliable information showing that the magnitude of this change could be sufficient to put the species in danger of extinction now or in the foreseeable future.

Analysis of Section 4(a)(1) Factors

The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

As described in the Status Review Report (NMFS 2021), the available data do not provide us with an understanding of *H. nobilis's* habitat usage, thus, it is difficult to identify any specific present or future threats that may affect the features of the habitat on which the species relies. As an alternative, we focus our discussion in the Status Review Report on threats to coral reef habitat as a whole and while there is clear evidence that coral reefs (*i.e., H. nobilis* habitat) will undergo substantial changes due to impacts from ocean warming, acidification, and a variety of other threats, it is unclear whether and to what degree the changes in coral reef composition and ecological function will affect the extinction risk of this sea cucumber species throughout its range. While the habitat complexity provided by the morphological structure of many corals may change due to selective elimination of certain coral species, there is no information to suggest which features of the coral reef or species of coral *H. nobilis* may be dependent on. Consequently, it is difficult to predict how the loss of coral reef habitat or changes in coral reef composition will directly affect extinction risk for *H. nobilis.* We recognize that the changes in coral reef habitat predicted over the next several decades will likely negatively affect sea cucumber populations; but whether these impacts will significantly increase the extinction risk of *H. nobilis* is unclear. Thus, the rated risk to the species assigned in the Status Review

Report was unknown with a confidence rating of 1.

Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The harvest of *H. nobilis* for the purpose of supplying Asian markets with bêche-de-mer (*i.e.,* the processed form of sea cucumbers, either boiled, dried, or smoked), is considered to be the greatest threat to the species. This harvest has resulted in declines in local population abundance of sea cucumbers since the early 1990s. Many of the harvested populations of sea cucumbers, including across the range of *H. nobilis,* are considered either to be fully exploited, overexploited, or depleted (See Figure 8 in NMFS 2021; Purcell *et al.* 2011). Teatfish species, including *H. nobilis,* are largely exploited in small-scale and artisanal fisheries throughout their range. Harvest at these scales has proven difficult to manage, with booms in fishing typically followed by closures or moratoriums on fishing once stocks have been depleted. Overall, there is little international or regional coordination in management of these fisheries (FAO 2019).

We assume that demand for 'high value' sea cucumber species, including *H. nobilis* will continue. The extent to which harvest is impacting *H. nobilis* populations in the Western Indian Ocean is largely unknown, although there are some indications that overharvest may be impacting populations in Chagos, Egypt, Madagascar, Mayotte, Saudi Arabia, and Tanzania as there have been documented declines in abundance.

Additionally, there is a lack of recent fisheries-dependent data as many of the countries have banned sea cucumber fishing, including Comoros, Egypt, India, Mauritius, Mayotte, Saudi Arabia, Tanzania, and Yemen. However, despite these bans, there is evidence of continued fishing pressure on sea cucumbers through illegal, unregulated, and unreported (IUU) fishing. IUU fishing is common in the range of *H. nobilis* (depicted in Figure 10 in NMFS 2021). Evidence of illegal fishing has specifically been documented in Saudi Arabia, Mayotte, Yemen, Egypt, Mauritius, and Tanzania.

Finally, overall and country specific trade data for *H. nobilis* are unknown. The trade value chains and fishery-to-market tracing do not provide species-level data. An estimated 10,000 tons of bêche-de-mer are traded internationally each year, corresponding to about 200 million individuals harvested (Purcell *et al.* 2016). Bêche-de-mer, including *H. nobilis,* are sold primarily to Asian markets in the Hong Kong Special Administrative Region (SAR), Singapore, Taiwan, People's Republic of China, Korea, and Malaysia (CITES 2019; Purcell *et al.* 2012). *H. nobilis* is sold for 20 U.S. Dollars (USD) to 80 USD/kg dry weight, depending on size and condition; prices in Hong Kong retail markets range from 106 USD to 139 USD/kg dried (Purcell *et al.* 2012). However, this product may now have a higher retail price. Purcell *et al.* 2018 report that demand, and hence prices of most bêche-de-mer species appear to have steadily increased since 2011; however, this study did not cover the value of *H. nobilis.* Being of high value, teatfish species are preferentially targeted by fishers and exporters. While *H. nobilis* may be following similar trends to other 'high-value' species, the lack of species-specific data makes it difficult to know to what extent.

Based on the above information, the rated risk to the species assigned in the Status Review Report was moderate with a confidence rating of 2.

Disease and Predation

The extent to which disease and parasites result in sea cucumber mortality in the wild is largely unknown. The impact of predation as a threat on *H. nobilis* also remains unknown. Thus, the rated risk to the species assigned in the Status Review Report was unknown with a confidence rating of 0.

Inadequacy of Existing Regulatory Mechanisms

The establishment of management strategies for *H. nobilis* has been and still is hindered by a lack of basic biological and ecological information as well as limited information on existing and historical sea cucumber fisheries (Bruckner 2006). The regulatory measures most common in sea cucumber fisheries for the Indo-Pacific are minimum legal size limits, gear restrictions (bans on the use of scuba), requirements for exporters to submit logbooks, and no-take reserves (FAO 2013; Purcell *et al.* 2011). There are sea cucumber fishing bans in place in Yemen, Egypt, Mauritius, Saudi Arabia, Tanzania, and Mayotte (Hasan 2009; Eriksson *et al.* 2012; FAO 2013). Madagascar's sea cucumber fisheries regulate the minimum legal size of capture to 11 cm body length for all sea cucumbers. They also prohibit the use of scuba for the collection of sea cucumbers (FAO 2013). India has banned the export of all wild taken specimens of species listed under CITES Appendix I, II, and III and heavy fines and imprisonment can be imposed (FAO 2013). The Seychelles has a licensing program that requires an annual sea cucumber fishing and processing license be purchased. Since 2001, a maximum of 25 licenses have been distributed each year. Additionally, fishers' logbooks are required to be submitted regularly. Non-compliance can result in non-renewal of their fishing license (Aumeeruddy and Conand 2008). The assessment of individual species and fishing effort are necessary to determine whether these existing regulations are likely to be effective at maintaining the sustainability of the resources. To date, however, the harvest of *H. nobilis* and its impact on the population has not been assessed.

Another regulatory mechanism that will affect *H. nobilis* is the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)—an international agreement between governments established with the aim of ensuring that international trade in specimens of wild animals and plants does not threaten their survival. *H. nobilis* is newly listed under Appendix II of CITES. In total three species of teatfish were listed under Appendix II of CITES in 2019 (with an effective date of August 2020); *H. whitmaei, H. fuscogilva,* and *H. nobilis.* The Food and Agriculture Organization of the United Nations (FAO) establishes an expert Panel in advance of each CITES Conference of the Parties (CoP) to review marine species proposals. This Expert Panel is tasked with assessing proposals from a scientific perspective and in accordance with CITES biological listing criteria (FAO 2008–2021). The assessment of this proposal concluded that *H. whitmaei* met the CITES Appendix II listing criteria, while *H. fuscogilva* did not meet the listing criteria, and a determination could not be made for *H. nobilis* due to insufficient data. However, all three species were listed under Appendix II of CITES under a ''look-alike'' provision.

Appendix II includes species that are not necessarily threatened with extinction, but for which trade must be controlled in order to avoid utilization incompatible with their survival. International trade of Appendix II species is permitted when export permits are granted from the country of origin. In order to issue an export permit, the exporting country must find that the animals were legally obtained and their export will not be detrimental to the survival of the species in the wild (referred to as a ''non-detriment finding'').

The extent to which existing regulatory mechanisms are inadequate

to protect *H. nobilis* populations from the main threat identified (*i.e.,* international trade) is difficult to evaluate. We concluded that while there are some regulatory mechanisms in place with the intent to control harvest, the enforcement of these regulations is insufficient and may be negatively affecting population abundance. However, because international trade is the main threat to the species (*i.e.,* overutilization for commercial purposes), the new CITES listings may provide some safeguards against future depletion of populations.

While local sea cucumber regulations (*e.g.,* moratoriums, fishing bans, limited entry into the fishery, size restrictions, and gear restrictions) throughout the range of *H. nobilis* may be adequate to protect the species from legal overutilization, the enforcement of these regulations is inadequate as evidenced by the continued IUU fishing that occurs in many parts of the species's range and may be contributing to population declines. Thus, we concluded that inadequacy of regulatory mechanisms presents a moderate extinction risk with a confidence rating of 2.

Other Natural or Manmade Factors Affecting Its Continued Existence

We considered factors including bycatch and effects of climate change on *H. nobilis.* However, as the primary habitat of *H. nobilis* is coral reefs, bycatch by trawlers that mainly trawl sea grass habits are not likely to have an effect on the extinction risk of *H. nobilis.* Additionally, the available literature does not indicate that *H. nobilis* has been observed as bycatch in these fisheries (Bruckner 2006). While climate change is a concern, there is a lack of data on how the effects of climate change (warming waters, acidification, and sea level rise) may affect *H. nobilis.* At this time, we were unable to find any information on other natural or manmade factors that may be affecting the continued existence of *H. nobilis.* Thus, the rated risk to the species assigned in the Status Review Report was unknown with a confidence rating of 0.

Extinction Risk Determination

Guided by the results of the demographic risk and section 4(a)(1) factor analyses above, we analyzed the overall risk of extinction of *H. nobilis* throughout its range. In this process, we considered the best available scientific and commercial information regarding *H. nobilis* across its range, including associated uncertainties, and analyzed the collective condition of its populations to assess the species's overall extinction risk.

Despite much uncertainty due to limited information, it is likely that *H. nobilis* will continue to experience declining trends in its abundance and productivity in the foreseeable future, specifically due to continued overutilization and the lack of enforcement of existing regulatory mechanisms. Whether current protective efforts for *H. nobilis* (*i.e.,* the recent CITES listing and fishing bans described above) are or will be effective is uncertain, as described above.

Information on the abundance and distribution of teatfish stocks in general does not indicate any wide-spread extirpations or a reduction of range, although declines in densities of teatfish have been reported from time series and snap-shot studies (Kinch *et al.* 2008; Hasan and El-Rady, 2012; Friedman *et al.* 2011; Lane and Limbong, 2013; Ducarme 2016; FAO 2019). For *H. nobilis* specifically, declines were recorded in several locations, including Chagos, Egypt, Madagascar, Mayotte, Saudi Arabia, and Tanzania. Additionally, a few site-specific surveys within these countries' waters noted an absence of the species; however, the species was still present in other survey locations within those countries. For example, while *H. nobilis* was not found during surveys at Eel Gardens, Egypt, in 2003 or 2006 (Hasan & Abd El-Rady, 2012), the species was recorded as having a population density of 0.66 individuals per hectare (indv ha^{-1}) for Egypt in 2004 (Lawrence *et al.* 2004), and there are anecdotal data that the species is still commonly seen by divers (FAO 2019). Thus, where there are available species-specific data, those data are largely insufficient to support any firm conclusions regarding the species's status within these locations.

Most of the available data only provide snap-shots of the species (*e.g,* density at a certain location and point in time) and do not allow for species-specific trend analyses across most of *H. nobilis'* range. Additionally, where data do indicate declines of *H. nobilis,* there are insufficient data on what *H. nobilis* densities should be to ensure reproductive success and sustainable populations. For example, in Chagos, the mean density of *H. nobilis* reported for Salomon Atoll declined from 83 ind. ha-1 in 2002 to 10 ind. ha-1 in 2006, with the authors of the survey indicating concern for the species. Yet, the mean density for the Seychelles was reported as 2.0 ind. ha-1, with this population considered to be under exploited (Aumeeruddy & Conand 2008). However, for most of the range, specifically 18 of the 25 countries where *H. nobilis* is reported to occur, species-specific information on the current as well as historical densities is are unknown.

Although *H. nobilis* is considered a 'high value' species, reliable catch and trade data for *H. nobilis* are limited. Most of the available data are not species specific but pertain to sea cucumbers, in general, which includes approximately 1700 extant species, making it difficult to parse out or determine the impacts of threats on *H. nobilis* and current status. Additionally, we could not find catch or trade data that show *H. nobilis* is the main species targeted throughout its range. In the Maldives and Mozambique, it is reported that *H. nobilis* is one of the top three fished sea cucumber species. In Oman, *H. scabra* was the main targeted sea cucumber species, and in Madagascar *H. nobilis* is only thought to be ''limitedly harvested'' with *H. fuscogilva* the targeted species.

Furthermore, our ability to make reliable predictions of the impacts of threats and *H. nobilis'* response into the future is limited by the variability in not only the quantity and quality of available data across the species' range regarding its occurrence and the potential impacts to the species from ongoing and predicted threats, but also by the high amount of uncertainty regarding how *H. nobilis* may respond to those threats, given that the demographic information for this species is severely limited. We recognize that a number of sea cucumbers are overfished, but being overfished is not necessarily equivalent to being at risk of extinction.

Given the limitations of the available data, including sparse species-specific information hindering status and trend analyses, significant uncertainty regarding the identification and magnitude of potential threats to the species throughout most of its range, and a lack of demographic data to assess how *H. nobilis* is or may respond to these threats, we are unable to determine, with any confidence, the impact of identified potential threats on the status of the species presently or in the foreseeable future. Thus, we find that the best available commercial and scientific data available do not support a conclusion that *H. nobilis* is at moderate or high risk of extinction currently or in the foreseeable future.

Significant Portion of Its Range

Under the ESA, a species may be listed if it is in danger of extinction or likely to become so within the foreseeable future throughout all or a

significant portion of its range. Although the available data do not support a conclusion that *H. nobilis* is at risk of extinction currently or in the foreseeable future based on the rangewide assessment, we examined whether there are any portions of the species' range where *H. nobilis* may be facing elevated extinction risk, and whether any such portions qualify as ''significant portions'' in order to determine whether the species may qualify for listing on the basis of its status within a portion of its range.

The Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species''(''SPR Policy,'' 79 FR 37578, July 1, 2014), partially guided this assessment. Under the SPR Policy, we must determine whether there is substantial information indicating that (1) any portions may be ''significant'' and (2) the species may be in danger of extinction in those portions or likely to become so within the foreseeable future. The order in which these determinations are made is flexible and typically determined based on the nature of the available information or circumstances for the particular species.

We note that the definition of ''significant'' in the SPR Policy has been invalidated in two District Court cases that addressed listing decisions made by the USFWS. The SPR Policy set out a biologically-based definition that examined the contributions of the members in the portion to the species as a whole, and established a specific threshold (*i.e.,* when the loss of the members in the portion would cause the overall species to become threatened or endangered). The courts invalidated the threshold component of the definition because it set too high a standard. Specifically, the courts held that, under the threshold in the policy, a species would never be listed based on the status of the species in the portion, because in order for a portion to meet the threshold, the species would be threatened or endangered rangewide. Center for Biological Diversity, *et al.* v. Jewell, 248 F. Supp. 3d 946, 958 (D. Ariz. 2017); Desert Survivors v. DOI 321 F. Supp. 3d. 1011 (N.D. Cal., 2018). NMFS did not rely on the definition of ''significant'' in the policy when making this 12-month finding. NMFS instead examined information relevant to making the second determination by considering whether there may be a concentration of threats in portions of the range and whether the species is at risk of extinction within those portions. When evaluating the threats that *H. nobilis* faces, we considered overutilization for international trade in bêche-de-mer and the lack of enforcement of existing regulatory mechanisms. These two factors are considered the main threats likely causing negative impacts to *H. nobilis* at the population level in at least some portions of its range (see Table 4 in NMFS 2021).

Based on our review of the available data, these main threats appear to be largely widespread throughout *H. nobilis'* range. Sea cucumbers in general face the threats of overutilization and illegal harvest for the purpose of supplying bêche-de-mer to Asian markets. This demand is ubiquitous throughout the western Indian Ocean (*i.e.* the range of *H. nobilis;* see Figures 8 and 10 in NMFS 2021). Given the wide-spread nature of these threats, we next considered whether the species may be responding differently in certain portions of its range to the point where it may be at risk of extinction from these threats within those portions.

Where species-specific information is available, the data show potential negative responses, as evidenced by population declines, in Chagos, Egypt, Madagascar, Mayotte, Saudi Arabia, and Tanzania. However, as stated previously in the extinction risk analysis, where data do indicate species-specific declines there is insufficient data to indicate the species is facing a risk of extinction in those locations. For example, in Chagos the mean density reported for Salomon atoll in 2002 was 83 ind. ha-1 and in 2006 was reported as 10 ind. ha-1. Although this decline to 10 ind. ha-1 could potentially be a cause for concern, in the nearby Seychelles, a mean density of 2.0 ind. ha-1, reported during a 2003–2004 survey, was considered to represent an underexploited *H. nobilis* population. Additionally, there are only anecdotal data for declines in Tanzania and Madagascar. Without additional information on minimum density thresholds or the reproductive potential or current productivity of *H. nobilis,* the available information does not allow us to conclude that these populations may be in danger of extinction. Furthermore, sea cucumber fishing is currently prohibited in Egypt (first in 2001–2002 and reinstated in 2003), Mayotte (since 2004), Saudi Arabia (since 2006) and Tanzania (since 2006). While illegal and unregulated fishing is an issue for sea cucumbers, these fishing bans should be reducing fishing pressure on the species, and, thus, potentially decreasing the species's risk of extinction in these areas.

While there are limited data on the locations listed above, demographic data to determine how *H. nobilis* may be responding to these threats are largely lacking. As a result, we are unable to determine the extinction risk of *H. nobilis* in any portion of its range. Thus, we are unable to conclude that the species may be at a moderate or high risk of extinction in any portion of its range or likely to become so within the foreseeable future. Because we have made this determination, we did not separately examine whether any portions qualify as ''significant.'' Furthermore, such an analysis would likely be challenged by the same type of data limitations, such as lack of understanding of population structure, population connectivity, and species-specific abundance data, and as a result, prevent a conclusion regarding whether any portions are biologically important such that they qualify as ''significant portions'' of the species' range.

Final Listing Determination

Section 4(b)(1) of the ESA requires that NMFS make listing determinations based solely on the best scientific and commercial data available after conducting a review of the status of the species and taking into account those efforts, if any, being made by any state or foreign nation, or political subdivisions thereof, to protect and conserve the species. We have independently reviewed the best available scientific and commercial information, including the petitions, public comments submitted on the 90-day finding (85 FR 48144, August 10, 2020), the Status Review Report (NMFS 2021), and other published and unpublished information. We considered each of the statutory factors to determine whether each contributed significantly to the extinction risk of the species. As previously explained, we could not identify a significant portion of the species's range that is threatened or endangered. Therefore, our determination is based on a synthesis and integration of the foregoing information, factors and considerations, and their effects on the status of the species throughout its entire range.

We have determined the species does not warrant listing at this time. This finding is consistent with the statute's requirement to base our findings on the best scientific and commercial data available. Given the limitations of the available data, including sparse species-specific information hindering status and trend analyses, significant uncertainty regarding the identification and magnitude of potential threats to the species throughout most of its range,

and a lack of demographic data to assess how *H. nobilis* is or may respond to these threats, we are unable to determine, with any confidence, the impact of the identified threats on the status of the species presently or in the foreseeable future. Therefore, *H. nobilis* does not meet the definition of a threatened species or an endangered species and does not warrant listing as threatened or endangered at this time.

This is a final action, and, therefore, we are not soliciting public comments.

References

A complete list of the references used in this 12-month finding is available at *https://www.fisheries.noaa.gov/species/black-teatfish#conservation-management* and upon request (see **FOR FURTHER INFORMATION CONTACT**).

Peer Review

In December 2004, the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review establishing minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation. The OMB Bulletin, implemented under the Information Quality Act (Pub. L. 106–554) is intended to enhance the quality and credibility of the Federal Government's scientific information, and applies to influential or highly influential scientific information disseminated on or after June 16, 2005. To satisfy our requirements under the OMB Bulletin, we obtained independent peer review of the Status Review Report. Three independent specialists were selected from the academic and scientific community for this review. All peer reviewer comments were addressed prior to dissemination of the final Status Review Report and publication of this 12-month finding.

The Peer Review Report can be found online at: *https://www.noaa.gov/organization/information-technology/information-quality-peer-review-id422*.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: November 29, 2021.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2021–26178 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB616]

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 Ecosystem Workgroup (EWG) is holding an online meeting, which is open to the public.

DATES: The online meeting will be held Friday, December 17, 2021, from 12 p.m. to 2 p.m., Pacific Standard Time, or until 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: Kit Dahl, Staff Officer, Pacific Council; telephone: (503) 820–2422.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to discuss the EWG's assignment to compile a list of potential tasks flowing from the results of the Fishery Ecosystem Plan Climate and Communities Initiative. In compiling the list, the EWG will consider the activities identified by the Ad Hoc Climate and Communities Core Team, and other advisory body reports and public comment submitted to the Pacific Council at its September 2021 meeting. The EWG also was asked to prioritize the list of activities and assess the likely workload associated with each. The EWG plans to submit a report with its findings to be included in the advance briefing materials for the March 2022 Pacific Council meeting. Time permitting, the EWG also may discuss other ecosystem-related items scheduled on the March 2022 Pacific Council meeting agenda.

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: November 29, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–26169 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB611]

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 78 South Atlantic Spanish Mackerel Assessment Webinar 2.

SUMMARY: The SEDAR 78 assessment of the South Atlantic Stock of Spanish mackerel will consist of a series of assessment webinars. A SEDAR 78 Assessment Webinar 2 is scheduled for January 5, 2022. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 78 South Atlantic Spanish Mackerel Assessment Webinar 2 has been scheduled for January 5, 2022, from 1 p.m. until 4 p.m., Eastern. 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. Registration for the webinar is available by contacting the SEDAR coordinator via email at *Kathleen.Howington@safmc.net.*

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 78 South Atlantic Spanish Mackerel Assessment Webinar 2 are as follows: Finalize any data issues as needed. Continue discussion on base model configuration and discuss proposed changes to model, sensitivity runs, and projections.

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: November 29, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–26186 Filed 12–1–21; 8:45 am]

BILLING CODE 3510–22–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Childcare Benefit Forms

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Corporation for National and Community Service, operating as AmeriCorps, has submitted a public information collection request (ICR) entitled Childcare Benefit Forms for review and approval in accordance with the Paperwork Reduction Act.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 3, 2022.

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: Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Courtney Russell, at 202–380–7825 or by email to *crussell@cns.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of AmeriCorps, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to 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.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on 9/1/2021 at Vol. 86, No. 167. This comment period ended November 1, 2021. No public comments were received on this Notice.

Title of Collection: Childcare Benefit Forms.

OMB Control Number: 3045–0142.

Type of Review: Renewal.

Respondents/Affected Public: AmeriCorps members and their childcare providers.

Total Estimated Number of Annual Responses: 700 AmeriCorps members and 1,400 childcare providers.

Total Estimated Number of Annual Burden Hours: 1,225.

Abstract: AmeriCorps is soliciting comments concerning its Child Care application forms. These forms are submitted by members of AmeriCorps and by the childcare providers identified by the member for the purpose of applying for, and receiving payment for, the care of children during the day while the member is in service. Completion of this information is

required to be approved and required to receive payment for invoices. AmeriCorps also seeks to continue using the currently approved information collection until the revised information collection is approved by OMB. The currently approved information collection is due to expire on 12/31/2021.

Dated: November 29, 2021.

Erin Dahlin,

Chief Program Advisor.

[FR Doc. 2021–26224 Filed 12–1–21; 8:45 am]

BILLING CODE 6050–28–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for AmeriCorps Member Application, Enrollment and Exit Form

AGENCY: Corporation for National and Community Service.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service, operating as AmeriCorps, is proposing a new information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 31, 2022.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail to: AmeriCorps, Attention Sharron Tendai, 250 E Street SW, Washington, DC 20525.

(2) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except federal holidays.

(3) Electronically through *www.regulations.gov.*

Comments submitted in response to this notice may be made available to the public through *regulations.gov*. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, 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. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Sharron Tendai, 202–606–3904, or by email at *stendai@cns.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: AmeriCorps Member Application, Enrollment, and Exit Form.

OMB Control Number: 3045–0054.

Type of Review: New.

Respondents/Affected Public: Individuals.

Total Estimated Number of Annual Responses: 521,000.

Total Estimated Number of Annual Burden Hours: 386,833.

Abstract: AmeriCorps is soliciting comments concerning its proposed new AmeriCorps Member Application, Enrollment, and Exit Form. Applicants will respond to the questions included in this information collection tool to apply to serve as AmeriCorps members, enroll in the National Service Trust, and exit their term of service. AmeriCorps also seeks to continue using a currently approved information collection until the new information collection is approved by OMB. The currently approved information collections are due to expire on February 28, 2022 and July 31, 2024.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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. All written comments will be available for public inspection on *regulations.gov*.

Dated: November 29, 2021.

Erin Dahlin,

Deputy Chief of Program Operations.

[FR Doc. 2021–26223 Filed 12–1–21; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0141]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Student Aid Internet Gateway (SAIG) Enrollment Document

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 January 3, 2022.

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: Student Aid Internet Gateway (SAIG) Enrollment Document.

OMB Control Number: 1845–0002.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Government.

Total Estimated Number of Annual Responses: 48,436.

Total Estimated Number of Annual Burden Hours: 10,015.

Abstract: This is a request for an extension without change of the approval of the Student Aid internet Gateway (SAIG) Enrollment forms. These forms allow various Department program partners to apply to participate with the Department in electronically transmitting and receiving data regarding federal student aid programs. These documents are updated annually.

Dated: November 29, 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. 2021–26214 Filed 12–1–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Fulbright-Hays Group Projects Abroad Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice; corrections.

SUMMARY: On November 12, 2021, the Department of Education (Department) published in the **Federal Register** a notice inviting applications (NIA) for new awards for fiscal year (FY) 2021 for the Fulbright-Hays Group Projects Abroad (GPA) Grant Program, Assistance Listing Numbers 84.021A and 84.021B. We are amending the NIA to extend the deadline for transmittal of applications until January 26, 2022.

DATES: Deadline for Transmittal of Applications: January 26, 2022.

FOR FURTHER INFORMATION CONTACT: Cory Neal, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202–4260. Telephone: (202) 453–6137. Email: *GPA@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On November 12, 2021, we published in the **Federal Register** the NIA for the FY 2021 GPA Grant Program (86 FR 62796). The application deadline in the NIA was January 11, 2022. We are amending the NIA to extend the deadline for transmittal of applications until January 26, 2022. All other requirements and conditions stated in the NIA remain the same.

Amendments

In FR Document 2021–24645 appearing on page 62796 of the **Federal Register** of November 12, 2021, we make the following amendments:

On page 62796, in the second column, under the **DATES** caption and following the heading ''Deadline for Transmittal of Applications'', remove ''January 11, 2022'' and add in its place ''January 26, 2022''.

Accessible Format: On request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document, the NIA, and a copy of the application in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Michele Asha Cooper,

Deputy Assistant Secretary for Higher Education Programs Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 2021–26229 Filed 12–1–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–481–000]

Red Barn Energy, 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 Red Barn Energy, 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 December 16, 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: November 26, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–26188 Filed 12–1–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–479–000]

Northern Wind Energy Redevelopment, 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 Northern Wind Energy Redevelopment, 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 December 16, 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: November 26, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–26193 Filed 12–1–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC21–39–000]

Commission Information Collection Activities (FERC Form 580); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC Form 580 (Interrogatory on Fuel and Energy Purchase Practices Pursuant to Section 205 of the Federal Power Act), which will be submitted to the Office of Management and Budget (OMB) for a review of the information collection requirements. The Commission received no comments on the 60-day notice.

DATES: Comments on the collection of information are due January 3, 2022.

ADDRESSES: Send written comments on FERC Form 580 to OMB through *www.reginfo.gov/public/do/PRAMain,* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number 1902–0137 in the subject line. Your comments should be sent within 30 days of publication of this notice in the **Federal Register**.

Please submit copies of your comments (identified by Docket No. IC21–39–000) to the Commission as noted below. Electronic filing through *http://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.

○ *Mail via U.S. Postal Service Only Addressed to:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (including courier) delivery to:* Federal Energy Regulatory

Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions

OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain;* Using the search function under the ''Currently Under Review field,'' select Federal Energy Regulatory Commission; click ''submit'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov* and telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC Form 580 (Interrogatory on Fuel and Energy Purchase Practices Pursuant to Section 205 of the Federal Power Act).

OMB Control No.: 1902–0137.

Type of Request: Three-year extension of the FERC Form 580 with no substantive changes to the current reporting requirements. Administrative changes to update the form are being made, as described below.

Abstract: The Commission collects FERC Form 580 information every other year as required under Section 205(f)(2) of the FPA,[1] which provides that the Commission must review, ''not less frequently than every 2 years,'' practices under automatic adjustment clauses (AACs).[2] As required by FPA section 205(f)(2), the Commission uses the information collected through the FERC Form 580 interrogatory to review utility purchase and cost recovery practices under AACs in order to ensure efficient use of resources.[3] The Commission uses the information to evaluate costs in individual rate filings and to supplement periodic utility audits. The public also uses the information in this manner. Without the FERC Form 580 interrogatory, the Commission would not have the requisite information available to conduct the necessary review the FPA mandates.

Type of Respondents: The filing must be submitted by all FERC-jurisdictional utilities owning and/or operating at least one steam-electric generating station of 50 MW or greater capacity or having a majority ownership interest in a jointly-owned steam-electric generating station of at least 50 MW. A jurisdictional utility without a cost-based tariff on file with the Commission is not required to file the form.

Administrative Updates to the FERC Form 580: Continuing on from the data collection that was requested from October 2020, the Commission will be issuing a request in 2022 for similar data that was authorized in the last renewal for FERC Form 580.[4] The request will solicit the same information as the previous request, except that the years will be changed from 2018–2019 to 2020–2021. In this case, the updated year designations will appear in questions 2 through 8 of FERC Form 580, as well as in question 5 of the Privileged Addendum to the FERC Form 580.

Estimate of Annual Burden.[5] The Commission estimates the annual[6] public reporting burden and cost[7] for the information collection as:

FERC FORM 580

[Interrogatory on Fuel and Energy Purchase Practices Pursuant to Section 205 of the Federal Power Act]

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden and cost ($) per response	Total annual burden hours and total annual cost ($)	Annual cost per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Respondents with FACs[8]	24	0.5	12	103 hrs.; $8,961.00	1,236.0 hrs.; $107,532.00	$4,480.50
Respondents with AACs, but no FACs	12	0.5	6	20 hrs.; $1,740.00	120.0 hrs.; $10,440.00	870.00
Respondents with no AACs and no FACs	23	0.5	11.5	2 hrs.; $174.00	23.0 hrs.; $2,001.00	87.00
Total			29.5		1,379.0 hrs.; $119,173.00	

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) 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.

Dated: November 26, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–26189 Filed 12–1–21; 8:45 am]

BILLING CODE 6717–01–P

[1] 16 U.S.C. 824d(f)(2).

[2] An automatic adjustment clause is a provision of a rate schedule which provides for increases or decreases (or both), without prior hearing, in rates reflecting increases or decreases (or both) in costs incurred by an electric utility. For additional information on AACs, see the Frequently Asked Questions (FAQs) and Desk Reference for FERC Form 580 on the Commission's website.

[3] By using the data in FERC Form 580, the Commission is able to review utility purchase and cost recovery practices and ensure the resources are in compliance with Commission regulations in 18 CFR 35.14.

[4] The current OMB approval (ICR 201908–1902–015) was issued on April 23, 2020, and expires January 31, 2023. While that approval includes the timeframe for the Commission's next required use of FERC–580 in 2022, we are submitting this request in order to update (administrative updates) FERC Form 580 for the data collection in 2022, and to request renewal of FERC–580 for another 3 years.

[5] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. See 5 CFR 1320 for additional information on the definition of information collection burden.

[6] The FERC Form 580 interrogatory is conducted every two years.

[7] Commission staff estimates that the industry's average hourly cost for this information collection is approximated by the FERC's average hourly cost (for wages and benefits) for 2021, or $87.00/hour.

[8] Fuel Adjustment Clause (FAC).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–480–000]

Rock Aetna Power Partners, 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 Rock Aetna Power Partners, 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 December 16, 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: November 26, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–26194 Filed 12–1–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–472–000]

Indra Power Business DE 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 Indra Power Business DE 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 December 16, 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: November 26, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–26192 Filed 12–1–21; 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: RP22–344–000.

Applicants: FP Wheeler Upstream LLC, Formentera Operations LLC.

Description: Joint Petition for Limited Waiver of Capacity Release Regulations, et al. of FP Wheeler Upstream LLC, et al. under RP22–344.

Filed Date: 12/02/21.

Accession Number: 20211124–5070.

Comment Date: 5 p.m. ET 12/6/21.

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.

Filings in Existing Proceedings

Docket Numbers: RP18–923–010.

Applicants: Enable Mississippi River Transmission, LLC.

Description: Compliance filing: Errata to 11.23.2021 Compliance Filing to be effective 1/1/2022.

Filed Date: 11/24/21.

Accession Number: 20211124–5128.

Comment Date: 5 p.m. ET 12/6/21.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

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: November 26, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–26191 Filed 12–1–21; 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 electric corporate filings:

Docket Numbers: EC22–23–000.

Applicants: Innovative Solar 42, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Innovative Solar 42, LLC.

Filed Date: 11/24/21.

Accession Number: 20211124–5195.

Comment Date: 5 p.m. ET 12/15/21.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL22–16–000.

Applicants: Pacific Gas and Electric Company.

Description: Petition for Declaratory Order of Pacific Gas and Electric Company.

Filed Date: 11/23/21.

Accession Number: 20211123–5232.

Comment Date: 5 p.m. ET 12/23/21.

Docket Numbers: EL22–17–000.

Applicants: National Grid.

Description: Petition for Declaratory Order Authorizing Abandonment Recovery of National Grid.

Filed Date: 11/19/21.

Accession Number: 20211119–5288.

Comment Date: 5 p.m. ET 12/20/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–434–000.

Applicants: Altop Energy Trading LLC.

Description: Supplement to November 19, 2021 Altop Energy Trading LLC tariff filing.

Filed Date: 11/24/21.

Accession Number: 20211124–5194.

Comment Date: 5 p.m. ET 12/1/21.

Docket Numbers: ER22–483–000.

Applicants: NMRD Data Center III, LLC.

Description: § 205(d) Rate Filing: NMRD Data Center III Encino PPA to be effective 1/23/2022.

Filed Date: 11/24/21.

Accession Number: 20211124–5183.

Comment Date: 5 p.m. ET 12/15/21.

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: November 26, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–26190 Filed 12–1–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[CERCLA–02–2022–2004; FRL–9294–01–R2]

Proposed CERCLA Section 122(h) Settlement Agreement for the Maywood Chemical Superfund Site, Boroughs of Maywood and Lodi, and the Township of Rochelle Park, Bergen County, New Jersey

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (''CERCLA''), notice is hereby given by the U.S. Environmental Protection Agency (''EPA''), Region 2, of a proposed settlement agreement (''Agreement'') with Jeco Corporation for the Maywood Chemical Superfund Site (''Site''), Boroughs of Maywood and Lodi, and the Township of Rochelle Park, Bergen County, New Jersey.

DATES: Comments must be submitted on or before January 3, 2022.

ADDRESSES: Comments can be sent via email to Kathryn DeLuca at *deluca.kathryn@epa.gov.* Comments should reference the Maywood Chemical Superfund Site, CERCLA Section 122(h) Agreement, Index No. CERCLA–02–2022–2004. The proposed settlement is available for public inspection at this website: *https://semspub.epa.gov/src/document/02/625503.*

FOR FURTHER INFORMATION CONTACT: Kathryn DeLuca, Attorney, Office of Regional Counsel, U.S. Environmental Protection Agency. Email: *deluca.kathryn@epa.gov.* Telephone: 212–637–3171.

SUPPLEMENTARY INFORMATION: Under the proposed Agreement, Jeco Corporation agrees to reimburse EPA for $125,500 in past and future oversight costs incurred in connection with radiological contamination at the property owned by Jeco Corporation that is part of the Site, located at 149–151 Maywood Avenue, Borough of Maywood and Township of Rochelle Park, Bergen County, New Jersey, designated as Block 124, Lot 30 in the Borough of Maywood and Block 17.02, Lot 1 in the Township of Rochelle Park on the tax map of Bergen County, New Jersey (''Jeco Property''). The Agreement also resolves EPA's Federal lien on the Jeco Property arising under Section 107(l) of CERCLA, 42 U.S.C. 9607(1).

For thirty (30) days following the date of publication of this document, EPA will receive written comments relating to the proposed Agreement. EPA will consider all comments received and may modify or withdraw its consent to the proposed Agreement if comments received disclose facts or considerations that indicate that the proposed Agreement is inappropriate, improper, or inadequate. EPA's response to any comments received will be available for public inspection online and/or at EPA Region 2, 290 Broadway, New York, New York 10007–1866.

John Prince,

Acting Director, Superfund & Emergency Management Division, Environmental Protection Agency, Region 2.

[FR Doc. 2021–26284 Filed 11–30–21; 4:15 pm]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0635; FRL 9323–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Primary Copper Smelters (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Primary Copper Smelters (EPA ICR No. 1850.09, OMB Control No. 2060–0476), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently-approved through November 30, 2021. Public comments were previously requested, via the **Federal Register** on February 8, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before January 3, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2020–0635, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov* or in person at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets*.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Primary Copper Smelters (40 CFR part 63, subpart QQQ) were proposed on April 20, 1998; promulgated on June 6, 2002; and most-recently amended on November 19, 2020. These regulations apply to each existing and new copper concentrate dryer, smelting furnace, slag cleaning vessel, copper converter department, and the entire group of fugitive emission sources located at a primary copper smelter facility that is a major source of hazardous air pollutant (HAP) emissions. Major sources of HAP emissions are sites that emit, or have the potential to emit, any single HAP at a rate of 9.07 megagrams (10 tons) or more per year or any combination of HAPs at a rate of 22.68 megagrams (25 tons) or more per year. New facilities include those that commenced either construction or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart QQQ.

Form Numbers: None.

Respondents/affected entities: Primary copper smelters.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart QQQ).

Estimated number of respondents: 2 (total).

Frequency of response: Semiannually.

Total estimated burden: 6,380 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $761,000 (per year), which includes $5,480 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an overall decrease in burden from the most-recently approved ICR. This increase is not due to any program changes, but is due to a decrease in the estimated number of sources subject to the NESHAP. The Agency has identified, through recent rulemaking efforts, that one of three primary copper smelters located in the United States is no longer a major source of HAP. Therefore, approximately two respondents will be subject to these standards over the three-year period covered by this ICR.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–25963 Filed 12–1–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX and OMB 3060–0463; FR ID 60521]

Information Collections Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it can

further reduce the information collection burden for small business concerns with fewer than 25 employees.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before January 3, 2022.

ADDRESSES: Comments should be sent 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. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–0463.

Title: Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities; Structure and Practices of the Video Relay Service Program; Misuse of Internet Protocol (IP) Captioned Telephone Service, CG Docket Nos. 03–123, 10–51, and 13–24.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit; Individuals or household; State, Local and Tribal Government.

Number of Respondents and Responses: 5,072 respondents; 7,988 responses.

Estimated Time per Response: 0.1 hours (6 minutes) to 80 hours.

Frequency of Response: Annually, semi-annually, eight times a year, monthly, on occasion, one-time, and quarterly reporting requirements; Recordkeeping and Third-Party Disclosure requirements.

Obligation to Respond: Required to obtain or retain benefit. The statutory authority for the information collection requirements is found at section 225 of the Communications Act, 47 U.S.C. 225. The law was enacted on July 26, 1990, in Title IV of the Americans with Disabilities Act of 1990, Public Law 101–336, 104 Stat. 327, 366–69.

Total Annual Burden: 14,524 hours.

Total Annual Cost: $291,700.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's updated system of records notice (SORN), FCC/CGB–1, ''Informal Complaints, Inquiries, and Requests for Dispute Assistance.'' As required by the Privacy Act, 5 U.S.C. 552a, the Commission also published a SORN, FCC/CGB–1 ''Informal Complaints, Inquiries, and Requests for Dispute Assistance,'' in the **Federal Register** on August 15, 2014 (79 FR 48152) which became effective on September 24, 2014.

Privacy Impact Assessment: The FCC completed a Privacy Impact Assessment (PIA) on June 28, 2007. It may be reviewed at *https://www.fcc.gov/general/privacy-act-information#pia.* The Commission is in the process of updating the PIA to incorporate various revisions to it as a result of revisions to the SORN.

Needs and Uses: On December 21, 2001, the Commission released the 2001 TRS Cost Recovery Order, document FCC 01–371, published at 67 FR 4203, January 29, 2002, in which the Commission, among other things:

(1) Required internet-based TRS providers to submit certain projected TRS-related cost and demand data to the TRS Fund administrator to be used to calculate the rate; and

(2) directed the TRS Fund administrator to expand its data collection forms accordingly.

In 2003, the Commission released the 2003 Second Improved TRS Order, published at 68 FR 50973, August 25, 2003, which among other things required that TRS providers offer certain local exchange carrier (LEC)-based improved services and features where technologically feasible, including a speed dialing requirement which may entail voluntary recordkeeping for TRS providers to maintain a list of telephone numbers. See also 47 CFR 64.604(a)(3)(vi)(B).

In 2007, the Commission released the Section 225/255 VoIP Report and Order, published at 72 FR 43546, August 6, 2007, extending the disability access requirements that apply to telecommunications service providers and equipment manufacturers under 47 U.S.C. 225, 255 to interconnected voice over internet protocol (VoIP) service providers and equipment manufacturers. As a result, under rules implementing section 225 of the Act, interconnected VoIP service providers are required to publicize information about telecommunications relay services (TRS) and 711 abbreviated dialing access to TRS. See also 47 CFR 64.604(c)(3).

In 2007, the Commission also released the 2007 Cost Recovery Report and Order and Declaratory Ruling, published at 73 FR 3197, January 17, 2008, in which the Commission:

(1) Adopted a new cost recovery methodology for interstate traditional TRS, interstate speech-to-speech service (STS), captioned telephone service (CTS), and Internet Protocol captioned telephone service (IP CTS) based on the

Multi-state Average Rate Structure (MARS) plan, under which interstate TRS compensation rates are determined by weighted average of the states' intrastate compensation rates, and which includes for STS additional compensation approved by the Commission for STS outreach;

(2) adopted a cost recovery methodology for Internet Protocol (IP) Relay based on a price cap like methodology;

(3) adopted a cost recovery methodology for video relay service (VRS) that adopted tiered rates based on call volume;

(4) clarified the nature and extent that certain categories of costs are compensable from the Fund; and

(5) addressed certain issues concerning the management and oversight of the Fund, including prohibiting financial incentives offered to consumers to make relay calls.

The 2007 TRS Cost Recovery Order requires that state relay administrators and TRS providers submit to the TRS Fund administrator the following information annually, for intrastate traditional TRS, STS, and CTS:

(1) The per-minute compensation rate(s) and other compensation received for the provision of TRS;

(2) whether the rate applies to session minutes or conversation minutes, which are a subset of session minutes;

(3) the number of intrastate session minutes; and

(4) the number of intrastate conversation minutes.

Also, STS providers must file a report annually with the TRS Fund administrator and the Commission on their specific outreach efforts directly attributable to the additional compensation approved by the Commission for STS outreach.

In 2011, to help prevent waste, fraud, and abuse, the Commission adopted three VRS orders to curtail these harmful practices. Each of these orders (collectively, the 2011 VRS Orders) included information collection requirements.

On April 6, 2011, in document FCC 11–54, the Commission released the 2011 Fraud Prevention Order, published at 76 FR 30841, May 27, 2011, which included several measures designed to eliminate the waste, fraud and abuse, while ensuring that VRS remains a viable and a valuable communication tool for Americans who use it on a daily basis.

On July 28, 2011, in document FCC 11–118 the Commission released the VRS Certification Order, published at 76 FR 47469, August 5, 2011, amending its rules for certifying internet-based TRS providers as eligible for payment from the Interstate TRS Fund (Fund) for their provision of internet-based TRS. On October 17, 2011, in document FCC 11–155, the Commission released the Second VRS Certification Order, published at 76 FR 67070, October 31, 2011, addressing three petitions related to the VRS Certification Order by revising the burdens contained in the requirements for the submission of documentation of a provider's VRS equipment and technologies and the submission of documentation regarding sponsorship arrangements.

The following are the final information collection requirements contained in the 2011 VRS Orders:

(1) The Chief Executive Officer (CEO), Chief Financial Officer (CFO), or other senior executive of a TRS provider shall certify, under penalty of perjury, that: (1) Minutes submitted to the Interstate TRS Fund (Fund) administrator for compensation were handled in compliance with the Commission's rules and are not the result of impermissible financial incentives to generate calls, and (2) cost and demand data submitted to the Fund administrator related to the determination of compensation rates are true and correct.

(2) VRS providers shall: (a) Submit to the Commission and the TRS Fund administrator a call center report twice a year and (b) notify the Commission and the TRS Fund administrator at least 30 days prior to any change to their call centers' locations.

(3) VRS providers shall submit detailed call data records (CDRs) and speed of answer compliance data to the Fund administrator.

(4) TRS providers shall use an automated record keeping system to capture the CDRs and shall submit such data electronically in standardized form to the TRS Fund administrator.

(5) Internet-based TRS providers shall retain the CDRs that are used to support payment claims submitted to the Fund administrator for a minimum of five years, in an electronic format.

(6) VRS providers shall: (a) Maintain copies of all third-party contracts or agreements and make them available to the Commission and the TRS Fund administrator upon request; and (b) describe all agreements in connection with marketing and outreach activities in their annual submissions to the TRS Fund administrator.

(7) TRS providers shall provide information about their TRS whistleblower protections to all employees and contractors, in writing.

In 2018, the Commission released the IP CTS Modernization Order, published at 83 FR 30082, June 27, 2018, in which the Commission:

(1) Determined that it would transition the methodology for IP CTS cost recovery from the MARS plan to cost-based rates and adopted interim rates; and

(2) added two cost reporting requirements for IP CTS providers: (i) In annual cost data filings and supplementary information provided to the TRS Fund administrator, IP CTS providers that contract for the supply of services used in the provision of TRS, shall include information about payments under such contracts, classified according to the substantive cost categories specified by the TRS Fund administrator; and (ii) in the course of an audit or otherwise upon demand, IP CTS providers must make available any relevant documentation. 47 CFR 64.604(c)(5)(iii)(D)(1), (6).

OMB Control Number: 3060–XXXX.

Title: Section 20.23(b)(1), (3)–(5), (7); (c)(1)–(2), (3), (3)(iii)–(iv), (4)(i)–(ii), (v); and (d), Contraband wireless devices in correctional facilities.

Form Number: N/A.

Type of Review: New information collection.

Respondents: Business or other for-profit entities, and state, local or tribal governments.

Estimated Number of Respondents and Responses: 531 respondents and 16,389 responses.

Estimated Time per Response: 1–10 hours.

Frequency of Response: One-time application and self-certification response, one-time DCFO authorization request response, on occasion qualifying request response, on occasion reversal response, recordkeeping requirement, third party notification requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for the currently approved information collection is contained in sections 1, 2, 4(i), 4(j), 301, 302, 303, 307, 308, 309, 310, and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(j), 301, 302a, 303, 307, 308, 309, 310, and 332.

Estimated Total Annual Burden: 142,568 hours.

Total Annual Costs: No costs.

Nature and Extent of Confidentiality: Certain information collected during the CIS application and certification process will be treated as confidential from public inspection. To the extent necessary, respondents may request confidential treatment of information collected. See 47 CFR 0.459.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: On July 13, 2021, the Commission released a Second Report and Order and Second Further Notice of Proposed Rulemaking, Promoting Technological Solutions to Combat Contraband Wireless Devices in Correctional Facilities, GN Docket No. 13–111, in which the Commission took further steps to facilitate the deployment and viability of technological solutions used to combat contraband wireless devices in correctional facilities. In the Second Report and Order, the Commission adopted a framework requiring the disabling of contraband wireless devices detected in correctional facilities upon satisfaction of certain criteria. The Commission further addressed issues involving oversight, wireless provider liability, and treatment of 911 calls. Finally, the Commission adopted rules requiring advance notice of certain wireless provider network changes to promote and maintain contraband interdiction system effectiveness.

In establishing rules requiring wireless providers to disable contraband wireless devices in correctional facilities and adopting a framework to enable designated correctional facility officials (DCFOs) relying on an authorized Contraband Interdiction System (CIS) to submit qualifying requests to wireless providers to disable contraband wireless devices in qualifying correctional facilities, the Commission found that a rules-based process will provide a valuable additional tool for departments of corrections to address contraband wireless device use. The framework includes a two-phase authorization process: (1) CIS applicants will submit applications to the Wireless Telecommunications Bureau (Bureau) describing the legal and technical qualifications of the systems; and (2) CIS applicants will perform on-site testing of approved CISs at individual correctional facilities and file a self-certification with the Commission. After both phases are complete, DCFOs will be authorized to submit qualifying requests to wireless providers to disable contraband devices using approved CISs at each correctional facility. In addition, the Commission adopted rules requiring wireless providers to notify certain types of CIS operators of major technical changes to ensure that CIS effectiveness is maintained. The Commission found that these rules will provide law enforcement with the tools necessary to disable contraband wireless devices, which, in turn, will help combat the serious threats posed by the illegal use of such devices.

The new information collection in 47 CFR 20.23(b)(1) regarding the application to obtain new CIS certification will be used by the Bureau to determine whether to certify a system and ensure that the systems are designed to support operational readiness and minimize the risk of disabling a non-contraband device, and ensure, to the greatest extent possible, that only devices that are in fact contraband will be identified for disabling. Bureau certification will also enable targeted industry review of solutions by allowing interested stakeholders to provide feedback on the application for certification, including the proposed test plan.

The new collections in 47 CFR 20.23(b)(3) include the requirement that the CIS operator must file with the Bureau a self-certification that complies with paragraph (b)(3)(ii) of section 20.23, confirming that the testing at that specific correctional facility is complete and successful, and the CIS operator must serve notice of the testing on all relevant wireless providers prior to testing and provide such wireless providers a reasonable opportunity to participate in the tests. Self-certification will help the Bureau to ensure that qualifying requests identify contraband wireless devices accurately and in accordance with legal requirements. In addition to being used by the Bureau, the self-certification will be relied upon by the DCFO in conjunction with qualifying requests for disabling at a particular correctional facility. The serving of notice to the wireless providers will give them awareness and an opportunity to participate in the process.

The new information collections in 47 CFR 20.23(b)(4) requires that wireless providers objecting to the certification filing submit objections to the Bureau within five business days and serve the DCFO and the CIS operator, which allows all stakeholders to participate in the process and raise objections. Section 20.23(b)(5) requires that CIS operators retest and recertify their systems at least every three years and comply with the same requirements as for initial self-certification. This requirement will enable the Bureau to ensure the ongoing accuracy and reliability of a given CIS at a particular facility. Section 20.23(b)(7) requires that a CIS operator retain records for at least five years and provide them upon request to the Bureau, which will support the Bureau's efforts to identify issues with CIS operations, resolve interference issues, and resolve complaints related to misidentification of contraband devices.

The new collections in 47 CFR 20.23(c)(1)–(2) include the requirement that individuals that seek to be recognized on the Commission's DCFO list must sent a letter to the Contraband Ombudsperson in order for the Commission to approve that person for the qualified DCFO list and provide certainty to wireless providers that disabling requests are made by duly authorized individuals. Qualifying requests that include the required information will be used by wireless carriers to prevent use of contraband devices on their network and on other wireless provider networks.

The new collections 47 CFR 20.23(c)(3)(iii)–(iv) provide that, upon receiving a disabling request from a DCFO, the wireless provider must verify the request, may reject the request and must notify the DCFO whether it is accepting or rejecting the request. This process ensures that a wireless provider responds to a DCFO within a reasonable timeframe—while giving the provider an opportunity to determine if there is an error—and to give the DCFO time to respond quickly if the request has been rejected. The wireless provider may contact the customer of record to notify them of the disabling and involve them in the process.

The new collections in 47 CFR 20.23(c)(4) provide that a wireless provider may reverse a disabled device where it determines that the device was erroneously identified as contraband, and the wireless provider must notify the DCFO of the reversal. The wireless provider may choose to involve the DCFO in the review and reversal process. The DCFO must also provide notice to the Contraband Ombudsperson of the number of erroneously disabled devices. This process ensures the integrity of the contraband device disabling process by giving the wireless provider the opportunity to reverse a disabled device—with the ability to extend review to the DCFO—and by creating safeguards to make sure that the process is efficient and reliable.

The new collections in 47 CFR 20.23(d) regarding notification from CMRS licensees to MAS operators of technical changes to their network are required so that MAS operators are given sufficient time to make necessary adjustments to maintain the effectiveness of their interdiction systems. In order to ensure that issues regarding notification to solutions providers of more frequent, localized wireless provider network changes are appropriately considered, CMRS licensees and MAS operators must negotiate in good faith to reach an agreement for notification for those

types of network adjustments not covered by the notice requirement. CMRS licensees must provide notice of technical changes associated with an emergency immediately after the exigency to ensure that MAS operators continue to be notified of network changes that could impact MAS effectiveness.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–26210 Filed 12–1–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID: 59971]

Privacy Act of 1974; System of Records

AGENCY: Federal Communications Commission.

ACTION: Notice of a modified system of records.

SUMMARY: The Federal Communications Commission (FCC, Commission, or Agency) proposes to modify an existing system of records, FCC–2, Business Contacts and Certifications, subject to the Privacy Act of 1974, as amended. This action is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of records maintained by the Agency. The Commission uses the information on individuals and businesses contained in the records in this system to collect and maintain points of contact at regulated entities and in related industries, and ensure compliance with FCC rules through certifications of information provided to the Commission. This modification expands the purpose of the system of records to include collecting and maintaining point of contact information for contractors, vendors, and those performing collateral duties for the FCC, and to ensure compliance with applicable federal laws, in addition to FCC rules.

DATES: This modified system of records will become effective on December 2, 2021. Written comments on the routine uses are due by January 3, 2022. The routine uses will become effective on January 3, 2022, unless written comments are received that require a contrary determination.

ADDRESSES: Send comments to Margaret Drake, at *privacy@fcc.gov,* or at Federal Communications Commission (FCC), 45 L Street NE, Washington, DC 20554 at (202) 418–1707.

FOR FURTHER INFORMATION CONTACT: Margaret Drake, (202) 418–1707, or *privacy@fcc.gov* (and to obtain a copy of the Narrative Statement and the Supplementary Document, which includes details of the modifications to this system of records).

SUPPLEMENTARY INFORMATION:

SYSTEM NAME AND NUMBER:

FCC–2, BUSINESS CONTACTS AND CERTIFICATIONS.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Federal Communications Commission (FCC), 45 L Street NE, Washington, DC, 20554; Universal Service Administrative Company, 700 12th Street NW, Suite 900, Washington, DC 20005; or FISMA compliant contractor.

SYSTEM MANAGER(S):

Federal Communications Commission (FCC); Universal Service Administrative Company (USAC); or FISMA compliant contractor.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

47 U.S.C. 151, 152, 155, 257, 303; and 5 U.S.C. 602(c) and 609(a)(3).

PURPOSES OF THE SYSTEM:

The FCC and organizations administering programs on behalf of the FCC use this system to collect and maintain points of contact at entities regulated by the FCC and in related industries, as well as contractors, vendors, and those performing collateral duties for the FCC, to ensure compliance with applicable federal laws and FCC rules through certifications of information provided to the Commission.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals and businesses.

CATEGORIES OF RECORDS IN THE SYSTEM:

Contact information, such as name, username, signature, phone numbers, emails, and addresses, as well as work and educational history.

RECORD SOURCE CATEGORIES:

Information in this system is provided by individuals or businesses who serve as points of contact at FCC contractors, vendors, those providing collateral duties to the FCC, regulated entities, and in related industries or certify data on behalf of an entity.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE 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 to authorized entities, as is determined to be relevant and necessary, outside the FCC as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows.

1. Public Access—Information regarding points of contact at regulated entities and in related industries, as well as certifications made by individuals on behalf of an entity, may be made available for public inspection to comply with FCC regulations that require public disclosure of this information.

2. Third Parties—To third parties, including individuals and businesses in the communications industry, FCC vendors and their contractors, and other federal agencies to administer or support programs on behalf of the FCC.

3. Adjudication and Litigation—To disclose to the Department of Justice (DOJ), or to other administrative or adjudicative bodies before which the FCC is authorized to appear, when: (a) The FCC or any component thereof; or (b) any employee of the FCC in his or her official capacity; or (c) any employee of the FCC in his or her individual capacity where the DOJ or the FCC have agreed to represent the employee; or (d) the United States is a party to litigation or has an interest in such litigation, and the use of such records by the DOJ or the FCC is deemed by the FCC to be relevant and necessary to the litigation.

4. Law Enforcement and Investigation—To disclose pertinent information to the appropriate Federal, State, local, tribal agency, or component of an agency, such as the FCC's Enforcement Bureau, responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where the FCC becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

5. Congressional Inquiries—To provide information to a Congressional office from the record of an individual in response to an inquiry from that Congressional office made at the written request of that individual.

6. Government-wide Program Management and Oversight—To provide information to the Department of Justice (DOJ) to obtain that department's advice regarding disclosure obligations under the Freedom of Information Act; or to the Office of Management and Budget (OMB) to obtain that office's advice regarding obligations under the Privacy Act.

7. Breach Notification—To appropriate agencies, entities, and persons when: (a) The Commission suspects or has confirmed that there has been a breach of PII maintained in the system of records; (b) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (including its information system, programs, and operations), the Federal Government, or national security; and; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

8. Assistance to Federal Agencies and Entities—To another Federal agency or Federal entity, when the Commission determines that information from this system is reasonably necessary to assist the recipient agency or entity in: (a) Responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, program, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

9. Non-Federal Personnel—To disclose information to non-federal personnel, including contractors, who have been engaged to assist the FCC in the performance of a contract service, grant, cooperative agreement, or other activity related to this system of records and who need to have access to the records in order to perform their activity.

In each of these cases, the FCC will determine whether disclosure of the records is compatible with the purpose for which the records were collected.

REPORTING TO CONSUMER REPORTING AGENCIES:

In addition to the routine uses cited above, the Commission may share information from this system of records with a consumer reporting agency regarding an individual who has not paid a valid and overdue debt owed to the Commission, following the procedures set out in the Debt Collection Act, 31 U.S.C. 3711(e).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

This an electronic system of records that resides on the FCC's network, USAC's network, or on an FCC vendor's network.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records in this system of records can be retrieved by any category field, *e.g.,* first name or email address.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The information in this system is maintained and disposed of in accordance with the National Archives and Records Administration (NARA) General Records Schedule 6.5, Item 020 (DAA–GRS–2017–0002–0002).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The electronic records, files, and data are stored within FCC, USAC, or a vendor's accreditation boundaries and maintained in a database housed in the FCC's, USAC's, or vendor's computer network databases. Access to the electronic files is restricted to authorized employees and contractors; and to IT staff, contractors, and vendors who maintain the IT networks and services. Other employees and contractors may be granted access on a need-to-know basis. The electronic files and records are protected by the FCC, USAC, and third-party privacy safeguards, a comprehensive and dynamic set of IT safety and security protocols and features that are designed to meet all Federal privacy standards, including those required by the Federal Information Security Modernization Act of 2014 (FISMA), the Office of Management and Budget (OMB), and the National Institute of Standards and Technology (NIST).

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to and/or amendment of records about themselves should follow the Notification Procedure below.

CONTESTING RECORD PROCEDURES:

Individuals wishing to request access to and/or amendment of records about themselves should follow the Notification Procedure below.

NOTIFICATION PROCEDURES:

Individuals wishing to determine whether this system of records contains information about themselves may do so by writing *Privacy@fcc.gov.* Individuals requesting access must also comply with the FCC's Privacy Act regulations regarding verification of identity to gain access to records as required under 47 CFR part 0, subpart E.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

HISTORY:

86 FR 40838 (July 29, 2021).

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2021–26163 Filed 12–1–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 31, 2021.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org*:

1. *Amalgamated Financial Corp., New York, New York;* to merge with Amalgamated Investments Company, and thereby indirectly acquire Amalgamated Bank of Chicago, both of Chicago, Illinois.

B. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *BancFirst Corporation, Oklahoma City, Oklahoma;* to acquire Worthington National Bank, Arlington, Texas.

Board of Governors of the Federal Reserve System, November 30, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–26297 Filed 12–1–21; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 13, 2021.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *PB Family Bancshares, Inc., Hastings, Minnesota;* to become a bank holding company by acquiring Premier Bank Minnesota, Farmington, Minnesota, and Premier Bank Rochester, Rochester, Minnesota.

Board of Governors of the Federal Reserve System, November 30, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–26300 Filed 12–1–21; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Meeting; National Advisory Committee on the Sex Trafficking of Children and Youth in the United States

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, Department of Health and Human Services (HHS).

ACTION: Announcement of meeting and call for public comment on states' efforts to improve the nation's response to the sex trafficking of children and youth.

SUMMARY: Notice is hereby given, pursuant to the provisions of the Federal Advisory Committee Act (FACA) and the Preventing Sex Trafficking and Strengthening Families Act, that a meeting of the National Advisory Committee on the Sex Trafficking of Children and Youth in the United States (Committee) will be held on December 9 and 10, 2021. The purpose of the meeting is for the Committee to review state self-assessment survey responses and finalize their January 2022 report. The members of the Committee request comments from the public to inform their ongoing work and January 2022 report. Please submit your comments to *NAC@nhttac.org* with the subject ''NAC Comments,'' as soon as possible and before December 6, 2021.

DATES: The meeting will be held on December 9 and 10, 2021.

ADDRESSES: The meeting will be held virtually. Please register for this event online at *https://www.acf.hhs.gov/otip/partnerships/national-advisory-committee.*

FOR FURTHER INFORMATION CONTACT: Katherine Chon (Designated Federal Officer) at *EndTrafficking@acf.hhs.gov* or (202) 205–5778, or 330 C Street SW, Washington, DC 20201. Additional information is available at *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.*

SUPPLEMENTARY INFORMATION: The formation and operation on behalf of the Committee are governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of federal advisory committees.

Purpose of the Committee: The purpose of the Committee is to advise the Secretary and the Attorney General on practical and general policies concerning improvements to the nation's response to the sex trafficking of children and youth in the United States. HHS established the Committee pursuant to Section 121 of the Preventing Sex Trafficking and Strengthening Families Act of 2014 (Pub. L. 113–183).

Tentative Agenda: The agenda can be found at *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.* To submit written statements, email *NAC@nhttac.org* by December 6, 2021. Please include your name, organization, and phone number. More details on these options are below.

Public Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and subject to the availability of space, this meeting is open to the public virtually.

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and § 10(a)(3) of the Federal Advisory Committee Act, the public may submit written statements in response to the stated agenda of the meeting or to the Committee's mission in general. Organizations with recommendations on strategies to engage states and stakeholders are encouraged to submit their comments or resources (hyperlinks preferred). Written comments or statements received after December 6, 2021, may not be provided to the Committee until its next meeting.

Verbal Statements: Pursuant to 41 CFR 102–3.140d, the Committee is not obligated to allow a member of the public to speak or otherwise address the Committee during the meeting. Members of the public are invited to provide verbal statements during the Committee meeting only at the time and manner described in the agenda. The request to speak should include a brief statement of the subject matter to be addressed and should be relevant to the stated agenda of the meeting or the Committee's mission in general.

Minutes: The minutes of this meeting will be available for public review and copying within 90 days at *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.*

Dated: November 29, 2021.

Linda Hitt,

Director, Executive Secretariat.

[FR Doc. 2021–26167 Filed 12–1–21; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0280]

Agency Information Collection Activities; Proposed Collection; Comment Request; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on ''Financial Disclosure by Clinical Investigators.''

DATES: Submit either electronic or written comments on the collection of information by January 31, 2022.

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 31, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 31, 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–2012–N–0280 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Financial Disclosure by Clinical Investigators.'' 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.

FOR FURTHER INFORMATION CONTACT: 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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following 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.

Financial Disclosure by Clinical Investigators

OMB Control Number 0910–0396—Extension

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

Table 1 shows information that is the basis of the estimated number of respondents in tables 2 through 4.

TABLE 1—ESTIMATED NUMBER OF APPLICATIONS, CLINICAL TRIALS, AND INVESTIGATORS SUBJECT TO THE REGULATION BY TYPE OF APPLICATION [1]

Application type	Total number of applications	Number of applications affected	Number of trials	Number of investigators
Drugs:				
New drug application (NDA), new molecular entity (NME)	55	55	3 to 10	3 to 100
NDA non-NME	78	37	3 to 10	3 to 100
NDA efficacy supplement	196	119	1 to 3	10 to 30
Abbreviated new drug application (ANDA)	821	1	1.1	2
ANDA supplement	10,894	1	1	2
CBER Biologics:				
Biologics license application (BLA)	10	10	3 to 10	3 to 100
BLA efficacy supplement	30	30	1 to 3	10 to 30
CDER Biologics:				
BLAs	25	25	3 to 10	3 to 100
BLA efficacy supplements	102	65	1 to 3	10 to 30
Medical Devices:				
Premarket approval (PMA)	39	39	1 to 31	10 to 20
PMA supplement	29	29	to 3	3 to 10
Reclassification devices	0	0	0	0
510(k)	3,947	247	1	3 to 10
De Novo requests	63	57	1 to 3	10 to 20

Source: Agency estimates.

FDA estimates the burden of this collection of information as follows:

Reporting Burden

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

FDA estimates that almost all applicants submit a certification statement under § 54.4(a)(1) and (2). Preparation of the statement using Form FDA 3454 should require no more than 1 hour per study. The number of respondents is based on the estimated number of affected applications.

When certification is not possible and disclosure is made using Form FDA 3455, the applicant must describe, under § 54.4(a)(3), the financial arrangements or interests and the steps that were taken to minimize the potential for bias in the affected study. As the applicant would be fully aware of those arrangements and the steps taken to address them, describing them will be straightforward. The Agency estimates that it will take about 5 hours to prepare this narrative. Based on our experience with this collection, FDA estimates that approximately 10 percent of the respondents with affected applications will submit disclosure statements.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Certification—54.4(a)(1) and (2)—Form FDA 3454	715	1	715	1	715
Disclosure—54.4(a)(3)—Form FDA 3455	72	1	72	5	360
Total					1,075

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping Burden

Under § 54.6 (21 CFR 54.6), the sponsors of covered studies must maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for 2 years after the date of approval of the applications. Sponsors of covered studies maintain many

records regarding clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigators' file.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Recordkeeping—54.6	715	1	715	0.25	179

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Third-Party Disclosure Burden

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that the time required for this task may range from 5 to 15 minutes; we used the median, 10 minutes, for the average burden per disclosure (see table 1).

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
54.4(b)—Clinical Investigators	13,082	1	13,082	0.17	2,224

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

The burden for this information collection request has changed since the last OMB approval. Our estimated burden for the information collection reflects a 298 hour increase. We have adjusted our estimated burden for the information collection to reflect the number of submissions we received in the last few years. Additionally, for products regulated by the Center for Devices and Radiological Health, we now include De Novo requests as a type of application that may rely on clinical studies. For products regulated by the Center for Drug Evaluation and Research, we now include biologics license applications (BLAs) and BLA efficacy supplements that were inadvertently excluded from our last information collection request as a type of application.

Dated: November 24, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26182 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1145]

Aurolife Pharma LLC, et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of five abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 3, 2022.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 072514	Clorazepate Dipotassium Tablets, 3.75 milligrams (mg), 7.5 mg, and 15 mg.	Aurolife Pharma LLC, 2400 U.S. Hwy. 130 N, Dayton, NJ 08810.
ANDA 077840	Ondansetron Hydrochloride Injection, Equivalent to (EQ) 2 mg base/milliliters (mL).	Hospira, Inc., 275 N Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 077988	Fluconazole in Dextrose 5% Injection, 200 mg/100 mL (2 mg/mL) and 400 mg/200 mL (2 mg/mL).	Woodward Pharma Services LLC, 47220 Cartier Dr., Wixom, MI 48393.

Application No.	Drug	Applicant
ANDA 203265	Lidocaine Patch, 5%	Noven Pharmaceuticals, Inc., 11960 SW 144th St., Miami, FL 33186.
ANDA 203967	Escitalopram Oxalate Solution, EQ 5 mg base/5 mL	Antrim Pharmaceuticals LLC, 655 W Northcroft Ct., Lake Forest, IL 60045.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 3, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on January 3, 2022 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: November 23, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26170 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0530]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tropical Disease Priority Review Vouchers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Tropical Disease Priority Review Vouchers.

DATES: Submit either electronic or written comments on the collection of information by January 31, 2022.

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 31, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 31, 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–2008–D–0530 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Tropical Disease Priority Review Vouchers.'' 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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following 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.

Tropical Disease Priority Review Vouchers

OMB Control Number 0910–0822—Extension

Section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360n) is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease products. Section 524 of the FD&C Act serves to stimulate new drug development for drugs to treat a ''tropical disease'' (as defined in section 524(a)(3)) by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524 of the FD&C Act, a sponsor of a ''tropical disease product application,'' as defined in section 524(a)(4), may be eligible for a voucher that can be used to obtain a priority review for any other application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (PHS Act).

Accordingly, we have developed the guidance for industry entitled ''Tropical Disease Priority Review Vouchers'' (available at *https://www.fda.gov/media/72569/download*). The guidance explains how FDA implements provisions of section 524 of the FD&C Act and how sponsors may qualify for a priority review voucher based on eligibility criteria set forth in the statute, how to use priority review vouchers, and how priority review vouchers may be transferred to other sponsors.

The guidance also communicates that, under the FDA Reauthorization Act of 2017, section 524 requires attestation by the sponsor of eligibility for a priority review voucher upon submission of the marketing application.

Description of Respondents: Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Voucher Request	4	1	4	8	32
Notifications of Intent to Use a Voucher	2	1	2	8	16
Letters Indicating the Transfer of a Voucher Letter	2	1	2	8	16
Acknowledging the Receipt of a Transferred Voucher	2	1	2	8	16
Attestation of eligibility	4	1	4	2	8
Total					88

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our evaluation of the information collection since last OMB review and approval, the burden estimate decreased based on receipt of fewer vouchers and other information collection activities.

Dated: November 24, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26196 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1222]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling: Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and

to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the regulation requiring the manufacturer, packer, or distributor of a dietary supplement to notify us that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by January 31, 2022.

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 31, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end January 31, 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:

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- 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–1222 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling: Notification Procedures for Statements on Dietary Supplements.'' 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.

FOR FURTHER INFORMATION CONTACT: 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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following 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.

Food Labeling: Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93

OMB Control Number 0910–0331—Extension

Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) and § 101.93 (21 CFR 101.93) require that, no later than 30 days after the first marketing, we be notified by the manufacturer, packer, or distributor of a dietary supplement that it is marketing a dietary supplement product that bears on its label or in its

labeling a statement provided for in section 403(r)(6) of the FD&C Act. In accordance with these requirements, submissions must include: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) the signature of a responsible individual or the person who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Our electronic form (Form FDA 3955) allows respondents to the information collection to electronically submit notifications to FDA via the Food Applications Regulatory Management (FARM) system. Firms that prefer to submit a paper notification in a format of their own choosing will still have the option to do so; however, Form FDA 3955 prompts respondents to include certain elements in their structure/function claim notification (SFCN) described in § 101.93 in a standard electronic format and helps respondents organize their SFCN to include only the information needed for our review of the claim. Note that the SFCN, whether electronic or paper, is used for all claims made pursuant to section 403(r)(6) of the FD&C Act, including nutrient deficiency claims and general well-being claims in addition to structure/function claims. The electronic form, and any optional elements prepared as attachments to the form (*e.g.,* label), can be submitted in electronic format via FARM. Submissions of SFCNs will continue to be allowed in paper format. We use this information to evaluate whether statements made for dietary ingredients or dietary supplements are permissible under section 403(r)(6) of the FD&C Act.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.93	3,690	1	3,690	0.75 (45 minutes)	2,768

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. This estimate is based on our experience with this information collection and the number of notifications received in the past 3 years, which has remained constant.

Dated: November 26, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26172 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the National Advisory Council on Migrant Health

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates to be considered for appointment as members of the National Advisory Council on Migrant Health (NACMH or advisory committee). The NACMH advises, consults with, and makes recommendations to the HHS Secretary concerning the organization, operation, selection, and funding of Migrant Health Centers (MHCs) and other entities under grants and contracts under the Public Health Service (PHS) Act. HRSA is seeking nominations to fill seven positions on the NACMH.

DATES: HRSA will receive written nominations for NACMH membership on a continuous basis.

ADDRESSES: Nomination packages must be submitted in hard copy to the Designated Federal Official (DFO), NACMH, Strategic Initiatives Division, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 16N38B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: All requests for information regarding NACMH nominations should be sent via email to Esther Paul, DFO, NACMH, HRSA at *hrsabphcoppdnacmh@hrsa.gov* or 301–594–4300. The NACMH charter and list of current membership are available on the NACMH website at *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html*.

SUPPLEMENTARY INFORMATION: NACMH was established and authorized under section 217 of the PHS Act (42 U.S.C. 218) to advise, consult with, and make recommendations to the HHS Secretary concerning the organization, operation, selection, and funding of MHCs and other entities under grants and contracts under section 330(g) of the PHS Act (42 U.S.C. 254b(g)). The NACMH meets twice each calendar year, or at the discretion of the DFO in consultation with the Chair.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on the NACMH to fill seven open positions. Specifically, HRSA is requesting nominations for the following positions: Board Member (three nominees), Board Member/Patient (three nominees), and Administrator Provider (one nominee). The Board Member nominees must be members or members-elect of a governing board of an organization receiving funding under section 330(g) of the PHS Act. The Board Member/Patient nominees must also be patients of the health centers that they represent. Additionally, Board Member nominees must be familiar with the delivery of primary health care to migratory and seasonal agricultural workers (MSAWs) and their families. The Administrator/Provider nominee must be qualified by training and experience in the medical sciences or in the administration of health programs for MSAWs and their families. Another individual or organization may nominate an interested applicant.

The HHS Secretary appoints NACMH members with the expertise needed to fulfill the duties of the advisory committee. The membership requirements set-forth under section 217 of the PHS Act (42 U.S.C. 218) require that the NACMH consist of 15 members, at least 12 of whom shall be members of the governing boards of MHCs or other entities assisted under section 330(g) of the PHS Act (42 U.S.C. 254b(g)). Of these 12 board members, at least nine shall be individuals who are MHC patients and familiar with the delivery of health care to MSAWs. The remaining three NACMH members shall be individuals qualified by training and experience in the medical sciences or in the administration of health programs. New members filling a vacancy occurring prior to term expiration may serve only for the remainder of such term. Members may serve after term expiration until their successors take office, but no longer than 120 days. Nominees must reside in the United States, and international travel cannot be funded.

Individuals selected for appointment to the NACMH will be invited to serve for up to 4 years. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending NACMH meetings and/or conducting other business on behalf of the NACMH, as authorized by 5 U.S.C. 5703 for persons employed intermittently in government service.

The following information must be included in the package of materials submitted for each individual nominated for consideration: (1) NACMH nomination form, which can be requested by contacting the DFO at the email provided above; (2) three letters of reference; (3) a statement of prior service on the NACMH; and (4) a current copy of the nominee's curriculum vitae. Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate.

HHS endeavors to ensure that NACMH membership is fairly balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with disabilities, are considered for membership. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, or cultural, religious, or socioeconomic status.

Individuals under consideration for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required in order for HRSA ethics officials to determine whether there is a potential conflict of interest between the SGE's public duties as a member of the NACMH and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

Authority: NACMH is authorized by section 217 of the PHS Act, Title 42 U.S.C. 218, and established by the HHS Secretary. It is governed by the Federal Advisory Committee Act (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–26199 Filed 12–1–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

FOR FURTHER INFORMATION CONTACT: Anastasia Donovan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Donovan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: In accordance with Section 9.19 of the Mandatory Guidelines, a notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list.*

The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/

or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid dated October 25, 2019 (84 FR 57554), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190, (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800–442–0438, (Formerly: STERLING Reference Laboratories)

Desert Tox, LLC, 5425 E Bell Rd, Suite 125, Scottsdale, AZ, 85254, 602–457–5411/623–748–5045

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare,* 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630, (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Laboratory Corporation of America Holdings, 7207 N Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

Legacy Laboratory Services Toxicology, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

MedTox Laboratories, Inc., 402 W County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088. Testing for Veterans Affairs (VA) Employees Only

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

Anastasia Marie Donovan,

Policy Analyst, Division of Workplace Programs.

[FR Doc. 2021–26179 Filed 12–1–21; 8:45 am]

BILLING CODE 4162–20–P

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register,** July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on January 23, 2017 (82 FR 7920). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Notice of Advisory Council on Historic Preservation Quarterly Business Meeting

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of Advisory Council on Historic Preservation quarterly business meeting.

SUMMARY: Notice is hereby given that the Advisory Council on Historic Preservation (ACHP) will have its next quarterly meeting on Wednesday, December 15, 2021, starting at 1:30 p.m. EDT.

DATES: The quarterly meeting will take place on Wednesday, December 15, 2021 starting at 1:30 p.m. EDT.

ADDRESSES: Due to continuing COVID-related conditions, the meeting will take place using *Zoomgov.com* videoconferencing. There will be no in-person attendance and, due to technical limitations, only ACHP and ACHP member staff will be able to watch live. However, a recording of the meeting will be posted on *www.achp.gov* when the proceedings conclude.

FOR FURTHER INFORMATION CONTACT: Tanya DeVonish, 202–517–0205, *tdevonish@achp.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Council on Historic Preservation (ACHP) is an independent federal agency that promotes the preservation, enhancement, and sustainable use of our nation's diverse historic resources, and advises the President and the Congress on national historic preservation policy. The goal of the National Historic Preservation Act (NHPA), which established the ACHP in 1966, is to have federal agencies act as responsible stewards of our nation's historic properties when making decisions that may affect them. The ACHP is the only entity with the legal responsibility to encourage federal agencies to factor historic preservation into their decision making. For more information on the ACHP, please visit our website at *www.achp.gov.*

The provisional agenda for the upcoming quarterly meeting of the ACHP is the following:

Call to Order 1:30 p.m. EDT

I. Vice Chairman's Welcome and Report
II. ACHP/HUD Secretary's Award for Excellence in Historic Preservation
III. Executive Director's Report
IV. ACHP Strategic Plan Update
V. Climate Change and Historic Preservation
  A. Climate Change Task Force Update
  B. America the Beautiful
VI. Historic Preservation Policy and Programs
  A. Legislation
  B. Other Reports
VII. Section 106
  A. Program Comment Panel Recommendations Implementation
  B. Other Reports
VIII. Native American Affairs
  A. White House Tribal Nations Summit Report
  B. Other Reports
IX. Communications, Education, and Outreach
  A. C–SPAN National Outreach
  B. Other Reports
X. ACHP Foundation Report
XI. New Business
XII. Adjourn

Authority: 54 U.S.C. 304102.

Dated: November 29, 2021.

Javier E. Marqués,

General Counsel.

[FR Doc. 2021–26207 Filed 12–1–21; 8:45 am]

BILLING CODE 4310–K6–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. 2021–0034]

Privacy Act of 1974; Computer Matching Program

AGENCY: Department of Homeland Security, U.S. Citizenship and Immigration Services

ACTION: Notice of a re-established matching program.

SUMMARY: Pursuant to the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 and the Computer Matching and Privacy Protections Amendment of 1990 (Privacy Act), and Office of Management and Budget (OMB) guidance on the conduct of matching programs, notice is hereby given of the re-establishment of a matching program between the Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) and the Massachusetts Department of Unemployment Assistance (MA–DUA). MA–DUA will match against DHS–USCIS data to verify the immigration status of non-U.S. citizens who apply for federal benefits (Benefit Applicants) under Unemployment Compensation (UC) that MA–DUA administers to determine whether Benefit Applicants possess the requisite immigration status to be eligible for the UC benefits it administers.

DATES: Please submit comments on the proposal by January 3, 2022. The matching program will be effective on January 3, 2022 unless comments have been received from interested members of the public that require modification and republication of the notice. The matching program will continue for 18 months from the beginning date and may be extended an additional 12 months if the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

ADDRESSES: You may submit comments, identified by docket number *DHS–2021–0034* 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, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number DHS–2021–0034. 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: To obtain additional information about this matching program and the contents of this Computer Matching Agreement between DHS–USCIS and MA–DUA, please view this Computer Matching Agreement at the following website: *https://www.dhs.gov/publication/computer-matching-agreements-and-notices.* For general questions about this matching program, contact Jonathan M. Mills, Acting Chief, USCIS SAVE Program at (202) 306–9874. For general privacy questions, please contact Lynn Parker Dupree, (202) 343–1717, Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION: DHS–USCIS provides this notice in accordance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503) and the Computer Matching and Privacy Protection Amendments of 1990 (Pub. L. 101–508) (Privacy Act); Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100–503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular A–108, 81 FR 94424 (December 23, 2016).

Participating Agencies: DHS–USCIS and MA–DUA.

Authority for Conducting the Matching Program: Section 121 of the Immigration Reform and Control Act (IRCA) of 1986, Public Law No. 99–603, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), Public Law 104–193, 110 Stat. 2168 (1996), requires DHS to establish a system for the verification of immigration status of noncitizen applicants for, or recipients of, certain types of benefits as specified within IRCA, and to make this system available to state agencies that administer such benefits. The Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), Public Law 104–208, 110 State. 3009 (1996) grants federal, state or local government agencies seeking to verify or ascertain the citizenship or immigration status of any individual within the jurisdiction of the agency with the authority to request such information from DHS–USCIS for any purpose authorized by law.

Purpose(s): The purpose of this Agreement is to establish the terms and

conditions governing MA–DUA's access to, and use of, the DHS–USCIS Systematic Alien Verification for Entitlements (SAVE) Program, which provides immigration status information from federal immigration records to authorized users. MA–DUA will use the SAVE Program to verify the immigration status of non-U.S. citizens who apply for federal benefits (Benefit Applicants) under Unemployment Compensation (UC) Programs to determine whether Benefit applicants possess the requisite immigration status to be eligible for the unemployment compensation administered by MA–DUA.

Categories of Individuals: The individuals about whom DHS–USCIS maintains information, which is contained in its Verification Information System (VIS) database used by the SAVE Program to verify immigration status, that are involved in this matching program include noncitizens (meaning any person as defined in Immigration and Nationality Act section 101(a)(3)), those naturalized, and to the extent those that have applied for Certificates of Citizenship, derived U.S. citizens, on whom DHS–USCIS has a record as an applicant, petitioner, sponsor, or beneficiary. The individuals about whom MA–DUA maintains information that is involved in this matching program include noncitizen Benefit Applicants for, or recipients of, UC administered by MA–DUA.

Categories of Records: Data elements to be matched between MA–DUA records and DHS–USCIS federal immigration records include the following: Last Name, First Name, Middle Name, Date of Birth, Immigration Numbers (*e.g.,* Alien Registration/USCIS Number, I–94 Number, SEVIS ID Number, Certificate of Naturalization Number, Certificate of Citizenship Number, or Unexpired Foreign Passport Number), and Other Information from Immigration Documentation (for example, Country of Birth, Date of Entry, Employment Authorization Category). Additional Data elements provided to MA–DUA from DHS–USCIS records related to the match may include: Citizenship or Immigration Data (for example, immigration class of admission and/or employment authorization), Sponsorship Data (for example, name, address, and social security number of Form I–864/I–864EZ sponsors and Form I–864A household members, when applicable) and Case Verification Number.

System of Records: DHS/USCIS–004 Systematic Alien Verification for Entitlements (SAVE) System of Records Notice, 85 FR 31798 (May 27, 2020).

Lynn Parker Dupree,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2021–26168 Filed 12–1–21; 8:45 am]

BILLING CODE 9110–9L–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[FR–7047–N–01]

60-Day Notice of Proposed Information Collection: Secretary Invite Form

AGENCY: Office of the Secretary, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 31, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna Guido, Management Analyst, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–5535 (this is not a toll-free number) or email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT: Patrice Taylor Department of Housing and Urban Development, 451 7th Street SW, 10218, Washington, DC 20410; telephone 202–402–6104, (this is not a toll-free number). Copies of available documents submitted to OMB may be obtained from Anna Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Secretary Invite Form.

OMB Approval Number: Pending.

Type of Request: Meeting Request.

Form Number: FR–7047–N–01 (2501–XXX).

Description of the Need for the Information and Proposed Use: Meeting request details used to schedule time with HUD's Secretary and other leadership.

Estimated Number of Respondents: 20 to 30 per month.

Estimated Number of Responses: 20 to 30 per month.

Frequency of Response: 20 to 30 per month.

Average Hours per Response: .25 hours.

Total Estimated Burdens: 60–90 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.

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.

Patrice Taylor,

Deputy Chief of Staff, Office of the Secretary.

[FR Doc. 2021–26166 Filed 12–1–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX21DJ730U3M100; OMB Control Number 1028–NEW]

Agency Information Collection Activities: Water Resources Management—Institutional Resiliency, Hazards Planning, and Data Delivery Needs Information Collection

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, we, the U.S. Geological Survey (USGS) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before January 31, 2022.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive, MS 159, Reston, VA 20192 or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–NEW in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Nicole Herman-Mercer by email at *nhmercer@usgs.gov* or by telephone at 303–236–5031. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA, 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.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper performance of functions of the USGS; (2) will this information be processed and used in a timely manner; (3) is our estimate of the burden for this ICR accurate; (4) how might the USGS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the USGS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Abstract: The United States is facing growing challenges related to the availability of water due to shifting demographics, aging water-delivery infrastructure, and the impacts of climate change, which include flood and drought. Working with incomplete knowledge, managers must consider the needs of various demographic groups and economic sectors when making management decisions as well as when responding to emergencies. We will collect information regarding the decision-making process, data, and data-format needs to support daily, long-term, and emergency response decision-making. Information will also be sought on the resiliency of water-resource management institutions. A lack of resiliency within water institutions can lead to poor decision-making and outcomes that produce conflict between water-use sectors, states, or communities and ultimately may led to crises. This information will support the delivery of appropriate data, in appropriate formats, at the right time for decision-making and emergency response, as well as how water-resource institutions can be more resilient in the face of the many water-resources challenges the nation currently faces.

Title of Collection: Water Resources Management—Institutional Resiliency, Hazards Planning, and Data Delivery.

OMB Control Number: 1028–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: State, local, Federal water-resource managers and water-resource stakeholders, and water hazard responders.

Total Estimated Number of Annual Respondents: 150.

Total Estimated Number of Annual Responses: 150.

Estimated Completion Time per Response: 60 minutes.

Total Estimated Number of Annual Burden Hours: 300.

Respondent's Obligation: Voluntary.

Frequency of Collection: Twice per year.

Total Estimated Annual Nonhour Burden Cost: None.

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 PRA (44 U.S.C. 3501 *et seq*).

Joseph Nielsen,

Director, Integrated Information Dissemination Division, Water Resources Mission Area.

[FR Doc. 2021–26208 Filed 12–1–21; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–33050; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before November 20, 2021, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by December 17, 2021.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before November 20, 2021. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

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.

Nominations submitted by State or Tribal Historic Preservation Officers:

CALIFORNIA

Sonoma County

Salt Point Landing Historical and Archaeological District, (Northern California Doghole Ports Maritime Cultural Landscape MPS), Address Restricted, Jenner vicinity, MP100007268

DISTRICT OF COLUMBIA

District of Columbia

Lucy Diggs Slowe Elementary School, (20th Century African American Civil Rights Sites in Washington, DC, 1912–1974 MPS), 3115 14th St. NE and 1404 Jackson St. NE, Washington, MP100007259

MARYLAND

Anne Arundel County

Sands, John, House, 130 Prince George St., Annapolis, SG100007260

MASSACHUSETTS

Worcester County

Southborough Center Historic District, Main and Common Sts., Middle, Cordaville, and Latisquama Rds., Southborough, SG100007264

MISSOURI

Jackson County

El Torreon Ballroom, 3101 Gillham Plz., Kansas City, SG100007262

Sunset Tower, (Working-Class and Middle-Income Apartment Buildings in Kansas City, Missouri MPS), 4821 Roanoke Pkwy., Kansas City, MP100007263

Jasper County

Cleveland Apartments, (Historic Resources of Joplin, Missouri MPS), 801–807 West 1st St. and 104 North Jackson Ave., Joplin, MP100007261

PENNSYLVANIA

Allegheny County

Fairfax Apartments, 4614 5th Ave., Pittsburgh, SG100007257

WYOMING

Big Horn County

Shell Community Hall, 201 Smith Ave., Shell, SG100007266

A request for removal has been made for the following resource:

NORTH DAKOTA

McLean County

Former McLean County Courthouse, (North Dakota County Courthouses TR), Main St., Washburn, OT85002987

Additional documentation has been received for the following resource:

ILLINOIS

Du Page County

Graue Mill, NW of jct. of Spring and York Rds., Oak Brook, AD75002077

Authority: Section 60.13 of 36 CFR part 60.

Dated: November 23, 2021.

Paul Lusignan,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2021–26204 Filed 12–1–21; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–125 (Fifth Review)]

Potassium Permanganate From China

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted this review on February 1, 2021 (86 FR 7743) and determined on May 7, 2021 that it would conduct a full review (86 FR 27477, May 20, 2021). Notice of the scheduling of the Commission's review and of a public hearing to be 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 June 7, 2021 (86 FR 30256). In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission conducted its hearing through written testimony and video conference on October 5, 2021. All persons who requested the opportunity were permitted to participate.

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on November 29, 2021. The views of the Commission are contained in USITC Publication 5241 (November 2021), entitled *Potassium Permanganate from China: Investigation No. 731–TA–125 (Fifth Review).*

By order of the Commission.

Issued: November 29, 2021.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2021–26220 Filed 12–1–21; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1296 (Final)]

Hot-Rolled Steel Flat Products From Turkey; Request for Comments Regarding the Institution of a Section 751(b) Review Concerning the Commission's Affirmative Determination

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission invites comments from the public on whether changed circumstances exist sufficient to warrant the institution of a review pursuant to the Tariff Act of 1930 (the Act) regarding the Commission's affirmative determination in investigation No. 731–TA–1296 (Final). The purpose of the proposed review is to determine whether revocation of the existing antidumping duty order on imports of hot-rolled steel flat products from Turkey is likely to lead to continuation or recurrence of material injury. The Commission further requests comments concerning the degree to which such a proceeding can be conducted in conjunction with the pending five-year review of the antidumping duty order on the same subject merchandise.

DATES: December 2, 2021.

FOR FURTHER INFORMATION CONTACT: Douglas Corkran (202–205–3057), 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 (*http://www.usitc.gov).* The public record for this matter may be viewed on the

Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—In September 2016, the Commission determined that a U.S. industry was materially injured by reason of imports of hot-rolled steel flat products from Turkey found by the U.S. Department of Commerce (Commerce) to be sold in the United States at less than fair value (81 FR 66996, Sept. 29, 2016).

On September 10, 2021, the Commission received a request to review its affirmative determination in investigation No. 731–TA–1296 (Final) pursuant to section 751(b) of the Act (19 U.S.C. 1675(b)). The request, filed by Eregli Demir ve Celik Fabrikalari T.A.S. (Erdemir), alleges there have been significant changed circumstances since the issuance of the Commission's 2016 determination. Specifically, Erdemir alleges that Commerce's recalculation of Colakoglu's antidumping duty margin to zero percent and its exclusion from the antidumping duty order as a result of judicial review constitute significantly changed circumstances from those in existence at the time of the original investigation because the facts underlying the Commission's negligibility determination completely changed. According to Erdemir, the exclusion of Colakoglu from the antidumping duty order places this case *in pari materia* with the injury case in the countervailing duty investigation and provides a compelling basis to find that imports from Turkey subject to the antidumping duty investigation are negligible.

Written comments requested.—Pursuant to section 207.45(b) of the Commission's Rules of Practice and Procedure, the Commission requests comments concerning whether the alleged changed circumstances, brought about by the aforementioned changes in the imports of hot-rolled steel flat products from Turkey subject to an antidumping duty order, are sufficient to warrant institution of a review.

The Commission further requests comments concerning the degree to which any changed circumstances proceeding concerning hot-rolled steel flat products from Turkey can be conducted in conjunction with the five-year review of the antidumping duty order on the same subject merchandise that Commerce has initiated and the Commission has instituted on September 1, 2021 (86 FR 49057). If the Commission initiates a changed circumstances review, the review is likely to be conducted on an overlapping basis with the five-year review concerning hot-rolled steel flat products from Turkey. Therefore, commenters are encouraged to address the nature of the respective inquiries, the data and other information necessary for the Commission's evaluation, and procedural considerations for the effective conduct of the reviews.

Written submissions.—Comments must be filed with the Secretary to the Commission by no later than 30 days after publication of this notice or by [XXX]. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Please note the Secretary's Office will accept only electronic filings at 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: This notice is published pursuant to section 207.45 of the Commission's rules.

By order of the Commission.

Issued: November 29, 2021.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2021–26222 Filed 12–1–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–888]

Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2022

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2022 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: The initial 2022 aggregate production quotas and assessment of annual needs are effective December 2, 2021.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (571) 776–2265.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedule I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100.

II. Background

The 2022 aggregate production quotas (APQ) and assessment of annual needs (AAN) represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine that may be manufactured in the United States in 2022 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes.

On October 18, 2021, a notice titled ''Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2022'' was published in the **Federal Register**. 86 FR 57690. This notice proposed the 2022 APQ for each basic class of controlled substance listed in schedules I and II and the 2022 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed

APQ and the proposed AAN on or before November 17, 2021.

III. Comments Received

Within the public comment period, DEA received 610 comments from DEA registrants, chronic pain patients, pain advocacy associations, professional associations, doctors, nurses, State Attorneys General, and others. The comments included requests for clarification about the data DEA used to determine diversion for the purposes of the APQ for certain schedule II opioids; concerns about potential drug shortages due to further quota reductions; concerns that medical professionals might be impeded from exercising their medical expertise regarding opioid prescriptions; concerns about the quota process; requests for a public hearing; and comments not pertaining to DEA regulated activities.

DEA's Regulatory Authority

Issue: DEA received comments that raised the question of whether DEA has the authority to regulate activities related to controlled substances, including the manufacture of Food and Drug Administration (FDA)-approved pharmaceutical products containing controlled substances.

DEA Response: The CSA, which was initially enacted in 1970 and has been amended several times, requires DEA to establish production quotas for certain controlled substances. 21 U.S.C. 826(a). In the CSA, Congress granted DEA (as delegated by the Attorney General under 21 U.S.C. 871(a)) the authority to promulgate ''rules and regulations'' relating to the ''registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals'' (21 U.S.C. 821), and to the ''registration and control of importers and exporters of controlled substances'' (21 U.S.C. 958(f)), as well as those ''necessary and appropriate for the efficient execution'' of the authorities granted by the CSA (21 U.S.C. 871(b)), among other provisions. In its findings, Congress acknowledged that many controlled substances ''have a useful and legitimate medical purpose.'' 21 U.S.C. 801(1).

Congress explicitly directed DEA to establish production quotas for controlled substances in schedule I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. 21 U.S.C. 826(a). In recognition of FDA's related but distinct role in regulating pharmaceutical products, DEA's regulations require DEA to consider relevant information from FDA before DEA establishes the APQs. As DEA has acknowledged in previous **Federal Register** publications relating to quotas, the responsibility to provide estimates of legitimate domestic medical needs resides with FDA. DEA considers this important information in proposing and revising the APQs.

Medication Shortages

Issue: DEA received many comments expressing general concerns that the proposed decreases to the production quotas of certain controlled substances may result in shortages of drug products containing those controlled substances.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet the estimated legitimate medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. DEA sets APQs in a manner to provide for all legitimate medical purposes.

Additionally, DEA and FDA are required to, and routinely do, coordinate efforts to prevent or alleviate drug shortages pursuant to 21 U.S.C. 826(h). Such efforts may include adjusting the APQ, adjusting individual domestic manufacturers' quotas, FDA approval of additional market competitors, and coordination between the agencies to allow importation of foreign-manufactured drug products that meet FDA approval. For example, in 2020, DEA adjusted its quota to increase the aggregate production quota for drug products containing fentanyl, hydromorphone, morphine, and codeine, and the assessments of annual needs for drug products containing pseudoephedrine and ephedrine. The increased production needs for those substances, which are used to treat patients in intensive care units and those on ventilators, was a result of the COVID–19 public health emergency. These actions were taken based on DEA's consultations with federal partners at the Department of Health and Human Services (HHS), drug manufacturers, drug distributors, and hospital associations. Similarly, in 2018, a domestic shortage of injectable hydromorphone was alleviated through FDA and DEA collaboration to identify other dosage-form manufacturers with injectable hydromorphone products in the market, and to determine whether those other dosage-form manufacturers had the capability to increase their production levels to meet legitimate patient need in a timely manner. When the agencies determined that the domestic manufacturers could not increase production adequately to meet legitimate patient need, DEA and FDA coordinated and used their respective regulatory authorities to allow for the limited importation of injectable hydromorphone into the United States.

Prescribing Hesitancy

Issue: Many commenters, most of whom self-identified as chronic pain patients, expressed general concerns that the *CDC Guidelines for Prescribing Opioids for Chronic Pain,* issued in 2016, are preventing doctors from prescribing pain medication in dosages that adequately control chronic pain, forcing them to taper opioid medication dosages inappropriately, and causing them to refuse to prescribe opioid prescriptions to chronic pain patients. These comments also raised concerns that some health insurers have mandated that opioid medication dosages be tapered for continued insurance coverage or have denied coverage for prescriptions from out-of-network providers. Commenters noted that worker's compensation insurers have denied opioid medication coverage for pain patients. One commenter raised concerns that chronic pain patients are not allowed to self-pay for opioid medications.

DEA Response: Provided that the prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice, neither the CSA nor DEA regulations impose a specific minimum or maximum limit on the amount of medication that may be prescribed on a single prescription, or limit the duration of treatment intended with a prescribed controlled substance. DEA has consistently emphasized and supported the authority of individual practitioners under the CSA to administer, dispense, and prescribe controlled substances for the legitimate treatment of pain within acceptable medical standards, as outlined in DEA's policy statement published in the **Federal Register** on September 6, 2006, titled Dispensing Controlled Substances for the Treatment of Pain. 71 FR 52716.

Use of Studies/Guidelines To Determine Medical Need

Issue: Ten State Attorneys General [1] (referred to collectively as State Attorneys General) suggested that DEA consider research studies and best practices developed by individual state-level partnerships with local medical communities and other individual state regulators to determine the extent of

[1] The comment received from the Office of the Attorney General, State of West Virginia, was also signed by the State Attorneys General of Kentucky, Arkansas, Alaska, Idaho, Louisiana, Mississippi, Nebraska, Utah and South Dakota.

overprescribing of controlled substances.

DEA Response: DEA has reviewed the conclusions of these studies and believes they are insufficient to support a reduction in the APQs because the studies examined a limited set of medical procedures that could not be generalized to all prescriptions dispensed in the United States. The studies have found, with respect to certain medical procedures, that physicians prescribe more controlled substances for post-operative pain than patients utilize. While the referenced studies are concerning, DEA believes they are insufficient to impact DEA's APQ determination.

Percentage of Prescription Opioids Being Diverted

Issue: Multiple commenters said that the APQs should not be reduced from calendar year 2021 APQ levels, given that less than 1 percent of prescription controlled substances are diverted. One commenter cited DEA's statements in the 2020 Proposed APQ to support this statistic.

DEA Response: DEA's regulations require it to consider numerous relevant factors in its determination of the APQ. One factor is the extent of diversion of controlled substances. Diversion is defined as all distribution, dispensing, or other use of controlled substances for other than legitimate medical purposes. The commenter is correct that in the *Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020 (84 FR 48170),* DEA determined that the quantity of FDA-approved drug products containing controlled substances that were diverted in 2018 represented less than one percent of the total quantity of controlled substances distributed to retail purchasers.

However, DEA also considers other relevant factors, as required by regulation, when determining the APQ. 21 U.S.C. 826(a), 21 CFR 1303.11(b). DEA's consideration of all of these relevant factors resulted in the proposed 2022 APQ as published.

Relevant Information From FDA

Issue: Comments raised questions regarding the data provided by FDA, including the methodology it used to determine domestic medical need.

DEA Response: The information DEA received from FDA included the observed and projected domestic usage of schedule II controlled substances, new drug application and abbreviated new drug application approvals, manufacturers discontinuing production, product shortages, and clinical trials for schedule I and II controlled substances. FDA utilizes a variety of data sources in developing its estimates, and also describes certain caveats regarding the forecasts it provides. The data provided by FDA contributed to DEA's estimate of declining legitimate domestic medical need for opioids.

FDA provides an important portion of the data that DEA analyzes in developing the annual APQs, but DEA also utilizes other data sources to meet its statutory and regulatory requirements. For instance, DEA utilized information provided by quota applicants and research protocols submitted directly to DEA to derive the estimates of scientific, research, and industrial needs; lawful export requirements; and current reserve stocks. No single data element is adequate to address all of the legal factors.

Issue: The State Attorneys General raised a concern that the proposed APQ for the five covered controlled substances defined in 21 U.S.C. 826(i)(1)(A) as fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone are not aligned with the decline in medical need for schedule II opioids as projected by FDA.

DEA Response: DEA notes that the decline of 18.88 percent was an average for certain schedule II opioids including but not limited to the five covered controlled substances predicted between 2021 and 2022. This estimated decline was for the domestic medical need only, which is one of several factors that DEA must consider when establishing APQ estimates for the entire calendar year.

Estimates of Diversion Mandated by the SUPPORT Act

Issue: The State Attorneys General inquired about DEA's method of assessing diversion of the five covered controlled substances, as compared with the other basic classes of controlled substances subject to quotas.

DEA Response: Pursuant to 21 CFR 1303.11(b)(5), DEA considered the extent of diversion of the basic class as a factor in setting each APQ for each respective basic class, as well as the extent of diversion for all other schedule I and II controlled substances in proposing the estimated APQ. As the State Attorneys General note, the Substance-Use Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act (SUPPORT Act, Pub. L. 115–271) requires that DEA provide the diversion estimate only for the five covered controlled substances. In compliance with the SUPPORT Act, DEA published the estimated diversion for the five covered controlled substances in its October 18, 2021 notice, and provides revised estimates in Tables 2 and 3 below.

Issue: DEA received comments that raised questions regarding DEA's use of law enforcement data, including seizure data and theft and loss reporting, in its estimation of diversion for the five covered controlled substances.

DEA Response: DEA considered the reliability of all reported law enforcement data for the purpose of calculating estimates of diversion for the APQs of the five covered controlled substances. DEA did not include seizure data in its estimate of diversion because DEA could not conclusively determine that the collected data did not overlap with other data sources used to calculate relevant diversion estimates, nor could DEA determine from the reported data whether the seized substances contained illicitly manufactured fentanyl.

Issue: Commenters questioned the inclusion of losses due to disasters.

DEA Response: DEA registrants are required to report thefts and significant losses to DEA. These reports are often submitted before the registrant has had the opportunity to fully investigate the reason for the loss. Loss reports may include incidents of employee pilferage that may not be reported initially as theft to DEA. A ''loss in transit'' is nominally a loss but may in fact represent diversion by employees or other individuals. Generally, loss is considered diversion because it involves controlled substances falling outside the closed system of distribution. However, DEA agrees that reported losses due to disaster (fire, weather, etc.) should be distinguished from diversion for APQ purposes. DEA therefore has adjusted its estimate of diversion of covered controlled substances in the supply chain by excluding those losses due to disaster, fire, weather, etc., as shown in Table 1.

TABLE 1—SUPPLY CHAIN LOSS DUE TO DISASTER

[Fire, etc]

Controlled substance	(g)
Fentanyl	1
Hydrocodone	123
Hydromorphone	5
Oxycodone	214
Oxymorphone	4

Issue: DEA received numerous comments expressing concerns that DEA's reduction of quotas for pain-relieving controlled substances does not correlate to a reduction in overdose deaths. According to the commenters, DEA and CDC data show that illicit fentanyl and heroin are responsible for the majority of overdose deaths. The commenters state that overdose deaths in the U.S. continue to rise because of illegal fentanyl, heroin, and illegally manufactured pain pills, not from pharmaceutical medications prescribed to chronic pain patients.

DEA Response: In establishing the APQ, DEA considers the legitimate medical need in the United States. DEA strives to ensure that the APQs are sufficient to provide for the legitimate controlled substance prescription requirements while limiting the potential for diversion of controlled substances. DEA also considers changes in currently accepted medical use in treatment as part of the determination of legitimate medical need, and establishes the APQ for specific controlled substances accordingly. 21 CFR 1303.11(b)(7).

Use of PDMP Data in Identifying Potential Diversion

Issue: DEA received numerous comments that raised questions regarding DEA's use of prescriptions filled for the five covered controlled substances in dosages exceeding 240 morphine milligram equivalents (MME) daily as a potential indicator of diversion. The commenters noted that CDC has published guidelines that recommend prescribers consider the medical necessity of exceeding a daily dosage limit of 90 MME. The State Attorneys General also asked whether, in flagging prescriptions that exceed 240 MME daily, DEA considered individual prescriptions, or considered combined prescriptions for patients at any given time.

DEA Response: DEA did not consider prescriptions written for the five covered controlled substances in quantities lower than 240 MME daily because some patients, including oncology patients in particular, have legitimate medical needs for covered controlled substance prescriptions in excess of 90 MME daily. DEA did not wish to inadvertently include legitimate prescriptions for these patients in its calculation of diversion. Daily dosages higher than 240 MME place individuals at a higher risk of overdose and death, and correlate with a heightened risk of diversion. DEA received aggregated data from state PDMPs that reflected only individual prescriptions.

Issue: Commenters asked whether the PDMP data responses from the states covered all time periods requested. If they did not, how did DEA's calculations account for missing data?

DEA Response: All responding states provided summarized PDMP data for 2018–2020, the entire time period requested by DEA.

Issue: Some commenters, including the State Attorneys General, expressed concerns that the PDMP data obtained from responding states that DEA used to identify diversion does not represent the entire U.S. population accurately.

DEA Response: DEA requested data through the National Association of State Controlled Substances Authorities (NASCSA), which includes the forty-nine member states that utilize PDMPs. As indicated in the proposed APQ, DEA did not receive PDMP data from all queried states for use in its determination of diversion. The sixteen states and one county providing PDMP data represent a geographically diverse cross-section of 78.5 million people, or 24 percent of the United States population. Based on publicly available, established statistical methods for sampling very large populations, polling approximately 10 percent of a given large population provides enough statistical power to draw reliable inferences about the population. A sample size of 24 percent therefore is large enough to accurately generalize that data outcome to the whole population of the United States and to be used in the calculation of estimated national levels of diversion of the covered controlled substances.

Issue: Commenters raised questions regarding patient privacy issues relating to the PDMP data provided to DEA by states.

DEA Response: DEA requested and received anonymized, aggregated PDMP data from the states. No individual patient names, addresses, or other discrete, personally identifiable information was shared with DEA.

Issue: The State Attorneys General commented that DEA should have used patient address information from the PDMP data to determine a metric for potential diversion based on geographic distances between patient, prescriber, and pharmacy.

DEA Response: DEA did not request, nor did it receive, any state PDMP data that included individualized identifying data such as patient addresses.

Issue: DEA received comments that raised questions about the accuracy of PDMP data regarding patients' current and discontinued use of opioid prescriptions containing the covered controlled substances within discrete time periods.

DEA Response: DEA requested aggregated PDMP data for filled prescriptions containing the five covered controlled substances. In many instances, prescriptions that are filled but not used by patients create the potential for diversion because of the opportunity for misuse by non-patients. The most common sources of misused pharmaceutical opioids are family and friends. The Substance Abuse and Mental Health Services Administration's 2019 National Survey on Drug Use and Health Annual National Report published data demonstrating that more than half (50.8 percent) of people who self-reported misusing prescription pain relief medicine obtained their most recent pain reliever from a friend or relative, either for free, by purchase, or by taking without asking. Such misuses of prescriptions constitute diversion.

Issue: One commenter questioned whether it is appropriate to use data showing instances of patients receiving specific controlled substance prescriptions issued by three or more doctors within a 90-day period as a metric to determine potential diversion.

DEA Response: DEA developed the metric of patients prescribed covered controlled substances from three or more prescribers in a 90-day period to identify potential doctor shopping, a common technique used to obtain large amounts of controlled substances for the purpose of abuse or diversion. Federal administrative and criminal case law demonstrates that multiple prescriptions from multiple prescribers in a short timeframe is a reliable indicator of diversion.[2]

Issue: DEA received comments from the State Attorneys General and the general public questioning whether DEA derived its diversion estimates from individual prescriptions paid for with cash, and if entire classes of prescribers or pharmacies with large cash transactions were excluded.

DEA Response: DEA received reports from state PDMP administrators which were designed by NASCSA to respond to DEA's request for aggregated information. The reports contained the number of patients and prescriptions that met each of the diversion metrics DEA identified. These reports did not include individualized information that would be contained on prescriptions. DEA did not consider whether this data

[2] The Medicine Shoppe, 29 FR 59504, 59507, 59512–13 (2014); Holiday CVS, LLC, d/b/a CVS Pharmacy Nos. 219 and 5195, 57 FR 62316 (2012).

included specific classes of prescribers or pharmacies.

Issue: The State Attorneys General suggested that DEA consider PDMP data about inconsistent or early refills of prescription opioids in estimating potential diversion.

DEA Response: Prescriptions for schedule II controlled substances cannot be refilled. 21 U.S.C. 829(a). All of the substances for which DEA requested PDMP data were schedule II controlled substances.

Schedule I Controlled Substances

Issue: Several commenters requested that DEA consider increasing production quotas for certain schedule I controlled substances, including: Bufotenine, 5-methoxy-N,N-dimethyltryptamine (5-MEO-DMT), ibogaine, psilocybin, mescaline, 3,4-methylenedioxymethamphetamine (MDMA), and dimethyltryptamine (DMT) for research activities and clinical trials in Canada and the United States.

DEA Response: The APQs established today reflect DEA's estimates of the medical, scientific, research, and industrial needs of the United States for 2022, as well as lawful export requirements and establishment and maintenance of reserve stocks. DEA can adjust the established APQs if these needs change. For instance, if DEA receives additional research protocols from DEA-registered researchers, or additional quota applications from DEA-registered manufacturers, DEA will consider revising the APQ.

DEA did receive additional quota applications from DEA-registered manufacturers for 5-MEO-DMT, psilocybin, and MDMA. DEA considered those applications accordingly, as discussed below. DEA has not received quota applications from DEA-registered manufacturers to support the requested changes in the APQ for the other controlled substances mentioned.

Issue: DEA received a comment from a biotech company suggesting that DEA discuss involving representatives from indigenous communities in determining APQ for controlled substances that are potentially derived from plants traditionally used by indigenous groups in the Americas and beyond.

Response: In accordance with 21 CFR 1303.11(c), DEA invites all interested persons to participate by commenting on proposed APQs. The CSA requires DEA to establish APQ to provide for the estimated medical, scientific, research, and industrial needs of the U.S., for lawful export requirements, and for the establishment and maintenance of reserve stocks. The APQs and the individual manufacturing quotas are informed in part by the quota requests submitted by DEA-registered manufacturers of these substances.

Issue: The Native American Church of North America commented on the proposal to set the APQ for mescaline at 100 grams. They commented that their peyote ceremonies are contingent on the continued availability of peyote in the wild for sacramental use, and that the non-Native use of mescaline in research and clinical studies will have a direct impact upon the church's ability to use, purchase, transport, and possess peyote pursuant to the American Indian Religious Freedom Act (AIRFA), as it will lead to commercialization and exploitation of peyote across its natural range and potential reclassification of its scheduling status.

DEA Response: Mescaline is the schedule I controlled substance naturally occurring in peyote. The 2022 APQ for mescaline will only be used for the production of synthetic mescaline which is utilized to produce analytical reference standards. Thus, the 2022 APQ for mescaline does not have any material effect on the use of peyote by members of the Native American Church.

Schedule II Controlled Substances

Issue: One commenter asked why DEA does not consider significantly reducing the hydrocodone quota to come in line with the rest of the world. The commenter also asked why DEA does not consider global use data in establishing APQ.

DEA Response: DEA is bound by the language of 21 U.S.C. 826 to consider the needs of the United States. After considering the factors defined in 21 CFR 1303.11(b), this APQ represents DEA's best estimate of domestic needs, as well as quantities needed for lawful export and for the establishment and maintenance of reserve stocks.

Issue: DEA received a comment suggesting that DEA evaluate adjustments for the APQ of oral solid and injectable dosage forms of medicines separately. The commenter specifically highlighted differences between dosage forms of certain opioids.

DEA Response: DEA sets APQ in a manner to include dispensings for legitimate medical purposes and, in turn, the APQ takes into consideration both injectable opioids and solid oral opioids to meet the estimated medical needs of the United States. The SUPPORT Act allows, but does not require, DEA to grant individual quotas to DEA-registered manufacturers in terms of dosage forms if the Agency determines that doing so will assist in avoiding the overproduction, shortage, or diversion of controlled substances. By issuing a single APQ covering all dosage forms of the basic class, rather than estimating APQ for each dosage form, DEA retains the flexibility to alleviate potential shortages and to react to unforeseen emergencies by adjusting the individual quotas granted to manufacturers under that APQ.

Assessment of Annual Needs for List I Chemicals

Issue: DEA received comments expressing concerns that the AAN limits the amount of pseudoephedrine (for sale), a chemical found in the allergy medication SUDAFED.

DEA Response: The CSA requires DEA to establish the AAN for ephedrine, pseudoephedrine, and phenylpropanolamine to provide for the estimated legitimate medical, scientific, research, and industrial needs of the United States, lawful exports, and reserve stocks. 21 U.S.C. 826(a). Control of the chemical pseudoephedrine in this manner over the past 15 years has not been shown to limit the availability of over-the-counter products such as Sudafed for legitimate needs. In anticipation of increased need due to the COVID–19 public health emergency, the AAN for pseudoephedrine (for sale) was increased in 2020; however, the expected need did not materialize. Therefore, DEA has reduced the AAN for pseudoephedrine (for sale) back to the 2019 level.

Comments From DEA-Registered Manufacturers

Issue: DEA received comments from three DEA-registered manufacturers regarding 13 different schedule I and II controlled substances, requesting that the proposed APQ for 5-MEO-DMT, d-amphetamine (for conversion), dexmethylphenidate (for sale), DMT, lisdexamfetamine, methadone, methadone intermediate, methylphenidate (for sale), noroxymorphone (for conversion), phenylacetone, psilocybin, psilocin, and remifentanil be established to sufficient levels to allow for manufacturers to meet medical and scientific needs.

DEA Response: DEA considered the comments for specific controlled substances and made adjustments as needed, which are described below in the section titled Determination of 2022 Aggregate Production Quotas and Assessment of Annual Needs.

U.S. Treaty Obligations

Issue: DEA received several comments requesting that the United States become a signatory to the Nagoya Protocol and Convention on Biological Diversity.

DEA Response: DEA does not have the authority to enter into or sign treaty agreements on behalf of the United States. This request is outside the scope of this notice.

Request for Public Hearing

Issue: One commenter requested a public hearing on the data and methodology used by DEA for this 2022 proposed APQ determination. The commenter also raised issues relating to the 2018 and 2019 APQs.

DEA Response: The decision whether to grant a hearing on the issues raised by the commenter lies solely within the discretion of the Administrator. 21 CFR 1303.11(c). This commenter is not a state. This request does not present any evidence that would lead to the conclusion that a hearing is necessary or warranted. The 2018 and 2019 APQs also fall outside of the scope of this order.

Stakeholder Forum

Issue: One commenter requested DEA schedule a public hearing or engage in an organized public process to allow interested parties to express their views and concerns about quota issues at least six months in advance of the proposed APQ.

DEA Response: DEA invites all interested persons to participate by commenting on proposed APQs. 21 CFR 1303.11(c). The **Federal Register** comment period provides an opportunity for all stakeholders to make their issues known to DEA.

Out of Scope Comments

DEA received comments that are outside the scope of this order. The comments were general in nature and raised issues of specific medical illnesses, medical treatments, and medication costs. These comments do not impact the analysis involved in establishing the 2022 APQ.

IV. Determination of 2022 Aggregate Production Quotas and Assessment of Annual Needs

In determining the established 2022 aggregate production quotas and assessment of annual needs, DEA has considered the above comments along with the factors set forth in 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a). These factors include, but are not limited to, the 2021 manufacturing quotas, current 2021 sales and inventories, anticipated 2022 export requirements, industrial use, additional applications for 2022 quotas, and information on research and product development requirements.

Based on all of the above, the Administrator establishes the 2022 APQ for 5-MEO-DMT, DMT, lisdexamfetamine, MDMA, phenylacetone, psilocybin, and psilocin at higher levels than was proposed.

DEA has determined that the proposed APQs for D-amphetamine (for conversion), dexmethylphenidate (for sale), methadone, methadone intermediate, methylphenidate (for sale), noroxymorphone (for conversion), and remifentanil are sufficient to provide for the 2022 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This final order establishes these APQ at the same amounts as proposed.

Estimates of Diversion Pursuant to the SUPPORT Act

As specified in the proposal, and as required by 21 U.S.C. 826(i), DEA calculated a national diversion estimate for each of the covered controlled substances.

DEA solicited PDMP data through NASCSA from state PDMP Administrators. Based on the data received, DEA considered the number of individuals who received a prescription for a covered controlled substance that met any of the three diversion metrics (''red flags'') mentioned in the October 18, 2021, notice for each of calendar years 2018–20. That number was then compared to the corresponding population for the states responding to DEA's request in order to estimate a percentage of the population issued a prescription meeting one of the red flag metrics. Using this estimated percentage for 2018–20, DEA analyzed trends in the data to predict the estimated percentage of patients who would be expected to meet these diversion metrics for 2022.

DEA also reviewed aggregate sales data for each of the covered controlled substances, which it extracted from IQVIA's National Sales Perspective.[3]

DEA multiplied the forecasted percentage of patients who received a prescription for a covered controlled substance that met any of the three diversion-related metrics for 2022 by the forecasted sales data from IQVIA for 2022 to estimate diversion for each of the covered controlled substances. This data, which remains unchanged, was published in the Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2022, and contributed to the final diversion estimates for covered controlled substances, as set forth in Table 3.

Registrant Reported Legitimate Distribution Chain Diversion

DEA extracted data from its Drug Theft and Loss database and categorized it by basic class. The quantity of active pharmaceutical ingredient (API) in each dosage form was determined, and then the quantity of API of each covered controlled substance was aggregated by metric weight where the data was available. DEA calculated the estimated amount of diversion by multiplying the strength of the API listed for each finished dosage form by the total amount of units reported to estimate the metric weight in grams of the controlled substance being diverted. The estimate of diversion for each of the covered controlled substances, which does not contain any loss reported due to fire, weather, or other disaster, is displayed in Table 2. This data contributed to the final diversion estimates for covered controlled substances, as set forth in Table 3.

TABLE 2—DIVERSION ESTIMATES BASED ON SUPPLY CHAIN DIVERSION DATA FOR COVERED CONTROLLED SUBSTANCES

Controlled substance	(g)
Fentanyl	76
Hydrocodone	19,325
Hydromorphone	896
Oxycodone	45,368
Oxymorphone	524

DEA's estimate of diversion for the five covered controlled substances was calculated by combining the diversion estimates from the state PDMP data and the supply chain diversion data. DEA reduced the aggregate production quotas for each covered controlled substance by the resulting quantities listed in Table 3.

TABLE 3—TOTAL ESTIMATES OF DIVERSION FOR COVERED CONTROLLED SUBSTANCES

Controlled substance	(g)
Fentanyl	92
Hydrocodone	154,916

[3] DEA has purchased this data from IQVIA for decades and routinely uses this information to administer several regulatory functions, including the administration of DEA's quota program.

TABLE 3—TOTAL ESTIMATES OF DIVERSION FOR COVERED CONTROLLED SUBSTANCES—Continued

Controlled substance	(g)
Hydromorphone	1,170
Oxycodone	210,206
Oxymorphone	524

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2022 APQ for the following schedule I and II controlled substances and the 2022 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 2022 quotas (g)
Schedule I	
-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	30
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
2′-fluoro 2-fluorofentanyl	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C–P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	100
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B–NBOMe; 2C–B–NBOMe; 25B; Cimbi-36)	30
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C–NBOMe; 2C–C–NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I–NBOMe; 2C–I–NBOMe; 25I; Cimbi-5)	30
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30
3,4,5-Trimethoxyamphetamine	30
3,4-Methylenedioxyamphetamine (MDA)	200
3,4-Methylenedioxymethamphetamine (MDMA)	8,200
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	40
3,4-Methylenedioxypyrovalerone (MDPV)	35
3–FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	25
4-Chloro-alpha-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25
4–CN-Cumyl-Butinaca	25
4-Fluoroisobutyryl fentanyl	30
4F–MDMB–BINACA	30
4–FMC; Flephedrone	25
4–MEC; 4-Methyl-N-ethylcathinone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-alpha-ethylaminopentiophenone (4–MEAP)	25
4-Methyl-alpha-pyrrolidinohexiophenone (MPHP)	25
4′-Methyl acetyl fentanyl	30
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog)	40
5F–AB–PINACA ; (1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
5F–ADB; 5F–MDMB–PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	25
5F–CUMYL–P7AICA; 1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3carboximide	25
5F–CUMYL–PINACA	25
5F–EDMB–PINACA	25
5F–MDMB–PICA	25
5F–AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	25
5F–APINACA; 5F–AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	25

Basic class	Established 2022 quotas (g)
5-Fluoro-PB–22; 5F–PB–22	25
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1Hindol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine (5–MEO–DMT)	2,550
AB–CHMINACA	30
AB–FUBINACA	50
AB–PINACA	30
ADB–FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl-alpha-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	25
Acryl Fentanyl	25
ADB–PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH–7921	30
All other tetrahydrocannabinol	2,000
Allylprodine	25
Alphacetylmethadol	25
alpha-Ethyltryptamine	25
Alphameprodine	25
Alphamethadol	25
alpha-Methylfentanyl	30
alpha-Methylthiofentanyl	30
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-pyrrolidinoheptaphenone (PV8)	25
alpha-pyrrolidinohexabophenone (alpha-PHP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Aminorex	25
Anileridine	20
APINCA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25
Benzethidine	25
Benzylmorphine	30
Betacetylmethadol	25
beta-Hydroxy-3-methylfentanyl	30
beta-Hydroxyfentanyl	30
beta-Hydroxythiofentanyl	30
beta-Methyl fentanyl	30
beta′-Phenyl fentanyl	30
Betameprodine	25
Betamethadol	4
Betaprodine	25
Brorphine	30
Bufotenine	15
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Crotonyl Fentanyl	25
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
delta-9-tetrahydrocannabinol	384,460
Desomorphine	25
Dextromoramide	25
Diapromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,200
Dihydromorphine	653,548
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine (DMT)	3,000
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25

Basic class	Established 2022 quotas (g)
Ethylone	25
Etonitazene	25
Etorphine	30
Etoxeridine	25
Fenethylline	30
Fentanyl carbamate	30
Fentanyl related substances	600
FUB–144	25
FUB–AKB48	25
Fub-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
gamma-Hydroxybutyric acid	29,417,000
Heroin	150
Hydromorphinol	40
Hydroxypethidine	25
Ibogaine	30
Isobutyryl Fentanyl	25
Isotonitazine	25
JWH–018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH–019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH–073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH–081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30
JWH–122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH–200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH–203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30
JWH–250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH–398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30
Ketobemidone	30
Levomoramide	25
Levophenyacylmorphan	25
Lysergic acid diethylamide (LSD)	500
MAB–CHMINACA; ADB–CHMINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	30
MDMB–CHMICA; MMB–CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB–FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB–CHMICA-(AMB–CHIMCA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
Marijuana	3,200,000
Marijuana extract	1,000,000
Mecloqualone	30
Mescaline	100
Methaqualone	60
Methcathinone	25
Methoxyacetyl fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	25
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT–45	30
Myrophine	25
NM2201: Naphthalen-1-yl 1-(5-fluorpentyl)-1H-indole-3-carboxylate	25
N,N-Dimethylamphetamine	25
Naphyrone	25
N-Ethyl-1-phenylcyclohexylamine	25
N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24
N-Ethylhexedrone	25
N-Ethylpentylone, ephylone	30
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Nicocodeine	25
Nicomorphine	25
N-methyl-3-piperidyl benzilate	30
Noracymethadol	25
Norlevorphanol	2,550
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
ortho-Fluoroacryl fentanyl	30
ortho-Fluorobutyryl fentanyl	30

Basic class	Established 2022 quotas (g)
Ortho-Fluorofentanyl,2-Fluorofentanyl	30
ortho-Fluoroisobutyryl fentanyl	30
ortho-Methyl acetylfentanyl	30
ortho-Methyl methoxyacetyl fentanyl	30
Para-Chlorisobutyrl fentanyl	30
Para-flourobutyryl fentanyl	25
Para-fluorofentanyl	25
para-Fluoro furanyl fentanyl	30
Para-Methoxybutyrl fentanyl	30
Para-Methoxymethamphetamine	30
para-Methylfentanyl	30
Parahexyl	5
PB–22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphan	25
Phenoperidine	25
Phenyl fentanyl	30
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Psilocybin	8,000
Psilocyn	4,000
Racemoramide	25
SR–18 and RCS–8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45
SR–19 and RCS–4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30
Tetrahydrofuranyl fentanyl	15
Thebacon	25
Thiafentanil	25
Thiofentanyl	25
Thiofuranyl fentanyl	30
THJ–2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	25
UR–144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
U–47700	30
Valeryl fentanyl	25
Schedule II	
1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	886,415
Alfentanil	3,260
Alphaprodine	25
Amobarbital	20,100
Bezitramide	25
Carfentanil	20
Cocaine	60,492
Codeine (for conversion)	1,364,981
Codeine (for sale)	22,260,178
D-amphetamine (for sale)	21,200,000
D,L-amphetamine	21,200,000
d-amphetamine (for conversion)	20,000,000
Dexmethylphenidate (for sale)	6,200,000
Dexmethylphenidate (for conversion)	6,500,000
Dextropropoxyphene	35
Dihydrocodeine	132,658
Dihydroetorphine	25
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	60,492
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	691,511
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	29,599,888

Basic class	Established 2022 quotas (g)
Hydromorphone	2,097,255
Isomethadone	30
L-amphetamine	30
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	23,010
Lisdexamfetamine	26,500,000
Meperidine	770,588
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	25,619,700
Methadone Intermediate	27,673,600
Methamphetamine	150
d-methamphetamine (for conversion)	485,020
d-methamphetamine (for sale)	40,000
l-methamphetamine	587,229
Methylphenidate (for sale)	41,800,000
Methylphenidate (for conversion)	15,300,000
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	2,584,860
Morphine (for sale)	22,525,461
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	22,044,741
Noroxymorphone (for sale)	1,000
Oliceridine	22,500
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	33,010,750
Oxycodone (for conversion)	519,061
Oxycodone (for sale)	54,003,559
Oxymorphone (for conversion)	28,204,371
Oxymorphone (for sale)	516,469
Pentobarbital	30,766,670
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	8,000,000
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	4,000
Tapentadol	13,447,541
Thebaine	57,137,944
List I Chemicals	
Ephedrine (for conversion)	100
Ephedrine (for sale)	4,136,000
Phenylpropanolamine (for conversion)	14,878,320
Phenylpropanolamine (for sale)	7,990,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	174,246,000

The Administrator also establishes APQ for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2022 APQ and AAN as needed.

Anne Milgram,

Administrator.

[FR Doc. 2021–26227 Filed 11–29–21; 4:15 pm]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Stipulation and Settlement Under the Comprehensive Environmental Response, Compensation and Liability Act

On November 15, 2021, a proposed Stipulation Resolving the General

Unsecured Claim of the United States Environmental Protection Agency (''Stipulation'') was lodged in the United States Bankruptcy Court for the District of Delaware in *In re Exide Holdings, Inc., et al.,* Case No. 20–11157 (CSS).

The proposed Stipulation resolves a proof of claim filed by the United States, on behalf of the Environmental Protection Agency (EPA), against Debtor Exide Technologies, LLC under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) with respect to the Portland Harbor Superfund Site (''Portland Harbor'') in Portland, Oregon; the Wiley's Bridge Lead Site (''Wiley's Bridge'') in Reading, Pennsylvania; the Brown's Battery Breaking Superfund Site (''Brown's Battery'') in Shoemakersville, Berks County, Pennsylvania; and the Reading Battery and Residential Sites (''Reading'') in Reading, Pennsylvania.

The proposed Stipulation provides EPA with an allowed claim of $17,569,392.16 allocated among the following sites: (a) $825,000 for Portland Harbor; $4,273,189.16 for Wiley's Bridge; (c) $471,203 for Brown's Battery; and (d) $12,000,000 for Reading.

The publication of this notice opens a period for public comment on the Stipulation. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division and should refer to *In re Exide Holdings, Inc., et al.,* D.J. Ref. No. 90–11–2–07802/8. 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:

By email to: pubcomment-ees.enrd@usdoj.gov.

By mail to: Assistant Attorney General, U.S. DOJ—ENRD, P.O., Box 7611, Washington, DC 20044–7611.

During the public comment period, the Stipulation 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 Stipulation 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 $2.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Jeffrey Sands,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–26171 Filed 12–1–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0030]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; Comments Requested; Electronic Applications for the Attorney General's Honors Program and the Summer Law Intern Program

AGENCY: Office of Attorney Recruitment and Management, Justice Management Division, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Justice Management Division, Office of Attorney Recruitment and Management (OARM), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until January 31, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Deana Willis, Assistant Director, Office of Attorney Recruitment and Management, 450 5th Street NW, Suite 10200, Washington, DC 20530; *Deana.Willis@usdoj.gov;* (202) 514–8902.

SUPPLEMENTARY INFORMATION: Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Office of Attorney Recruitment and Management, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Evaluate whether, and if so, how, the quality, utility, and clarity of the information to be collected can be enhanced; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of information collection:* Extension of a Currently Approved Collection.

2. *The title of the form/collection:* Electronic Applications for the Attorney General's Honors Program and Summer Law Intern Program.

3. *The agency form number, if any, and the applicable component of the department sponsoring the collection:* There is no agency form number for this collection. The applicable component within the Department of Justice is the Office of Attorney Recruitment and Management, Justice Management Division, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. Other: None. The application form is submitted voluntarily, once a year, by law students and recent law school graduates (*e.g.,* judicial law clerks) who will be in this applicant pool only once.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 3,500 respondents will complete the application in approximately 1 hour per application. It is further estimated that it takes an average of an additional 45 minutes to review the instructions, search existing data sources, gather the data needed, and complete and review the application. In addition, an estimated 600 respondents (Honors Program candidates selected for interviews) will complete a Travel Survey/Interview Scheduling form used to schedule interviews and prepare official travel authorizations prior to the interviewees' performing pre-employment interview travel (as defined by 41 CFR 301–1.3), as needed, in approximately 10 minutes per form, plus an estimated 400 respondents who

will complete a Reimbursement Form (if applicable) in order for the Department to prepare the travel vouchers required to reimburse candidates for authorized costs they incurred during pre-employment interview travel at approximately 10 minutes per form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated revised total annual public burden associated with this application is 6,292 hours.

If additional information is required, please contact: Melody Braswell, Department Clearance Officer, U.S. Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Room 3E.405B, Washington, DC 20530.

Dated: November 29, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–26209 Filed 12–1–21; 8:45 am]

BILLING CODE 4410–PM–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) of 1995 requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This information collection is currently approved under emergency procedures, which includes waiver of that public comment notice. This publication complies with the PRA requirement to publish the waived notice as a prerequisite to requesting standard review and approval from OMB.

DATES: Submit comments on or before January 31, 2022.

ADDRESSES: Send all comments via email to *PPP_Info_Collections@sba.gov.* Comments should refer to the information collection by title or OMB Control Number (3245–0407) and be submitted by the deadline above.

FOR FURTHER INFORMATION CONTACT: Adrienne Grierson, Deputy Director Office of Financial Program Operations, 202–205–6573, *adrienne.grierson@sba.gov* or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 1102 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, authorized SBA to guarantee loans made by banks or other financial institutions under a temporary program titled the ''Paycheck Protection Program'' (PPP). These loans were available to eligible small businesses, certain non-profit organizations, veterans' organizations, Tribal business concerns, independent contractors, and self-employed individuals adversely affected by the COVID–19 Emergency. SBA's authority to guarantee PPP loans expired on August 8, 2020. On December 27, 2020, SBA received reauthorization under the Economic Aid Act, Public Law 116–260, to resume guaranteeing PPP loans through March 31, 2021. The Economic Aid Act also allowed certain eligible borrowers that previously received a PPP loan to receive a Second Draw PPP loan and amended certain other PPP statutory provisions. On March 11, 2021, the American Rescue Plan Act, Public Law 117–2, was enacted, amending various PPP statutory provisions. On March 30, 2021, the PPP Extension Act of 2021 was enacted, extending the SBA's PPP program authority through June 30, 2021.

Since the initial approval of this information collection, the information collection has been revised to meet the ever-evolving needs of the PPP program, as necessitated by statutory program amendments, public feedback, or other factors. The information collection is currently approved under the emergency procedures authorized by 5 U.S.C. 3507(j) and 5 CFR 1320.13; this approval is set to expire on January 31, 2022.

Although SBA's PPP program authority has expired, this information collection is still needed for the following reasons: (1) PPP borrowers may apply for forgiveness of their loans up to the date of loan maturity, which may be as late as 2026; (2) SBA may review a PPP loan at any time; and (3) pending litigation may require the collection of information. Therefore, as required by the Paperwork Reduction Act, SBA is publishing this notice as a prerequisite to seeking OMB's approval to use this information collection beyond January 31, 2022. There are no proposed changes to any of the information to be submitted by lenders or borrowers.

Summary of Information Collection

Title: Paycheck Protection Loan Program Borrower Information Form and Lender's Application for Loan Guaranty.

OMB Control Number: 3245–0407.

(i) *SBA Form 2483, Paycheck Protection Program Borrower Application Form,* collects information from applicants concerning the ownership of the business and from the applicant's owners of 20% or more, the loan purpose, any applicable history of prior defaulted government debt (except student loan debt), and any applicable criminal history.

Estimated Number of Respondents: 9,279,434.

Estimated Annual Responses: 9,279,434.

Estimated Annual Hour Burden: 1,237,258.

(ii) *SBA Form 2483–C, Paycheck Protection Program Borrower Application Form for Schedule C Filers Using Gross Income,* collects information from applicants concerning the ownership of the business, the applicant's gross income, the loan purpose, any applicable history of prior defaulted government debt (except student loan debt), and any applicable criminal history. This form is used by Schedule C filers using gross income to calculate their loan amount instead of SBA Form 2483.

Estimated Number of Respondents: 239,160.

Estimated Annual Responses: 239,160.

Estimated Annual Hour Burden: 31,888.

(iii) *SBA Form 2484, Lender's Application—Paycheck Protection Program Loan Guaranty,* collects information from lenders concerning the eligibility of the applicant, the applicant's gross income (if applicable), and the loan terms and conditions.

Estimated Number of Respondents: 5,467.

Estimated Annual Responses: 9,218,594.

Estimated Annual Hour Burden: 3,841,081.

(iv) *SBA Form 3506, CARES Act Section 1102 Lender Agreement,* collects information from federally insured depository institutions, federally insured credit unions, and Farm Credit System regulated agricultural lenders (other than the Federal Agricultural Mortgage Corporation) that do not already participate in the 7(a) loan program, to evaluate their eligibility to participate in the PPP.

Estimated Number of Respondents: 775.

Estimated Annual Responses: 775.

Estimated Annual Hour Burden: 129.

(v) *SBA Form 3507, CARES Act Section 1102 Lender Agreement—Non-Bank and Non-Insured Depository Institution Lenders,* collects information from depository or non-depository institutions and certain service providers that have contracted with insured depository institutions to support their lending activities to evaluate their eligibility to participate in the PPP.

Estimated Number of Respondents: 169.

Estimated Annual Responses: 169.

Estimated Annual Hour Burden: 70.

(vi) *SBA Form 3508, Paycheck Protection Program—Loan Forgiveness Application.* A borrower that received a First Draw PPP loan or a Second Draw PPP loan submits this completed form or the lender's equivalent form to its PPP lender so the lender can determine whether the application meets the criteria for loan forgiveness. This form is used by borrowers that are not eligible to use the SBA Form 3508EZ and the SBA Form 3508S.

Estimated Number of Respondents: 591,180.

Estimated Annual Responses: 591,180.

Estimated Annual Hour Burden: 1,773,539.

(vii) *SBA Form 3508EZ, Paycheck Protection Program—PPP Loan Forgiveness Application Form EZ.* A borrower that received a First Draw PPP loan or Second Draw PPP Loan submits this completed form or the lender's equivalent form to its PPP lender so that the lender can determine whether the application meets the criteria for loan forgiveness. This form is used by borrowers that did not reduce employee salary and wages by more than 25 percent during the covered period and are not subject to FTE reduction penalties, either because they did not reduce FTEs or they qualify for a safe harbor.

Estimated Number of Respondents: 1,773,539.

Estimated Annual Responses: 1,773,539.

Estimated Annual Hour Burden: 591,180.

(viii) *SBA Form 3508S, Paycheck Protection Program—PPP Forgiveness Application Form 3508S.* A borrower that received a First Draw PPP loan or a Second Draw PPP loan of $150,000 or less submits this completed form or lender's equivalent form to its PPP lender, either directly or through SBA's PPP Platform. The information is used to determine whether the application meets the criteria for loan forgiveness.

Estimated Number of Respondents: 9,458,875.

Estimated Annual Responses: 9,458,875.

Estimated Annual Hour Burden: 2,364,719.

(ix) *SBA Form 3508D—Paycheck Protection Program Borrower's Disclosure of Certain Controlling Interests.* A First Draw PPP Loan borrower that received a loan before December 27, 2020, uses this form to disclose to SBA that a Covered Individual, as defined in the Economic Aid Act, directly or indirectly held a Controlling Interest, as defined in the Economic Aid Act, at the time the borrower submitted its First Draw PPP Loan application to its PPP lender.

Estimated Number of Respondents: 350.

Estimated Annual Responses: 350.

Estimated Annual Hour Burden: 29.

(x) *[No Form Number] Lender Reporting Requirements Concerning Requests for Loan Forgiveness.* Lenders participating in the PPP are required to submit information to SBA to support the small business' requests for forgiveness and the lenders' decisions to approve or deny those requests. SBA will use the information to determine borrowers' and lenders' compliance with PPP requirements and the appropriate amount of loan forgiveness.

Estimated Number of Respondents: 5,467.

Estimated Annual Responses: 11,824,000.

Estimated Annual Hour Burden: 2,107,150.

(xi) *[No Form Number] Lender Reporting Requirements for Loan Review.* For a PPP loan of any size, SBA may undertake a review at any time in SBA's discretion. When a loan is selected for review by SBA, lenders are required to submit information that will allow SBA to determine whether the loan meets PPP requirements, including borrower eligibility, loan amounts, and eligibility for forgiveness. Some of the requested information (*e.g.,* loan application, forgiveness application and forgiveness supporting documents) will be provided by the borrowers to the lenders.

Estimated Number of Respondents: 5,467.

Estimated Annual Responses: 2,000,000.

Estimated Annual Hour Burden: 1,000,000.

Solicitation of Public Comments

SBA invites the public to submit comments, including specific and detailed suggestions on ways to improve the collection and reduce the burden on respondents. Commenters should also address (i) whether the collection of information is necessary for the agency to properly perform its functions, including whether it has any practical utility; (ii) whether the burden estimates are accurate; (iii) whether there are ways to minimize the information collection burden on those who are required to respond, including through the use of automated techniques or other forms of information technology; and (iv) whether there are ways to enhance the quality, utility, and clarity of the information to be collected.

Curtis B. Rich,

Management Analyst.

[FR Doc. 2021–26165 Filed 12–1–21; 8:45 am]

BILLING CODE 8026–03–P

STATE JUSTICE INSTITUTE

SJI Board of Directors Meeting, Notice

AGENCY: State Justice Institute.

ACTION: Notice of meeting.

SUMMARY: The SJI Board of Directors will be meeting on Monday, December 6, 2021 at 1:00 p.m. ET. The purpose of this meeting is to consider grant applications for the 1st quarter of FY 2022, and other business.

FOR FURTHER INFORMATION CONTACT: Jonathan Mattiello, Executive Director, State Justice Institute, 12700 Fair Lakes Circle, Suite 340, Fairfax, VA 22033, 703–660–4979, *contact@sji.gov.*

Authority: 42 U.S.C. 10702(f).

Jonathan D. Mattiello,

Executive Director.

[FR Doc. 2021–26206 Filed 12–1–21; 8:45 am]

BILLING CODE 6820–SC–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Termination of Action in the Digital Services Tax Investigation of India and Further Monitoring

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: On October 8, 2021, India joined the United States and 134 other jurisdictions participating in the OECD/G20 Inclusive Framework on Base Erosion and Profit Shifting in reaching a political agreement on a two-pillar solution to address tax challenges arising from the digitalization of the world economy. As part of Pillar 1, all

parties agreed to remove existing Digital Services Taxes (DSTs) and other relevant similar measures, and to coordinate the withdrawal of these taxes. On November 24, 2021, India and the United States issued statements describing a transitional approach to India's DST prior to entry into force of Pillar 1. These statements reflect a political agreement that, in defined circumstances, the DST liability that U.S. companies accrue in India during the interim period will be creditable against future taxes accrued under Pillar 1 of the OECD agreement. Based on the commitment of India to remove its DST pursuant to Pillar 1 and on India's political agreement to this transitional approach prior to Pillar 1's entry into force, the U.S. Trade Representative has determined to terminate the section 301 action taken in the investigation of India's DST. In coordination with the U.S. Department of the Treasury (Treasury), USTR will monitor implementation of the removal of India's DST as provided for under Pillar 1 and the transitional approach agreed to by India.

DATES: The additional duties on products of India are terminated as of November 28, 2021.

FOR FURTHER INFORMATION CONTACT: For questions concerning this notice, please contact Benjamin Allen, Thomas Au, Patrick Childress, or Kate Hadley, Assistant General Counsels at (202) 395–9439, (202) 395–0380, (202) 395–9531, and (202) 395–3911, respectively, Robert Tanner, Director, Services and Investment at (202) 395–6125, or Brendan Lynch, Deputy Assistant U.S. Trade Representative for South and Central Asian Affairs at (202) 395–2851.

SUPPLEMENTARY INFORMATION:

I. Proceedings in the Investigation

This investigation is addressed to India's 2020 ''equalisation levy'', which is referred to throughout the investigation as India's DST. *See, e.g.,* 86 FR 30356 (June 7, 2021) and the India DST report, published at *https://ustr.gov/sites/default/files/enforcement/301Investigations/Report%20on%20India%E2%80%99s%20Digital%20Services%20Tax.pdf.* For further background on the proceedings in the section 301 investigation of India's DST, please see prior notices including: 85 FR 34709 (June 5, 2020); 86 FR 2478 (January 12, 2021); 86 FR 16824 (March 31, 2021); and 86 FR 30356 (June 7, 2021).

On June 2, 2021, the U.S. Trade Representative determined to take action in the form of additional duties on certain products of India and to immediately suspend those additional duties for up to 180 days. 86 FR 30356 (June 7, 2021).

II. OECD/G20 Negotiations

One-hundred forty-one jurisdictions are engaged in international tax negotiations under the OECD/G20 Inclusive Framework on Base Erosion and Profit Shifting. On October 8, 2021, India joined the United States and 134 other participants in reaching political agreement on a Statement on a Two-Pillar Solution to Address the Tax Challenges Arising from the Digitalisation of the Economy. OECD/G20 Base Erosion and Profit Shifting Project, *Statement on a Two-Pillar Solution to Address the Tax Challenges Arising from the Digitalisation of the Economy* (Oct. 8, 2021) at *https://www.oecd.org/tax/beps/statement-on-a-two-pillar-solution-to-address-the-tax-challenges-arising-from-the-digitalisation-of-the-economy-october-2021.pdf* (the OECD/G20 Two-Pillar Solution). The statement provides that Pillar 1 will be implemented through a multilateral convention. With respect to DSTs, the statement provides:

> The Multilateral Convention (MLC) will require all parties to remove all Digital Services Taxes and other relevant similar measures with respect to all companies, and to commit not to introduce such measures in the future. No newly enacted Digital Services Taxes or other relevant similar measures will be imposed on any company from 8 October 2021 and until the earlier of 31 December 2023 or the coming into force of the MLC. The modality for the removal of existing Digital Services Taxes and other relevant similar measures will be appropriately coordinated.

III. India's Agreement

On November 24, 2021, The Ministry of Finance of the Government of India and Treasury issued statements reflecting a political agreement on a transitional approach to India's DST while implementing Pillar 1. *India and USA agree on a transitional approach on Equalisation Levy 2020,* Ministry of Fin. of the Gov't of India (Nov. 24, 2021), *https://pib.gov.in/PressReleasePage.aspx?PRID=1774692; Treasury Announces Agreement on the Transition from Existing Indian Equalization Levy to New Multilateral Solution Agreed by the OECD–G20 Inclusive Framework,* U.S. Dep't of the Treas. (Nov. 24, 2021), *https://home.treasury.gov/news/press-releases/jy0504.* Under this agreement and in defined circumstances, the liability from India's DST that U.S. companies accrue in India during the interim period will be creditable against future taxes accrued under Pillar 1 of the OECD agreement. The period during which the credit accrues will be from April 1, 2022, until either the implementation of Pillar 1 or March 31, 2024, whichever is earlier. In return, the United States commits to terminate the existing section 301 trade action on goods of India, and not to impose further trade actions against India with respect to its existing DST until the earlier of the date the Pillar 1 multilateral convention comes into force or March 31, 2024. *Id.*

IV. Termination of Action

Section 307 of the Trade Act of 1974, as amended (Trade Act) (19 U.S.C. 2417), provides that ''[t]he Trade Representative may modify or terminate any action, subject to the specific direction, if any, of the President with respect to such action, that is being taken under section [301] of this title if . . . such action is being taken under section [301(b)] of this title and is no longer appropriate.'' The U.S. Trade Representative has found that the political agreement of India to the OECD/G20 Two-Pillar Solution, which provides for the removal of DSTs upon entry into force of Pillar 1, and the transitional approach agreed to by India provide a satisfactory resolution of the matters covered by the section 301 investigation of India's DST. Accordingly, pursuant to section 307 of the Trade Act, the U.S. Trade Representative has determined that the suspended trade action in this investigation is no longer appropriate and that the action should be terminated.

The U.S. Trade Representative's determination was made in consultation with Treasury and considers the advice of the interagency Section 301 Committee, consultations with representatives of the domestic industry concerned, and public comments and advisory committee advice received during the investigations.

In order to implement the termination of the section 301 action in the investigation of India's DST, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified by the Annex to this notice.

V. Ongoing Monitoring

Section 306(a) of the Trade Act (19 U.S.C. 2416(a)) provides that ''[t]he Trade Representative shall monitor the implementation of each measure undertaken, or agreement that is entered into, by a foreign country to provide a satisfactory resolution of a matter subject to investigation. . . .'' Section 306(b) (19 U.S.C. 2416(b)) provides that ''[i]f, on the basis of the monitoring

carried out under subsection (a), the Trade Representative considers that a foreign country is not satisfactorily implementing a measure or agreement referred to in subsection (a), the Trade Representative shall determine what further action the Trade Representative shall take under section [301(a)].'' Pursuant to section 306(a) of the Trade Act, the U.S. Trade Representative, in coordination with Treasury, will monitor the implementation of the political agreement on an OECD/G20 Two-Pillar Solution as pertaining to DSTs, India's agreement as reflected in the November 24 statements, and associated measures. Pursuant to section 306(b) of the Trade Act, if the U.S. Trade Representative, in consultation with Treasury, subsequently considers that India is not satisfactorily implementing these political agreements or associated measures, then the U.S. Trade Representative will consider further action under section 301.

Annex

The U.S. Trade Representative has decided to terminate the additional duties under heading 9903.90.03 of the HTSUS on articles the product of India, as provided for in U.S. notes 24(a) and 24(b) to subchapter III of chapter 99 of the HTSUS. The termination of these additional duties is effective on November 28, 2021.

In accordance with this determination, the U.S. Trade Representative has determined to modify the HTSUS by: (1) Deleting U.S. notes 24(a) and 24(b) to subchapter III of chapter 99 of the HTSUS; and (2) by deleting HTSUS heading 9903.90.03. The modifications of the HTSUS are effective on November 28, 2021. Any provisions of previous notices issued in this investigation that are inconsistent with this notice are superseded to the extent of such inconsistency.

Greta Peisch,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2021–26198 Filed 12–1–21; 8:45 am]

BILLING CODE 3290–F2–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2021–0910]

Proposed Standardized Curricula Part 135 Delivered by Part 142 Training Centers, Aircraft Master Schedule

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of availability; request for comments.

SUMMARY: This notice announces the availability of the proposed aircraft master schedule for the standardized curricula for certain air carriers and operators whose pilots receive training from FAA-certificated training centers. The FAA invites public comment.

DATES: The FAA must receive comments on these proposed documents by December 22, 2021.

ADDRESSES: You may send comments identified by docket number FAA–2021–0910 using any of the following methods:

Mail: U.S. Department of Transportation (DOT), Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Hand Delivery or Courier: Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: Fax comments to Docket Operations at 202–493–2251.

Privacy: DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joshua Tarkington, Flight Standards, Air Transportation Division, Training and Simulation Group (AFS–280), *Joshua.Tarkington@faa.gov,* (860) 708–3839. Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

SUPPLEMENTARY INFORMATION: The standardized curriculum concept for Title 14 Code of Federal Regulations (14 CFR) part 135 training provided by part 142 training centers is a voluntary approach to training. Additional information about standardized curricula is available in Advisory Circular (AC) 142–1, Standardized Curricula Delivered by Part 142 Training Centers.

Background

The FAA tasked the Aviation Rulemaking Advisory Committee (ARAC) in March 2020, which was further designated to the Training Standardization Working Group (TSWG), with providing advice and recommendations to the ARAC on the most effective ways to achieve standardization (where appropriate) and significant administrative efficiency in check pilot qualification, flight instructor qualification, and part 135 air carrier training curricula delivered by part 142 training centers, known as the Standardized Curriculum Concept. TSWG membership includes representatives from training centers, aircraft manufacturers, operators, and aviation industry organizations.

Standardized curricula will provide a common method for quality training accessible to any certificate holder that obtains approval to use the curriculum in its FAA-approved training program. The Standardized Curriculum Concept aims to provide an efficient means to approve training curricula offered by part 142 training centers while increasing the consistency of training, testing, and checking delivered to part 135 operators. The use of standardized curricula is strictly voluntary and is one means to comply with the applicable regulatory requirements of parts 135 and 142. The standardized curriculum does not modify existing regulatory requirements for pilot training or qualification.

One of the tasks to the ARAC included the following:

- Development of a master schedule that lists the priority of aircraft or series of aircraft for standardized curriculum development.

In order to determine a prioritized list of aircraft for which a standardized curriculum would be appropriate, the working group reviewed training data from centers that represent approximately 80% of air carrier training events. The TSWG chose this methodology to provide a valid sampling of training centers and preferred aircraft training platforms. The group reviewed the aircraft-specific data and ranked the highest density training events to the lowest. This approach ensured the aircraft priority matched industry demand.

Comments Invited

The FAA invites public comments on the TSWG proposed Standardized Curricula for Part 135 Delivered by Part 142 Training Centers, Aircraft Master Schedule. The FAA will consider the public comments submitted during this

comment period in finalizing the Aircraft Master Schedule.

Robert C. Carty,

Deputy Executive Director, Flight Standards Service.

[FR Doc. 2021–26217 Filed 12–1–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2021–0909]

Proposed Standardized Curricula for Part 135 Delivered by Part 142 Training Centers, Instructor/Check Pilot Qualification Curriculum

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of availability; request for comments.

SUMMARY: This notice announces the availability of the proposed standardized curricula for instructor and check pilot qualifications for certain air carriers. This curriculum may be delivered by FAA-certificated training centers. The FAA invites public comment.

DATES: The FAA must receive comments on these proposed documents by December 22, 2021.

ADDRESSES: You may send comments identified by docket number FAA–2021–0909 using any of the following methods: Mail: U.S. Department of Transportation (DOT), Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Hand Delivery or Courier: Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: Fax comments to Docket Operations at 202–493–2251.

Privacy: DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy*.

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joshua Tarkington, Flight Standards, Air Transportation Division, Training and Simulation Group (AFS–280), *Joshua.Tarkington@faa.gov,* (860) 708–3839. Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

SUPPLEMENTARY INFORMATION: The standardized curriculum concept for Title 14 Code of Federal Regulations (14 CFR) part 135 training provided by part 142 training centers is a voluntary approach to training. Additional information about standardized curricula is available in Advisory Circular (AC) 142–1, Standardized Curricula Delivered by Part 142 Training Centers.

Background

The FAA tasked the Aviation Rulemaking Advisory Committee (ARAC) in March 2020, which was further designated to the Training Standardization Working Group (TSWG), with providing advice and recommendations to the ARAC on the most effective ways to achieve standardization (where appropriate) and significant administrative efficiency in check pilot qualification, flight instructor qualification, and part 135 air carrier training curricula delivered by part 142 training centers, known as the Standardized Curriculum Concept. TSWG membership includes representatives from training centers, aircraft manufacturers, operators, and aviation industry organizations.

Standardized curricula will provide a common method for quality training accessible to any certificate holder that obtains approval to use the curriculum in its FAA-approved training program. The Standardized Curriculum Concept aims to provide an efficient means to approve training curricula offered by part 142 training centers while increasing the consistency of training, testing, and checking delivered to part 135 operators. The use of standardized curricula is strictly voluntary and is one means to comply with the applicable regulatory requirements of parts 135 and 142. The standardized curriculum does not modify existing regulatory requirements for pilot training or qualification.

One of the tasks to the ARAC included the following: Development of Instructor and Check Pilot Qualification Curriculum for standardized curriculum.

In response to that task, the TSWG developed a recommended curriculum, the Instructor/Check Pilot Standardized Curriculum, as a means to meet the requirements in part 135 for qualifying instructors and check pilots approved for use at a part 142 training center. This recommended curriculum tracks with the regulatory requirements for qualification as a 14 CFR part 135 instructor or check pilot, and includes the curriculum and subjects necessary to complete:

- Initial qualification
- Recurrent training every 12 calendar months
- Requalification
- Bridging, which provides a path for those who are currently qualified as instructor/evaluators for parts 135 or 142 the training required to include the Standardized Training Curriculum
- Variables such as transitioning to a new flight simulator/training device, operating system, and subsequent aircraft types

Comments Invited

The FAA invites public comments on the TSWG proposed Standardized Curricula for Part 135 Delivered by Part 142 Training Centers, Instructor/Check Pilot Qualification Curriculum. The FAA will consider the public comments submitted during this comment period in finalizing the Instructor/Check Pilot Qualification Curriculum.

Robert C. Carty,

Deputy Executive Director, Flight Standards Service.

[FR Doc. 2021–26216 Filed 12–1–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0012]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt eight individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. They are unable to meet the vision requirement in one eye for various reasons. The exemptions enable these individuals to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: The exemptions were applicable on November 19, 2021. The exemptions expire on November 19, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–2021–0012, in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its regulatory process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

On October 19, 2021, FMCSA published a notice announcing receipt of applications from eight individuals requesting an exemption from vision requirement in 49 CFR 391.41(b)(10) and requested comments from the public (86 FR 57887). The public comment period ended on November 18, 2021, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in § 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on medical reports about the applicants' vision, as well as their driving records and experience driving with the vision deficiency. The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the October 19, 2021, **Federal Register** notice (86 FR 57887) and will not be repeated here.

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their limitation and demonstrated their ability to drive safely. The eight exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, macular scar, prosthesis, and retinal detachment. In most cases, their eye conditions did not develop recently. Five of the applicants were either born with their vision impairments or have had them since childhood. The three individuals that developed their vision conditions as adults have had them for a range of 11 to 21 years. Although each applicant has one eye that does not meet the vision requirement in § 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and, in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV.

Doctors' opinions are supported by the applicants' possession of a valid license to operate a CMV. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV with their limited vision in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions.

The applicants in this notice have driven CMVs with their limited vision in careers ranging for 3 to 68 years. In the past 3 years, no drivers were involved in crashes, and no drivers were convicted of moving violations in CMVs. All the applicants achieved a record of safety while driving with their vision impairment that demonstrates the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

Consequently, FMCSA finds that in each case exempting these applicants from the vision requirement in § 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and includes the following: (1) Each driver must be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in § 391.41(b)(10) and (b) by a certified medical examiner (ME) who

attests that the individual is otherwise physically qualified under § 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the ME at the time of the annual medical examination; and (3) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the eight exemption applications, FMCSA exempts the following drivers from the vision requirement, § 391.41(b)(10), subject to the requirements cited above:

Ruben Ahuyon (TX)
Victor N. Crisafulli (NY)
Roger Guin (NC)
Michael H. Jorgensen (MN)
Alejandro V. Lopez (CA)
Jay D. May (AZ)
John Robison (GA)
Kenneth P. Stephens (IA)

In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–26147 Filed 12–1–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is updating the identifying information on its Specially Designated Nationals and Blocked Persons List (''SDN List'') for a person whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism,'' as amended by Executive Order 13886 of September 9, 2019, ''Modernizing Sanctions to Combat Terrorism''.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT:

OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

1. On October 26, 2021, OFAC published the following revised information for the following person on OFAC's SDN List whose property and interests in property are blocked pursuant to Executive Order 13224, as amended.

Individual

1. ISMAIL, Talib Husayn Ali Jarak (a.k.a. ESMAEL, Taleb H. A. J.), Block 8, Street 20, House No. 33, Jabriya, Kuwait; Street 21, Salem Al Mubarak Avenue, Block 20, Building 13, Salmiya, Kuwait; P.O. Box 3390, Safat 13034, Kuwait City, Kuwait; P.O. Box 126, Safat 13002, Kuwait City, Kuwait; Block 8, Street 103, Building 33, Apartment 33, Jabriya, Kuwait; Mubarak Al Kabir, Darwaza abdul Razak Square, Kuwait City, Kuwait; DOB 30 Apr 1956; POB Kuwait City, Kuwait; nationality Kuwait; Gender Male (individual) [SDGT] (Linked To: HIZBALLAH).

Dated: October 26, 2021.

Bradley T. Smith,

Acting Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2021–26156 Filed 12–1–21; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms: 8653, 8654, 13206, 13715, 13977, 139778, 14204, 14310, and 14335

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning the VITA/TCE (Volunteer Income Tax Assistance/Tax Counseling for the Elderly) Volunteer Program.

DATES: Written comments should be received on or before January 31, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Paul Adams, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the form and instructions should be directed to Sara Covington, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or at (737)800–6149 or through the internet at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: VITA/TCE Volunteer Program.

OMB Number: 1545–2222.

Form Numbers: 8653, 8654, 13206, 13715, 13977, 13978, 14204, 14310 and 14335.

Abstract: The Internal Revenue Service offers free assistance with tax return preparation and tax counseling using specially trained volunteers. The Volunteer Income Tax Assistance (VITA) and Tax Counseling for the Elderly (TCE) programs assist seniors and individuals with low to moderate incomes, those with disabilities, and those for whom English is a second language.

Current Actions: There is a change in the paperwork burden previously approved by OMB. The agency has requested to add Forms 13977, 13978, and 14335 to this collection and has updated the form to meet 508 compliance. The information on the form can only be submitted to the IRS at *https://www.irs.gov/individuals/irs-tax-volunteers.* This process is part of Link and Learn (a self-paced e-learning

for the Volunteer Income Tax Assistance and Tax Counseling for the Elderly (VITA/TCE) program).

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals and Households.

Estimated Number of Respondents: 49,100.

Estimated Average Time per Respondent: 21 minutes.

Estimate Total Annual Burden Hours: 17,034.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 28, 2021.

Paul Adams,

Senior Tax Analyst.

[FR Doc. 2021–26159 Filed 12–1–21; 8:45 am]

BILLING CODE 4830–01–P

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Federal Register

Vol. 86, No. 229

Thursday, December 2, 2021

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CFR PARTS AFFECTED DURING DECEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List November 24, 2021

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